

REPORT TO
DEPARTMENT OF AGRICULTURE
19 JUNE 2019

REVIEW OF AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT ACT 2013



OPERATION OF THE AMENDMENTS





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C O N T E N T S

GLOSSARY OF TERMS	V
EXECUTIVE SUMMARY	I
1	
INTRODUCTION	1
1.1 Stakeholder consultation	1
1.2 Discussion paper themes	2
1.3 Scope of this review	4
1.4 Report structure	5
2	
BACKGROUND	6
2.1 Agvet legislation	6
2.2 Recent reports	7
2.3 Related bills and reviews	9
3	
DISCUSSION THEME 1	12
3.1 Application assessment efficiency and effectiveness	12
3.2 Conclusions	21
4	
DISCUSSION THEMES 2 – 6	23
4.1 Reconsiderations (chemical review)	23
4.2 Compliance and enforcement	25
4.3 Improved consistency in protection provisions	27
4.4 Legislation improvements	29
4.5 Variations to relevant particulars and conditions	29
4.6 Conclusion	31
A	
SUBMISSIONS	A-1
B	
DISCUSSION PAPER	B-1
FIGURES	
FIGURE 1.1 SUBMISSIONS BY STAKEHOLDER GROUP	2
FIGURE 3.1 IMPACT OF REVISED WRITTEN GUIDANCE ON COMPLIANCE TIME/COSTS	13
FIGURE 3.2 IMPACT OF PRE-APPLICATION ASSISTANCE ON COMPLIANCE TIME/COSTS	15
FIGURE 3.3 IMPACT OF PRELIMINARY ASSESSMENT ON COMPLIANCE TIME/COSTS	16
FIGURE 3.4 IMPACT OF ONLINE APPLICATION LODGEMENT ON COMPLIANCE TIME/COSTS	19
FIGURE 4.1 IMPACT OF PRESCRIBED / NOTIFIABLE VARIATIONS ON COMPLIANCE TIME/COSTS	30

C O N T E N T S

TABLES

TABLE 1.1	COVERAGE OF AGVET DISCUSSION PAPER THEMES IN REPORTS AND SUBMISSIONS	11
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BOXES

BOX 1.1	THEMES AND DISCUSSION POINTS	3
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GLOSSARY OF TERMS

Administration Act	Agricultural and Veterinary Chemicals (Administration) Act 1992
Agvet chemicals	Agricultural and veterinary chemicals
Agvet Act	Agricultural and Veterinary Chemicals Act 1994
Agvet Code	The Agricultural and Veterinary Chemicals Code, as set out in the Schedule to the Code Act and adopted by the states and territories in legislation
Agvet legislation	Collective term for the Administration Act, Code Act, Agvet Code and all other associated acts, regulations and legislative instruments
Amendment Act	Agricultural and Veterinary Chemicals Legislation Amendment Act 2013
APVMA	Australian Pesticides and Veterinary Medicines Authority
Code Act	Agricultural and Veterinary Chemicals Code Act 1994
Department	Department of Agriculture
Levy Act	Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994
Reconsideration	The APVMA's procedure for chemical review. A reconsideration process has phases of activity that became mandatory in legislation from 1 July 2014 (e.g. the preparation of work plans and the issuing of notices of reconsideration).
Removing Re-approval and Re-registration Act	Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014



EXECUTIVE SUMMARY

Agricultural and veterinary chemicals (agvet chemicals) comprise a broad range of substances including insecticides, herbicides, fungicides, rodenticides, parasiticides, vaccines and antibiotics. They play an important role in controlling diseases; protecting the health and safety of humans; protecting crops, livestock and domestic pets; and safeguarding the environment from invasive weeds and pests.

Safe access to, and effective regulation of, agvet chemicals is essential to guard against the potentially harmful effects of these chemicals. However, poorly designed and implemented regulation can limit productivity benefits, deter investment, constrain jobs and economic growth and undermine the confidence that national and international markets have in commodities which are exposed to agvet chemicals.

Agvet chemicals are regulated under primary and subordinate legislation collectively known as “agvet legislation”.

In response to concerns about the complexity of this legislation the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Amendment Act) was enacted. The Act introduced numerous reforms to simplify, modernise and improve the effectiveness of agvet chemical regulation in Australia. Most of the amendments commenced on 1 July 2014.

This review, which is required by the Amendment Act, examines the *operation* of the amendments in the Act. The review did not consider the implementation of the amendments, which has already been comprehensively examined by the Auditor-General and House of Representatives and Senate committees.

A call for submissions was sent to stakeholders in February 2019, along with a discussion paper outlining the amendments made by the Amendment Act and inviting comments on the operation of those amendments. Details about the review and the call for submissions were also published on the Department of Agriculture’s (the Department) website, and on the review website set up by ACIL Allen. Fourteen submissions were received and the public submissions were made available on the ACIL Allen website.

Much of the feedback received in the submissions addressed the operation of the amendments in the Act. However, there was also a significant amount of feedback that was out of scope and unable to be reflected in this report. It should be noted that much of this feedback falls within the scope of other agvet consultations and were (or will be) duly considered in those forums. ACIL Allen would like to thank all stakeholders who made a submission for taking the time and effort to contribute to this review.

Overall, stakeholders who made submissions to this review generally welcome and support the 2014 reforms to simplify, modernise and improve the effectiveness of agvet chemical regulation, with no major concerns about the current operation of the amendments.

The operation of the amendments has resulted in tangible improvements in some areas, such as the efficiency, transparency and predictability of reconsiderations. In other areas the impact of the amendments has been limited or yet to be seen, either because the Australian Pesticides and Veterinary Medicines Authority (APVMA) has not used the provisions effectively, insufficient time has passed to see the full impact of some amendments, or the need for the measures has not yet arisen. More time is needed before an assessment of some of the changes can be made.

When compared with the findings of previous reviews and audits conducted between 2014 and 2019, it appears that overall the operation of the 2014 amendments have resulted in improvements to agvet regulation in Australia, although the impact of many of these changes has only been felt gradually due to the incremental nature of their implementation (which was out of scope for this review). In addition, while the amendments to reorganise and simplify the Agvet Code have improved its readability, some stakeholders still consider the provisions to be confusing and complex.

Suggestions raised in the discussion paper relating to broadening the scope of certain measures from the 2014 reforms received mixed views from stakeholders. The Department may wish to consider these views during the development and implementation of any future reforms to agvet regulation.

In conclusion, the key findings of this review were that stakeholders were generally supportive of the 2014 reforms, which have delivered some efficiencies; however, more reform is required to simplify the legislation. It may therefore be beneficial to conduct a comprehensive examination of the entire agvet framework in the near future.



The enactment of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act) on 29 June 2013 introduced numerous reforms to the regulation of agvet chemicals in Australia.

Section 4 of the Amendment Act requires there to be a review of the operation of the amendments made by the Act, with a report to be tabled in both Houses of Parliament within 15 sitting days after 1 July 2019:

4 Review of operation of amendments

(1) The Minister must cause a review to be conducted of:

- (a) the operation of the amendments made by this Act; and*
- (b) any other related matter that the Minister specifies.*

(2) At least one of the persons conducting the review must be a person who is not otherwise appointed, employed or engaged by the Commonwealth.

(3) The review must include a request for, and consideration of, submissions from members of the public.

(4) The Minister must cause a written report of the review to be laid before each House of the Parliament within 15 sitting days of that House after 1 July 2019.

The above provision became the basis for the terms of reference of this review, conducted by ACIL Allen Consulting (ACIL Allen) in early 2019.

1.1 Stakeholder consultation

The Department wrote to 146 stakeholders on 15 February 2019 to inform them that ACIL Allen would be conducting the review and inviting submissions. The Department encouraged stakeholders to participate in the review.

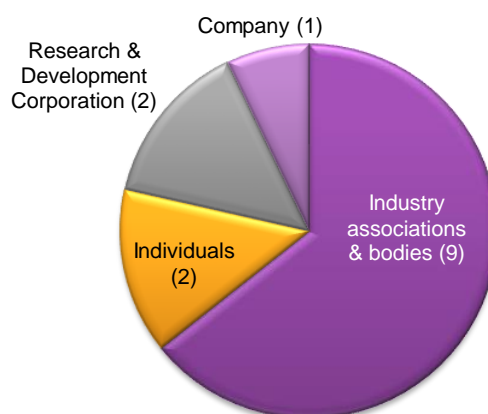
ACIL Allen called for submissions on 18 February 2019 by writing to the same 146 stakeholders. It also circulated a discussion paper (attached at **Appendix B**) to those stakeholders outlining the amendments made by the Amendment Act and inviting comments on the operation of those amendments.

On the same day, ACIL Allen established a dedicated webpage (www.acilallen.com.au/agvetreview) where it published information about the review, including the subsequent public submissions that were received. The Department also provided information about the review on its own website and included a link to the review webpage.

ACIL Allen sent another email to stakeholders on 15 March 2019 and called as many as possible during the following week to remind them about the submission closing date.

Fourteen submissions were received. **Figure 1.1** shows the breakdown of submissions received by stakeholder group.

FIGURE 1.1 SUBMISSIONS BY STAKEHOLDER GROUP



SOURCE: ACIL ALLEN CONSULTING (2019)

This report considers the objectives of the amendments made by the Amendment Act and evaluates the effectiveness of the amendments in meeting those objectives. In doing so, it notes relevant findings on the operation of the amendments that have been made in other reports, such as the 2017 Auditor-General's report on the implementation of the Amendment Act,¹ the 2018 House of Representatives committee report on APVMA regulatory reforms² and the 2019 Senate committee report on the independence of regulatory decisions made by the APVMA.³ Where possible, this report tracks the progress of those findings against the feedback received in submissions to this review.

1.2 Discussion paper themes

The discussion paper issued by ACIL Allen as part of this review was divided into six themes. Each theme offered a range of discussion points, which were intended as a guide only. Stakeholders were invited to comment on any or all of the discussion points, or any other matter related to the operation of the amendments.

Discussion paper themes and discussion points are set out in **Box 1.1**.

The discussions in chapters 3 and 4 of this report are aligned with the themes in the discussion paper.

¹ Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Report no. 56, 2016-17 (hereafter referred to as the 2017 ANAO report).

² House of Representatives Standing Committee on Agriculture and Water Resources, *APVMA Regulatory Reforms*, May 2018 (hereafter referred to as the 2018 House of Representatives report).

³ Senate Rural and Regional Affairs and Transport References Committee, *The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)*, February 2019 (hereafter referred to as the 2019 Senate report).

BOX 1.1 THEMES AND DISCUSSION POINTS

**Application assessment efficiency and effectiveness**

1. The effectiveness of the 'elapsed time' model versus the 'stop the clock' model, and whether the elapsed time model can be made more flexible through broadening the scope of 'time-shift' applications.
2. Whether the amendments have assisted stakeholders with the application process.
3. Whether there should be more flexibility in the time period used to rectify defects in applications.
4. Whether the preliminary assessment step should be retained.
5. The value and practical effects of the APVMA's use of international assessments and data for assessing applications.
6. Any other issues (caused by the amendments) relating to the efficiency and effectiveness of assessments.

Reconsiderations (chemical review)

7. Whether the amendments, including the published work-plans and timeframes, have improved the transparency and predictability of reconsiderations.

Compliance and enforcement

8. Whether the amendments have improved compliance and enforcement.
9. Whether, as a legislative priority, agvet legislation should be aligned with the *Regulatory Powers (Standard Provisions) Act 2014*.
10. Whether the Agvet Code should be simplified through greater use of conditions of registration to regulate the labelling of chemical products, and less reliance on specific labelling offences.
11. Whether more measures should be included in disallowable legislative instruments made by the APVMA.

Improved consistency in data protection provisions

12. Whether the amendments have improved data protection and made the associated provisions easier to understand.
13. Whether stakeholders have experienced benefits from using data contained in withdrawn and refused applications, or permit applications, for a subsequent product registration.
14. Whether Part 3 of the Agvet Code should be omitted to allow stakeholders to rely on commercial arbitration legislation for persons to negotiate access to both protected information and information with limits on its use.
15. Whether 'protected information' and 'information with limits on its use' should be consolidated.

Legislation improvements

16. Whether the simplification and re-organisation of provisions has helped them to better understand the legislation.
17. Whether the redrafting of existing 'legislative tests' into the four 'meets the X criteria' tests in subsection 3(1) of the Agvet Code has assisted them to comply with safety, trade, efficacy and labelling criteria.

Variations to relevant particulars and conditions

18. The value and practical effects of having multiple processes for varying relevant particulars.
19. The effectiveness of existing processes for varying conditions, and whether there should be a streamlined means of varying conditions (recognising the technical assessment that can be required).
20. Whether agvet legislation could be simplified by dealing with variations to approval and registration as new approvals and registrations.
21. What mechanisms would stakeholders support for dealing cost-effectively with incorrect information in notifiable variations and prescribed variations?

SOURCE: ACIL ALLEN CONSULTING (2019)

1.3 Scope of this review

This review focused on the operation of the amendments in the Amendment Act, rather than the implementation of the amendments, which was comprehensively considered in the 2017 Auditor-General's report and the 2018 House of Representatives committee report.

While some of the feedback received in submissions was confined to the review's scope, much of the feedback went further.

Common issues raised in submissions that were out of scope for this review included:

- timeframe performance of the APVMA
- impact of delays in assessment approvals
- development of a minor use program
- repeal or reinstatement of the Re-approval and Re-Registration Scheme
- impact of the announcement to relocate the APVMA to Armidale.

The issues and suggestions raised by stakeholders that were out of scope were therefore not considered in this report. They are, however, being considered (or have already been considered), in other consultations, including on the:

- Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 (discussed in chapter 2)
- Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (also discussed in chapter 2)
- Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019.

In response to the comments raised in submissions about a minor use program, the Department advised that the Government has committed \$14.3 million funding over six years from 2014-15 to improve farmer access to chemicals for minor uses through the Improved Access to Agricultural and Veterinary Chemicals grants program. To date 149 grants, totalling \$7.96 million, have been awarded across four grant rounds, and a forum to prioritise projects for the fifth round of the grants program will be held in October 2019 where another \$2 million will be made available.

In addition to the grants program, the funding has been used to establish:

- an Australian list of crop groupings with similar botanical and other characteristics, and reference crops
- an industry-run forum for farming bodies, commodity-based groups, RDCs and chemical manufacturers to share and prioritise their chemical needs.

It should be noted that there have been numerous reviews of agvet chemical-related legislation, regulations and administration over the past decade (many of which have overlapped with the ACIL Allen review); however, none of these reviews have comprehensively examined the entire agvet framework.

Further, industry associations pointed out that their members are regulated by several bodies simultaneously, such as the APVMA, Therapeutic Goods Administration and/or under the National Industrial Chemicals Notification and Assessment Scheme, all of which have been undergoing reform and consultation with industry.

Repealed or unimplemented provisions

Two provisions in the Amendment Act were unable to be reviewed. The first of these was a mandatory re-approval and re-registration scheme. The Amendment Act introduced the scheme for the re-approval and re-registration of registered products to increase the scrutiny of chemical constituents and products. At that time, government considered that the scheme would increase public assurance that existing chemicals and products do not pose an unmanageable risk to human health or the environment, thus promoting public confidence in agvet chemical regulation.⁴ In his second reading speech the then Parliamentary Secretary for Agriculture, Fisheries and Forestry, the Hon Sid Sidebottom MP, said:

Introduction of a mandatory re-approval and re-registration scheme brings Australia into line with other countries which have similar schemes such as the United States and Europe. The scheme has been designed to complement the specific characteristics of the Australian agvet market so it delivers the desired outcomes without unnecessarily resulting in withdrawal of safe and useful chemicals. This measure responds to community concerns by ensuring that approved or registered chemicals continue to meet appropriate health and safety standards.

Commonwealth, Parliamentary Debates, House of Representatives, 28 November 2012.

However, the provisions only operated for a short time until their repeal in 2014 under the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* (Removing Re-approval and Re-registration Act), in line with the election commitment of the newly-elected government to remove re-registration.⁵

The second provision that was unable to be reviewed was an amendment to the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Levy Act) to enable any Australian Government agency to collect the levy on product sales on behalf of the APVMA. The amendments:

- authorised the Minister to specify a collection agency in place of the APVMA in a written instrument, where the Minister responsible for that agency agreed
- authorised collecting agencies generally to issue notices, collect information, undertake assessments and collect levies payable under the Levy Act.

At the time, it was considered that these amendments would be an opportunity to improve efficiency. However, to date they have not taken effect because the Minister has as yet not authorised another agency to collect the levy.

Notifiable and prescribed variations

The terms of reference for this review (set out at the beginning of this chapter) allow the Minister to request the review of 'any other related matter'. Under this term the Minister requested a review of notifiable and prescribed variations – particularly the extent to which these have been successful and could be expanded.

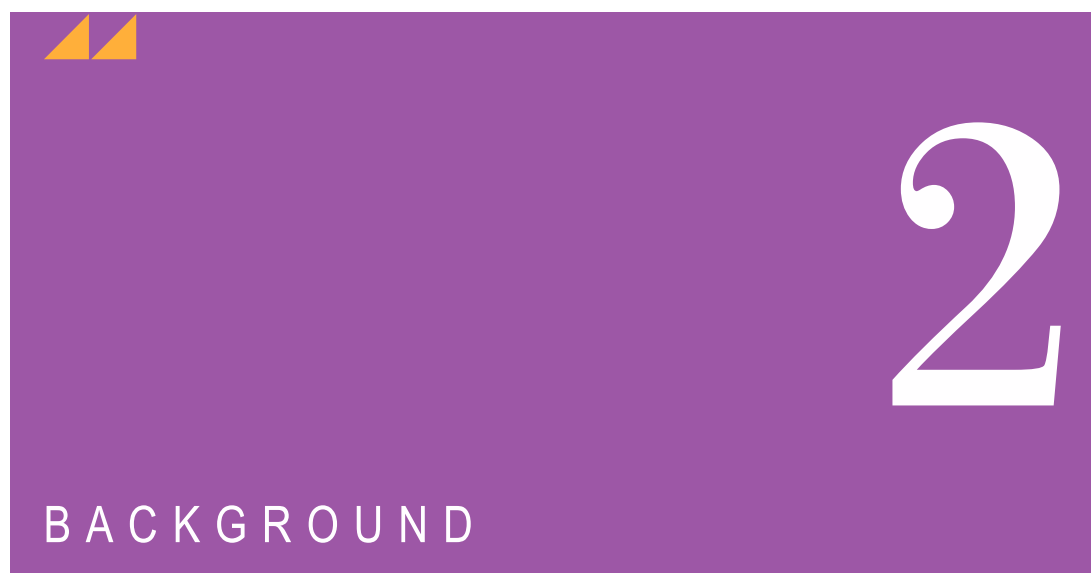
1.4 Report structure

The remaining chapters of this report are as follows:

- *Chapter 2* provides background information to agvet legislation and other relevant reviews.
- *Chapter 3* considers the first discussion paper theme of application assessment efficiency and effectiveness, including all of the sub-themes relating to that subject such as the elapsed time model and international assessments.
- *Chapter 4* analyses the remainder of the discussion paper themes, being reconsiderations, compliance and enforcement, consistency in data protection provisions, legislation improvements, and variations to relevant particulars and conditions.

⁴ Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, p 3.

⁵ Commonwealth, *Parliamentary Debates*, House of Representatives, 19 March 2014, 2377 (Barnaby Joyce, Minister for Agriculture for Agriculture and Deputy Leader of The Nationals).



Australia's agricultural industry is worth an estimated \$60 billion annually,⁶ and over \$3 billion of agvet chemicals are sold across the country each year.⁷

The sale and use of agvet chemicals are regulated through a National Registration Scheme, which is a partnership between the Australian, state and territory governments. The legislation that gives effect to the scheme includes the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) and the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act).

The supply of agvet chemicals under the scheme (up to the point of supply, including retail sale) is regulated by the APVMA. The control of use of agvet chemicals after supply is the responsibility of individual states and territories.

The provisions in the Code Act and the Schedule to it (the Agvet Code) allow the APVMA to:

- assess and register agvet products
- review active chemical constituents and products and their labels
- issue permits and licences for the manufacture of chemical products
- monitor compliance with registration, permit and licence conditions
- enforce the Agvet Code, including through the suspension and cancellation of product registration.

2.1 Agvet legislation

The term “agvet legislation” captures the suite of Commonwealth primary and subordinate legislation, including the Administration Act, the Code Act and Agvet Code, and any regulations or legislative instruments made under them.

The 2013 Amendment Act was enacted in response to criticisms about the complexity of agvet legislation. The reforms followed several reviews and other legislative changes to the regulation, including the:

- 2008 Productivity Commission review into chemicals and plastics regulation⁸
- 2010 *Agricultural and Veterinary Chemicals Code Amendment Act*, which increased regulatory efficiencies by removing red tape⁹

⁶ Australian Bureau of Agricultural and Resource Economics and Sciences, Farm Production Value Forecast to Rise in Mixed Agricultural Outlook, 19 June 2018, available at <http://www.agriculture.gov.au/abares/news/media-releases/2018/farm-prod-value-forecast-rise-mixed-ag-outlook> (accessed 25 March 2019).

⁷ 2017 ANAO report, p 7.

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

⁹ Commonwealth, *Parliamentary Debates*, House of Representatives, 17 March 2010, 2708 (Tony Burke, Minister for Agriculture, Fisheries and Forestry).

- 2011 Department of Agriculture report into the regulation of agvet chemicals¹⁰
- 2013 Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES) review of regulatory burdens on agriculture and forestry business.¹¹

The Amendment Act further simplified, re-organised and modernised the suite of agvet legislation to provide an assessment process that is easier to understand and more cost-effective to administer.¹²

The Amendment Act amended the Administration Act, Code Act, Levy Act and the *Agricultural and Veterinary Chemicals Act 1994* (Agvet Act), with most amendments commencing on 1 July 2014.

The amendments aimed to:

- improve the efficiency and effectiveness of application processes and timeliness of agvet chemical approvals, registrations and reconsiderations
- enhance the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations through development, publication and implementation of a risk framework
- improve the efficiency and effectiveness of regulatory arrangements for the approval, registration and reconsideration of agvet chemicals
- improve consistency in data protection provisions and removing disincentives for industry to provide data in support of ongoing registration of agvet chemicals.

The amendments also:

- enabled the APVMA to better align regulatory effort with chemical risk
- implemented a mandatory re-approval and re-registration scheme
- provided the APVMA with a graduated range of compliance enforcement powers and introduced a power to apply statutory conditions to registrations and approvals
- provided for an agency other than the APVMA to collect the chemical products levy to address perceptions of a conflict of interest (where it is cost effective to do so).¹³

2.2 Recent reports

Since the 2014 reforms there have been several reviews and reports relevant to the regulation of agvet chemicals. These are outlined briefly below and considered in more detail throughout the remainder of the report.

Table 1.1 provides a snapshot of the coverage of issues raised in previous reports and the submissions to this review, against the themes raised in the discussion paper.

Agricultural Competitiveness White Paper

In 2015, the Australian Government released the Agricultural Competitiveness White Paper. The White Paper noted that the large regulatory burden imposed by agvet chemical regulation is often disproportionate to the risks these products pose, which in turn slows access to newer and better products, increases chemical cost, and may give overseas producers an advantage in accessing new chemicals well before their Australian counterparts.

The paper acknowledged the 2014 reforms but stated that ‘more needs to be done.’ It discussed further action the Government will take to reduce this burden on Australian agricultural producers and outlined a ‘new approach for the APVMA to streamline access to products and better manage the risks these products can pose, while ensuring human health protection’.¹⁴

¹⁰ Department of Agriculture, Fisheries and Forestry, *Better Regulation of Agricultural and Veterinary Chemicals*, 2011.

¹¹ Gibbs, C., Harris-Adams, K., and Davidson, A., *Review of Selected Regulatory Burdens on Agriculture and Forestry Businesses*, 2013, ABARES.

¹² Commonwealth, *Parliamentary Debates*, House of Representatives, 28 November 2012, 13658 (Sid Sidebottom, Parliamentary Secretary for Agriculture, Fisheries and Forestry).

¹³ Revised Explanatory Memorandum, *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013*, pp 1-2.

¹⁴ Commonwealth of Australia 2015, *Agricultural Competitiveness White Paper*, Canberra, p 38.

Productivity Commission: Regulation of Australian Agriculture

Following the White Paper, the Australian Government requested that the Productivity Commission inquire into ‘the regulatory burden on farm businesses’.

The Productivity Commission’s 2016 report noted that despite the fact that the regulation of agvet chemicals has been through numerous reviews and reforms, concerns remain. These concerns primarily relate to unnecessarily lengthy, complex and duplicative registration procedures, and interjurisdictional inconsistencies – particularly for control-of-use regimes – which can make it costly and confusing to comply with regulatory requirements. It recommended the removal of unnecessary barriers to accessing agvet chemicals.¹⁵

Auditor-General: Pesticide and Veterinary Medicine Regulatory Reform

In 2017, the Auditor-General (or the Australian National Audit Office (ANAO)) undertook an independent performance audit to assess the effectiveness of the APVMA’s implementation of reforms to agvet regulation, and the extent to which the Authority has achieved operational efficiencies and reduced the cost burden on regulated entities.

The audit found that the implementation of the reforms had been ‘mixed’ – while key reforms had been implemented on schedule, the full scope of the reform program was yet to be implemented. In particular, it found that the risk-based regulatory framework and upgrades to internal IT systems required to meet legislative objectives had not been implemented. It also found that the APVMA had not established a robust performance measurement framework to measure the effectiveness of the reform program in achieving greater efficiency of its activities and in reducing the regulatory burden on industry.¹⁶

Review of International IP & Registration Arrangements for the Regulation of AgVet Chemicals

ACIL Allen conducted this review for the Department in 2017. The review found that there was a need for further regulatory reform to ensure Australian primary producers get faster access to new and innovative agvet chemical products, which are generally safer, more effective and better for the environment than their predecessors, and would improve the productivity, profitability and international competitiveness of Australian agriculture.

During the review, industry representatives highlighted the regulator’s ability to exceed its statutory timeframes for assessments, which inhibited the ability of patent holders to realise returns on R&D and threatened the supply of new products into the Australian market. This contrasted with the concerns of public sector stakeholders regarding the difficulties of balancing the needs of agricultural producers for timely access to both innovative and generic chemical products, while maintaining the health and safety standards that are the first priority of Australia’s system for regulating agvet chemicals.

Other concerns raised at the time included that the suite of agvet legislation itself is a barrier to providing more timely access to customers seeking chemical products due to its significant complexity and difficulty of navigation.

As such, a finding from ACIL Allen’s 2017 report stated: ‘The legislative review announced by the Deputy Prime Minister¹⁷ is urgently needed. The legislation and regulations urgently need to be simplified and rewritten.’¹⁸ ACIL Allen maintains this view.

¹⁵ Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p 291.

¹⁶ 2017 ANAO report, p 7.

¹⁷ The then Deputy Prime Minister signalled his intentions for a comprehensive legislative review in an interview on 27 April 2017.

¹⁸ ACIL Allen, *Review of International IP & Registration Arrangements for the Regulation of AgVet Chemicals*, November 2017.

Standing Committee on Agriculture and Water Resources inquiry

In 2018, the House of Representatives Standing Committee on Agriculture and Water Resources conducted an inquiry into the extent to which the APVMA implemented the recommendations made by the Auditor-General. Noting that the APVMA agreed with all four recommendations, the committee's inquiry focused on the steps the APVMA had taken in the six months since the audit report was tabled.

The committee found that the APVMA had made progress since the Auditor-General's report. It emphasised the need for the regulation of Australia's agvet industry to be efficient and effective and made four recommendations, including that there be a follow-up audit to monitor the APVMA's ongoing implementation of reforms.¹⁹

2.3 Related bills and reviews

Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017

The Operational Efficiency Bill 2017 was introduced to Parliament on 25 October 2017. The bill later lapsed and is intended for re-introduction in 2019. The bill makes a range of minor and technical amendments to the operations of the APVMA to realise operational efficiencies, reduce administrative burden and unnecessary regulation, clarify ambiguities and remove redundant provisions. The bill sought to:

- simplify reporting requirements for annual returns
- increase the flexibility of the APVMA to manage errors in applications at the preliminary assessment stage
- enable the APVMA to grant part of a variation application under s 27 of the Agvet Code²⁰
- enable a person to apply to vary the relevant particulars or conditions of a label approval that is suspended, to the extent that the variation relates to the grounds for suspension
- establish civil pecuniary penalties for contraventions of provisions relating to providing false or misleading information in the Agvet Code and the Administration Act
- amend the notification requirements in s 8E of the Agvet Code²¹ so that the APVMA and Food Standards Australia New Zealand will have the flexibility to agree on appropriate timeframes for notifications
- amend the definition of expiry date in the Agvet Code to mean the date after which a chemical product 'must not' be used
- make minor and technical amendments to the Administration Act and the Agvet Code, including repealing redundant provisions.²²

The then Minister for Agriculture and Water Resources, the Hon Barnaby Joyce MP, described the bill as addressing 'simple, non-controversial changes that could be done now that improve the efficiency of the regulator and increase the speed to which farmers can get access to safe effective chemicals', while noting that there would be a detailed legislative review of agvet chemical legislation.²³

The bill lapsed upon the prorogation of Parliament as a result of the 2019 general election.

¹⁹ House of Representatives Standing Committee on Agriculture and Water Resources, *APVMA Regulatory Reforms*, May 2018.

²⁰ Under s 27 a holder may apply to the APVMA to vary the relevant particulars or conditions of the approval of an active constituent, registration of a chemical product, or approval of a label.

²¹ Under s 8E, the APVMA must notify Food Standards Australia New Zealand if an approval, registration, variation or permit proposed under the Code would, if it were given, made or issued, be likely to require a variation to the Maximum Residue Limits Standard.

²² Explanatory Memorandum, *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*, p 1.

²³ Commonwealth, *Parliamentary Debates*, House of Representatives, 25 October 2017, 11889 (Barnaby Joyce, Minister for Agriculture and Water Resources).

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

The Streamlining Regulation Bill 2018 was introduced into the Australian Parliament on 18 October 2018 and similarly lapsed. The objectives of this bill were to improve the efficiency and effectiveness of agvet chemical regulation through further streamlining of the regulations, while maintaining protections for the health and safety of people, animals, plants and the environment. This included through:

- enabling the use of new, simpler processes for chemical product assessment based on risk
- providing the APVMA and industry with more flexibility to deal with certain types of new information given during the application process
- providing for extensions to limitation periods and protection periods as an incentive for chemical companies to register certain new uses (particularly minor uses) of chemical products
- supporting computerised decision-making by the APVMA
- providing for a legislative instrument to be made by the APVMA in the future to prescribe a scheme allowing the use of accredited third party providers to undertake assessment services
- improving risk communication about chemical products by increasing the transparency of voluntary recalls
- harmonising the need to inform the APVMA of new information so that the same obligations apply to all holders and applicants
- providing a more practical mechanism for dealing with minor variations in the constituents in a product, that normally occur in the manufacturing process
- providing the APVMA with more proportionate options for dealing with false or misleading information, and clarifying what information must be included on a label
- addressing some deficiencies or inconsistencies in the regulations, including through removing unnecessary and redundant provisions.²⁴

This bill also lapsed upon the prorogation of Parliament as a result of the 2019 general election.

Future review

Under s 72 of the Administration Act, the Minister must ensure that there is a comprehensive review of the suite of agvet legislation every 10 years. The next review is due to be completed by July 2024.

²⁴ Commonwealth, *Parliamentary Debates*, House of Representatives, 18 October 2018, 10398 (David Littleproud, Minister for Agriculture and Water Resources); Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.

TABLE 1.1 COVERAGE OF AGVET DISCUSSION PAPER THEMES RELATING TO 2013 AMENDMENT ACT IN REPORTS AND SUBMISSIONS

Report / submission	THEME 1: Application assessment efficiency and effectiveness							THEME 2	THEME 3	THEME 4	THEME 5	THEME 6
	Guidelines	Pre-application assistance	Preliminary assessment	Timeliness of assessments	Shut the gate provisions	Electronic communication	International assessments	Re-considerations (chemical review)	Compliance and enforcement	Consistency in data protection provisions	Legislation improvements	Variations to relevant particulars and conditions
2015 White Paper							✓					
2017 Productivity Commission report							✓					
2017 ANAO report	✓	✓		✓		✓		✓	✓			✓
2018 House of Representatives report		✓				✓	✓					
2019 Senate report							✓	✓				
Sub 1 - Infopest												✓
Sub 2 - Name suppressed												
Sub 3 – Grain & Research Development Corp							✓	✓	✓	✓		
Sub 4 - Confidential												
Sub 5 – CropLife Australia		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
Sub 6 - A Johnston & R Wood								✓				
Sub 7 - Cotton Australia				✓			✓	✓	✓			
Sub 8 - Australian Food Sovereignty Alliance								✓			✓	
Sub 9 - Aerial Application Association of Australia												
Sub 10 - Name suppressed				✓								
Sub 11 - Animal Medicines Australia												
Sub 12 - Grain Producers Australia			✓	✓			✓	✓	✓	✓	✓	✓
Sub 13 – Veterinary Manufacturers & Distributors Association	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓
Sub 14 – Dairy Australia/Agline Ag			✓	✓			✓	✓		✓		

SOURCE: ACIL ALLEN CONSULTING (2019)

3

DISCUSSION
THEME 1

SNAPSHOT OF KEY FINDINGS

- The APVMA has published guidelines outlining principles and processes for regulating agvet chemicals, however concerns have been raised about the quality and clarity of the guidance material and a lack of resources to implement the guidelines.
- Pre-application assistance is viewed as a positive step as it provides applicants with confidence that applications meet the APVMA's requirements prior to submission. However, there are concerns about inconsistencies and limitations in the scope of the assistance.
- There are mixed views on the operation of amendments to the preliminary assessment process. Some stakeholders support it on the basis that it ensures that applications have been completed correctly, leading to timely assessments, while one stakeholder contended that limiting preliminary assessments to administrative matters has not been successful and advised that considerations are underway to broaden the scope to include some technical assistance.
- Stakeholders support the suggestion for some flexibility to address minor errors at the preliminary assessment stage to reduce the administrative burden on the APVMA and applicants.
- The predictability of assessment timeframes has improved, however there are mixed views as to whether this is a direct result of the new elapsed time model.
- Stakeholders support making the elapsed time model more flexible through broadening the scope of timeshift applications.
- The 'shut the gate' provisions have been effective in improving application quality, although concerns were raised about the issuing of unnecessary s 159 notices to request information that the APVMA should already possess.
- The ability to lodge applications online is viewed positively by stakeholders, however there are issues with inefficiencies due to some parts of the application process still being required to be submitted in hardcopy.
- The 2014 amendments aimed to ensure that there are no impediments to the APVMA's discretionary use of international data and assessments conducted by comparable overseas agencies. While the APVMA has taken steps to support staff to maximise the use of international assessments, stakeholders have consistently advocated in all the post-reform reviews for greater use of this provision.

3.1 Application assessment efficiency and effectiveness

3.1.1 Guidelines

In order to improve the transparency and predictability of regulatory decisions, the Amendment Act provided for the APVMA to make, publish and have regard to guidelines, as part of an overarching risk-based compendium to be developed, maintained and published by the APVMA. Section 6A of the

Agvet Code requires the guidelines to include the principles and process for regulating agvet chemicals.

Findings from previous reviews

The 2017 ANAO report noted that – as at 1 July 2014 – the APVMA had published revised guidelines on the registration of products, approval of chemicals and management of applications; and had released 13 formal guidelines under s 6A outlining the principles and processes for topics such as ‘Preliminary Assessment’ and ‘Altering Applications’. The APVMA had also redeveloped its website content to provide comprehensive information to industry stakeholders about the registration of products, approval of chemicals and management of applications to support the broader reform program.²⁵

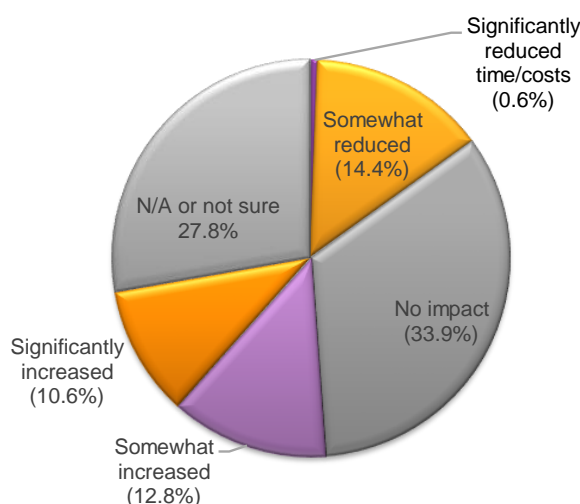
During a 2015 internal review by the APVMA, staff noted concerns about the quality of the guidance material prepared, including missing and outdated content, errors and the lack of a user friendly structure.²⁶

The ANAO surveyed regulated entities about the quality of the APVMA’s guidance materials and found mixed views. Around one third of respondents stated that the APVMA’s website was easy to navigate and that its guidance to industry was clear, while around 40 per cent considered that guidance was unclear. In regard to the range of coverage of the guidance, around 42 per cent considered that the APVMA’s written advice covered a sufficient range of topics, while 30 per cent did not express a strong view on the matter.²⁷ No further breakdown or analysis of these findings was provided.²⁸

The ANAO reported that the APVMA had continued to develop its guidance for industry into 2017, including by developing a project plan to transform the user experience by delivering improved search and web functionality and tailored guidance to support the top 20 most common application types.

Figure 3.1 shows the survey responses from regulated entities during the 2017 ANAO report on how much revised written guidance (comprising website information and s 6A Guidelines) had impacted compliance times and costs. The majority of respondents (61.7 per cent) stated that there had either been no impact or they were not sure. Only 15 per cent of respondents reported that the revised written guidance had somewhat or significantly reduced compliance time/costs, while 23.4 per cent stated that it had somewhat or significantly increased their costs.

FIGURE 3.1 IMPACT OF REVISED WRITTEN GUIDANCE ON COMPLIANCE TIME/COSTS



SOURCE: 2017 ANAO REPORT, P 46.

²⁵ Australian National Audit Office, *Pesticide and Veterinary Medicine Regulatory Reform*, Report no. 56, 2016-17, p 25.

²⁶ *ibid.*

²⁷ *ibid.*, p 26.

²⁸ The ANAO’s survey results are reproduced in several places throughout this report. As is the case in this section, no further breakdown or analysis of those figures was provided in the ANAO report beyond what has been reflected in this report.

Feedback from this review

According to the Veterinary Manufacturers and Distributors Association (VMDA), the APVMA has not had the resources to properly implement the new guidelines, which has adversely impacted the operation of this amendment.²⁹ According to the Department, the APVMA was provided with \$8 million and five years in which to implement the changes.

No comments were received during this review regarding improvements (or otherwise) to the transparency and predictability of regulatory decisions arising from the reforms to guidelines.

3.1.2 Pre-application assistance

The 2014 amendments created new pre-application assistance arrangements to provide applicants with the opportunity to obtain technical advice from the APVMA to assist them in preparing their application. Under the arrangements, applicants can also obtain an appraisal of a trial protocol or receive advice on project plans for a global joint review.³⁰

Findings from previous reviews

An internal APVMA review of its pre-application assistance scheme service in October 2014 found that the scheme had not delivered the service and benefits intended by the reforms, and that the regulator had failed to meet the reasonable expectations of industry.

The review made 40 recommendations which resulted in changes to the management of requests for assistance, the offering of face-to-face meetings and appraisal of trial protocols, and simplified fee structures.³¹

In its 2017 audit the ANAO reviewed the extent to which the APVMA had finalised applications for pre-application assistance within target timeframes (which was out of scope for this review), however it did not analyse the outcomes of applications submitted following use of the scheme. The ANAO suggested there would be benefit in the APVMA monitoring the progress of applications that have received pre-application assistance to better measure the scheme's effectiveness.³²

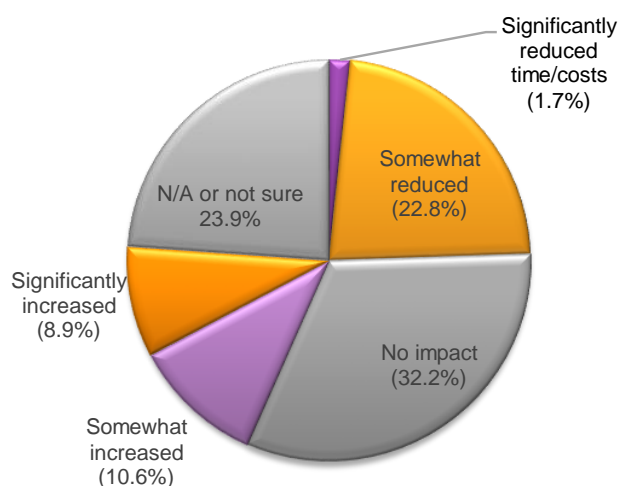
The ANAO surveyed regulated entities as to how much pre-application assistance had impacted compliance costs. The results are shown below in **Figure 3.2**. Only one quarter (24.5 per cent) of respondents stated that pre-application assistance had significantly or somewhat reduced time or costs for their organisation. Most respondents reported that there had been no impact (32.2 per cent), or that it had somewhat or significantly increased time or costs (19.5 per cent).

²⁹ Submission 13, VMDA, p 1.

³⁰ APVMA, *Pre-application assistance*, available at <https://apvma.gov.au/node/106> (accessed 11 April 2019).

³¹ 2017 ANAO report, p 26.

³² *ibid*.

FIGURE 3.2 IMPACT OF PRE-APPLICATION ASSISTANCE ON COMPLIANCE TIME/COSTS

SOURCE: 2017 ANAO REPORT, P 46.

The pre-application assistance process was also raised during the House of Representatives committee inquiry, with stakeholders viewing it as a positive step, despite some issues regarding inconsistencies and limitations in scope.³³

Feedback from this review

CropLife supported the pre-application assistance program, commenting that it provides applicants with confidence that applications meet the APVMA's requirements prior to submission.³⁴

The VMDA felt that the program has operated 'moderately well', however claimed that some APVMA staff with 'inappropriate risk averse attitudes' were not committing to agreements made during the pre-application process.³⁵

No other comments regarding pre-application assistance were received during this review.

3.1.3 Preliminary assessment

Prior to the 2014 reforms, preliminary assessments of applications by the APVMA included an assessment of the adequacy of the technical information provided. This resulted in the APVMA considering the technical information twice – once at the preliminary assessment stage and again at the application assessment stage.

The Amendment Act removed this duplication by limiting the scope of preliminary assessments to an administrative check to determine whether an application appears to meet the application requirements, rather than a technical assessment.³⁶ To further improve efficiency, the APVMA must now refuse inferior or deficient applications, thereby only assessing applications that meet the required standard at the time of lodgement³⁷ (n.b. refusal of deficient applications can occur at any stage in the application process).

³³ 2018 House of Representatives report, p 9.

³⁴ Submission 5, CropLife Australia, p 4.

³⁵ Submission 13, Veterinary Manufacturers and Distributors Association, p 2.

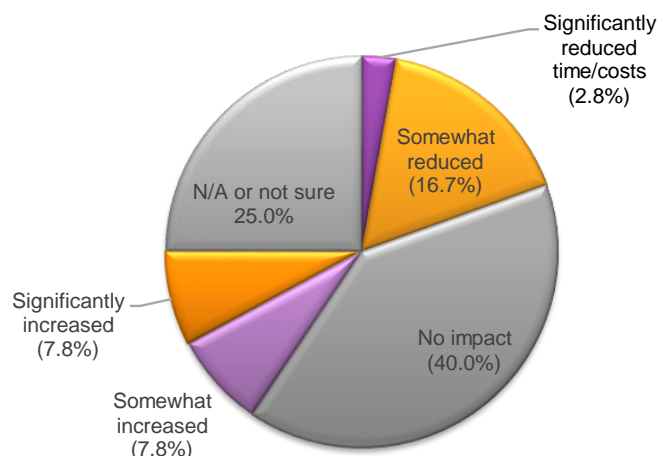
³⁶ Amendment Act, s 11.

³⁷ Amendment Act, s 11; Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, 30; Commonwealth, *Parliamentary Debates*, House of Representatives, 28 November 2012, 13658 (Sid Sidebottom, Parliamentary Secretary for Agriculture, Fisheries and Forestry).

Findings from previous reviews

Feedback from stakeholders during the ANAO audit included concerns that the restrictions on changes to applications at the preliminary assessment stage had increased burden on industry.³⁸ However, survey responses from regulated entities during that audit (shown in **Figure 3.3**) found that only 15.6 per cent of respondents found that preliminary assessment had somewhat or significantly increased their compliance time/costs, whereas the majority of respondents (65 per cent) said there had either been no impact or they were not sure if there had been any impact. Around 20 per cent of respondents stated that preliminary assessment had somewhat or significantly reduced their compliance time/costs.

FIGURE 3.3 IMPACT OF PRELIMINARY ASSESSMENT ON COMPLIANCE TIME/COSTS



SOURCE: 2017 ANAO REPORT, P 46

Feedback from this review

CropLife Australia and Grain Producers Australia supported the preliminary assessment process. Although not an applicant itself, Grain Producers Australia described preliminary assessment as an efficient mechanism to ensure the completeness of applications, leading to more timely assessments.³⁹

CropLife noted that the process ensures applications are submitted correctly and all relevant assessment modules are identified. However, it suggested that more flexibility to manage minor errors at this early stage would be beneficial as it would reduce some of the administrative burden on both the APVMA and applicants. CropLife expressed support for providing applicants with one opportunity to address identified deficiencies during the preliminary assessment process, although added that should this occur, sufficient operational guidance must be developed by the APVMA to ensure consistency in determining which deficiencies are reasonably rectifiable.⁴⁰

Grain Producers Australia also expressed support for some flexibility in rectifying defects in applications, particularly in the case of technically difficult applications that require significant industry coordination to generate and assemble data. However, to avoid abuse of the system, it suggested introducing penalties for applicants who regularly submit incomplete applications with defects, in order to avoid APVMA resources 'being unnecessarily tied up addressing these issues.'⁴¹

³⁸ 2017 ANAO report, p 42.

³⁹ Submission 12, Grain Producers Australia, p 10.

⁴⁰ Submission 5, CropLife Australia, p 4.

⁴¹ Submission 12, Grain Producers Australia, p 10.

On the other hand, the VMDA was of the view that the operation of amendments limiting the scope of preliminary assessments to administrative matters had not been successful, and noted that a proposal had been made to amend the regulations to allow the APVMA to provide assistance with some technical matters (for a fee) at this stage.⁴² However, this proposal was not followed through by the Government.

3.1.4 Timeliness of assessment decision-making (elapsed time model)

Delays in the completion of assessments can occur for several reasons, including long processing times by the APVMA or incomplete/poor quality applications submitted by applicants. Delays can add to the time required by industry to introduce new and varied products to market and can increase the risk of certain products being unavailable for a cropping season.

Prior to 2014, application assessment timeframes were calculated by ‘stopping the clock’ when a request for additional material was made by the APVMA. Performance against those timeframes was calculated using the days which the clock was ‘on’ and excluded non-assessment time during which the APVMA waited for applicants to provide additional material.⁴³ The ‘stop the clock’ model did not provide for certainty and predictability in assessment timeframes for either the applicants or the APVMA.

To address concerns about the time taken by the APVMA to complete applications and improve timeframe predictability, the 2014 reforms provided new statutory timeframes for assessments based on the ‘elapsed time’ from lodgement to finalisation, which includes the time taken to provide more information.

Findings from previous reviews

The 2017 ANAO audit examined data trends on the timeliness of assessments and found that overall there appeared to be an initial improvement in performance compared with the pre-reform period. However, it cautioned that the improved performance should be viewed in the context of the APVMA receiving fewer applications since the 2014 reforms – particularly fewer submissions for application categories with a timeframe greater than six months.⁴⁴

The ANAO reported that the initial improvement in performance was followed by fluctuations in the level of assessments completed on time, an increasing backlog of overdue assessments that are yet to be finalised at the end of each month, and a decline in timeframe performance in the six months to March 2017.⁴⁵

Feedback from this review

Concerns about the APVMA’s timeframe performance were raised by CropLife Australia and Grain Producers Australia which noted that only 24 per cent of crop protection product applications were finalised within statutory timeframes in the June 2017 quarter, down from 83 per cent in the September 2016 quarter.⁴⁶ Reports from the APVMA show that timeframe performance has since improved to 85 per cent in the December 2018 quarter.⁴⁷

The conclusions regarding the APVMA’s improved timeframe performance were, however, disputed by the VMDA, which declared: ‘Despite claims to the contrary from the APVMA, performance against timeframes for applications for new products have not improved.’ The VMDA contended that the performance data relates to minor assessments ‘with little or no technical evaluation component.’⁴⁸

⁴² Submission 5, Veterinary Manufacturers and Distributors Association, p 1.

⁴³ 2017 ANAO report, p 37.

⁴⁴ *ibid*, p 38.

⁴⁵ *Ibid*, p 9.

⁴⁶ Submission 5, CropLife, p 1; Submission 12, Grain Producers Australia, p 8.

⁴⁷ APVMA, Quarterly report: October – December 2018, available at <https://apvma.gov.au/node/44401> (accessed 19 June 2019).

⁴⁸ Submission 13, Veterinary Manufacturers and Distributors Association, p 1.

The introduction of the elapsed time model was supported by Cotton Australia on the basis that it has provided more certainty for applicants as to the expected time for a decision. It suggested that there may still be scope for improving efficiency in this area, although it did not identify how these improvements could be achieved.⁴⁹

CropLife advised that it had seen improvements in the predictability of assessment timeframes but was reluctant to attribute those improvements directly to the new elapsed time model. Rather, CropLife suggested that it was more likely 'a consequence of operational efforts by the APVMA to meet [its] timeframes more consistently'.⁵⁰ No other information was received during this review to test the validity of this theory.

One of the questions in the discussion paper (issued as part of this review) was whether the elapsed time model could be made more flexible through broadening the scope of 'timeshift' applications. Timeshift applications allow applicants to submit information in stages, while the assessment is underway, according to an agreed project plan.⁵¹

CropLife supported the expansion of timeshift applications, commenting that the introduction of this option had significantly improved the predictability of applications eligible for that pathway and facilitated more timely application assessments.⁵² The VMDA also supported the expansion of timeshift applications, which it considered may assist with making timeframes more practical.⁵³

In March 2019 the Government introduced the Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019 which extended the kinds of applications that can be considered using a timeshift approach.

3.1.5 'Shut the gate' provisions

Prior to the 2014 reforms, applicants could lodge an incomplete application and provide data for the APVMA's consideration at any time during the assessment process. In practice, this meant that the APVMA reassessed applications every time an applicant provided new information. These arrangements, combined with the issues arising from assessment timeframes operating under the 'stop the clock' model, unnecessarily delayed the finalisation of assessments for applications and prevented the APVMA from dealing with applications efficiently.

The reforms therefore introduced 'shut the gate provisions' to prevent applicants from submitting incomplete applications and 'drip-feeding' information to the APVMA as it became available. These provisions were created through the introduction of the following amendments, used in combination with the operation of s 159 notices⁵⁴:

- the elapsed time model (discussed in the preceding section)
- a requirement for the APVMA to refuse inferior or deficient applications (discussed earlier in the 'preliminary assessment' section, although such refusal can arise at any stage)
- a requirement to specify the information the APVMA considers when assessing applications.

The provisions restrict the APVMA to only considering information provided within the application at the time it is lodged, new information sought by the APVMA during the assessment, and information required under the Agvet Code.⁵⁵

The 'shut the gate' provisions were also applied to reconsiderations. These provisions are discussed in the next chapter.

⁴⁹ Submission 7, Cotton Australia, p 1.

⁵⁰ Submission 5, CropLife Australia, p 4.

⁵¹ Department of Agriculture and Water Resources, *Proposed changes to timeshift applications and other measures, and to support operational efficiency Agricultural and Veterinary Chemicals Legislation Amendment Regulations 2018*, Canberra, December 2018, p 7.

⁵² Submission 5, CropLife Australia, p 4.

⁵³ Submission 13, Veterinary Manufacturers and Distributors Association, p 1.

⁵⁴ Under section 159 of the Agvet Code the APVMA can require an applicant to do specified things, such as clarify aspects of an application, or provide specified information, such as reports or samples. The APVMA may lodge a s 159 notice where an application is deficient and they are unable to assess the application against the relevant statutory requirements. It should also be noted that the first time a s 159 is issued during an assessment, the statutory timeframe for that assessment is compulsorily extended.

⁵⁵ Agvet Code, s 8C.

Feedback from this review

CropLife Australia's submission provided positive feedback that the 'shut the gate' provisions have been effective in improving application quality.⁵⁶

In regard to the 'anti-drip feeding' aspect of the reforms, the VMDA contended that this had created unnecessary work for applicants where APVMA staff have identified errors and/or omissions by way of issuing a s 159 notice that APVMA staff could and should already have. To illustrate its point it stated:

An example of this is to query the pH of a product when it is different from that of the reference product, whereas the APVMA assessor/risk manager should be aware of the safe and effective pH range of injections for all species and could and should therefore make the assessment without the need for the 159 notice.

Submission 13, Veterinary Manufacturers and Distributors Association, p 1.

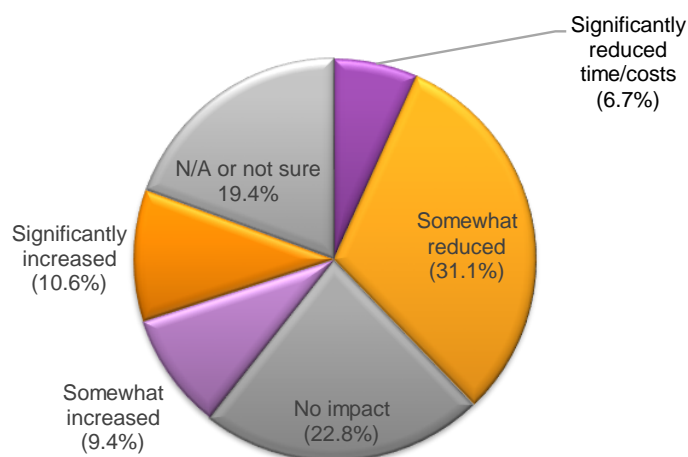
3.1.6 Electronic communication

To improve efficiency and reduce administrative costs and administrative errors in applications, the reforms introduced a new provision that allows certain information to be provided to the APVMA electronically, including applications, notifications, reports, declarations, certificates and statements of reason.⁵⁷

Findings from previous reviews

Stakeholders during the 2017 ANAO audit generally provided positive feedback in relation to the ability to lodge applications online. Nearly 40 per cent of respondents surveyed by the ANAO stated that the new functionality had significantly or somewhat reduced compliance time/costs to their organisation (although 20 per cent of respondents stated that it had significantly or somewhat increased time/costs (see **Figure 3.4**).

FIGURE 3.4 IMPACT OF ONLINE APPLICATION LODGEMENT ON COMPLIANCE TIME/COSTS



SOURCE: 2017 ANAO REPORT, P 46

Stakeholder feedback received during the 2018 House of Representatives committee inquiry was also generally positive. The ability to lodge applications online was described as useful, however it was noted that only some parts of the application process could be lodged electronically while others had to be submitted in hardcopy and then entered into the APVMA database manually, resulting in inefficiencies.⁵⁸

⁵⁶ Submission 5, CropLife Australia, p 4.

⁵⁷ Section 156A of the Agvet Code, which was inserted via s 161 of the Amendment Act.

⁵⁸ 2018 House of Representatives report, p 18.

Feedback from this review

The VMMA asserted that the operation of the electronic communications amendments has not yet been efficient because the APVMA's IT systems are 'archaic and do not interact well with applicants and do not work well for APVMA staff.' However, the VMMA also submitted that changes being made as a result of the APVMA's relocation to Armidale are expected to resolve these issues.⁵⁹

3.1.7 International assessments

The 2014 amendments aimed to ensure that there were no impediments to the APVMA's discretionary use of overseas data and assessments.

Findings from previous reports

The 2015 Agricultural Competitiveness White Paper outlined the Government's intention to consider products that are available in trusted overseas countries by examining the extent that risks in those countries differ to those in Australia, for instance different human health requirements, agricultural practices or environmental assets.⁶⁰

The 2016 Productivity Commission inquiry found that while the APVMA does take into account some international data and assessments in its registration processes, there was scope for greater use of evidence from other countries with strong regulatory and enforcement regimes. The Commission stated that the limited use of international evidence in registration processes is a contributing factor to the time and cost associated with registration, noting that chemicals must be assessed and registered by the APVMA even if they have previously been assessed and registered by an overseas regulatory authority.⁶¹

The Productivity Commission recommended that the APVMA make greater use of international evidence in its decisions on agvet chemicals (including through greater use of data and assessments from trusted comparable international regulators), and that the reforms underway in this area be expedited.⁶²

During the 2018 House of Representatives committee inquiry, stakeholders reflected that consideration of international data and assessments by the APVMA had been inconsistent, and once more advocated for greater use of such information to improve efficiency. The Chief Executive Officer (CEO) of the APVMA admitted that the agency had previously been 'a little bit risk averse' in its use of international assessments, however told the committee that it would increase its use of international assessments where applicable rather than redoing each step of the application assessment process.⁶³

The issue of international assessments was again raised during the 2019 Senate committee inquiry. Stakeholders continued to push for greater use of international data and assessments within a risk-based assessment framework to facilitate faster and more efficient processing of applications, while at the same time emphasising the importance of taking into account the situations and circumstances of Australian agriculture and the applicability of particular agvet chemicals to the local environment.⁶⁴

In January 2019 the Government responded to the Productivity Commission's 2016 report and advised that the APVMA had released updated guidance for the submission of international data, standards and assessments, which was supported by a legal direction to the APVMA issued by its CEO requiring staff to maximise the use of international assessments supplied with an application in order to improve the efficiency and timeliness of assessments.⁶⁵

⁵⁹ Submission 13, Veterinary Manufacturers and Distributors Association, p 2.

⁶⁰ Australian Government 2015, *Agricultural Competitiveness White Paper*, 2015, p 38.

⁶¹ Productivity Commission, *Regulation of Australian Agriculture*, No. 79, November 2016, p 299.

⁶² Ibid, p 303.

⁶³ 2018 House of Representatives report, p 17.

⁶⁴ 2019 Senate report, p 44.

⁶⁵ Australian Government, *Productivity Commission Inquiry into the Regulation of Australian Agriculture: Australian Government Response*, January 2019, p 11.

Feedback from this review

The increased use of overseas data and assessments conducted by comparable agencies, while recognising differences in national approaches, was again welcomed by stakeholders during this review. Cotton Australia highlighted that the use of international data and assessments was particularly beneficial in industries where the Australian market share is relatively small and there is less incentive for companies to generate data specific to Australian conditions, as the costs and timeframes associated with registering agricultural chemical products for specialty and minor crops often outweigh the potential financial benefit for companies to produce them, resulting in producers resorting to using products 'off-label' which created potential risks with product safety, efficacy and resistance management.⁶⁶

CropLife Australia observed that the improved use of overseas data and assessments is now being realised as efficiency gains in the application assessment process.⁶⁷ However, the VMDA suggested that the operation of these 2014 provisions has not been widespread and asserted that the APVMA continues to be 'overly risk averse' when considering international information when considering applications.⁶⁸

The GRDC suggested that to facilitate greater use of international data and assessments, the APVMA should provide a guidance document setting out the applicability, acceptability and merit of such information – particularly the acceptability of overseas residue, efficacy and crop safety data to Australian use patterns and Good Agricultural Practice.⁶⁹

3.2 Conclusions

The 2014 reforms included a range of amendments aimed at improving the efficiency and effectiveness of the APVMA's assessment of applications, involving all stages of the process from pre-application assistance through to decision-making.

Review participants supported the reforms to pre-application assistance, electronic communication and international assessments. Some stakeholders felt that there could be better use of these provisions by the APVMA – particularly international data and assessments, which has been raised in all of the post-reform reports referred to in this review – however this relates to implementation, which was out of scope for this review.

Stakeholders expressed mixed views on the operation of amendments to preliminary assessments and the 'shut the gate' provisions. CropLife and Grain Producers Australia were supportive of preliminary assessments on the basis that they ensure that applications have been properly completed, which leads to timely assessments, whereas the VMDA suggested that limiting the scope of preliminary assessments to administrative matters was too restrictive. The VMDA was also critical of the 'anti-drip' feeding aspect of the reforms arising from the 'shut-the-gate' provisions, contending that it had created more work for applicants, while CropLife supported the provisions, stating that they had improved application quality. It should be noted that the recent expansion of timeshift applications in the Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019 may have since alleviated some of the VMDA's concerns by providing greater flexibility to provide information while an assessment is underway.

In regard to calculating the timeliness of assessment decision-making, Cotton Australia supported the elapsed time model but suggested there may still be scope to improve efficiency. CropLife acknowledged that there have been improvements to timeliness but did not know whether this could be attributed to the new model. There was, however, support to increase the flexibility of the elapsed time model through broadening the scope of timeshift applications.

⁶⁶ Submission 7, Cotton Australia, pp 1-2.

⁶⁷ Submission 5, CropLife Australia, p 5.

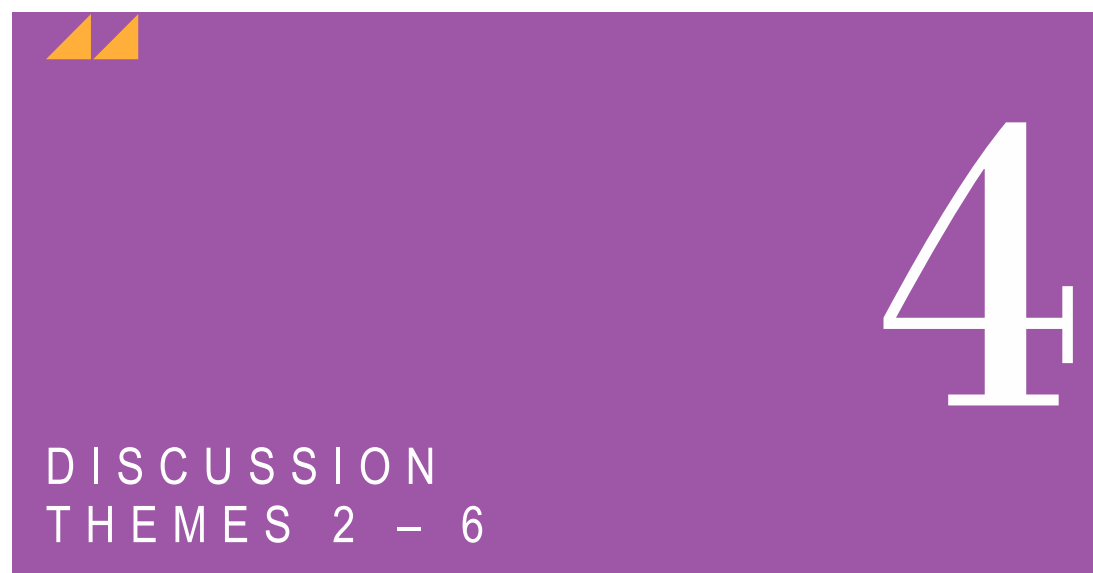
⁶⁸ Submission 13, Veterinary Manufacturers and Distributors Association, p 1.

⁶⁹ Submission 3, GRDC, p 3.

Some flexibility was also advocated by CropLife and Grain Producers Australia to allow applicants to rectify certain defects in applications at the preliminary assessment, such as minor errors or errors in technically difficult applications that require significant industry input. Although the intent of the reform is to refuse deficient applications, stakeholders suggested that introducing some limited flexibility, such as by giving applicants one opportunity to address identified deficiencies during the preliminary assessment process, would reduce the administrative burden on all stakeholders – including the APVMA. The Department noted that the now lapsed 2017 Operational Efficiency Bill contained a proposed measure to this effect.

When compared with the findings of previous reviews and audits conducted between 2014 and 2019, it can be seen that overall the operation of the 2014 amendments have resulted in improvements to the effectiveness and efficiency of application assessments, although the impact of many of these changes have only been felt gradually due to the incremental nature of their implementation.

With these conclusions in mind, the following chapter explores stakeholder evidence relating to Themes 2 - 6 of the discussion paper.



SNAPSHOT OF KEY FINDINGS

- The introduction of published work-plans and statutory timeframes for the completion of reconsiderations has improved the transparency and predictability of reconsiderations.
- The requirements for reconsiderations to focus on specific areas of concern and the APVMA to specify the information it must take into account during a reconsideration have improved efficiency.
- Certainty around the reconsideration process has increased since the introduction of 'shut the gate' provisions.
- Stakeholders have mixed views on whether the Agvet Code should be simplified through greater use of conditions of registration to regulate the labelling of chemical products, with less reliance on specific labelling offences. Some feel that there would be risks and complications in doing so, while others welcome reform to simplify labelling regulation.
- There is some support for the suggestion to align agvet legislation with the *Regulatory Powers (Standard Provisions) Act 2014*, to improve monitoring and investigation powers.
- There is also support for the suggestion for more measures to be included in disallowable legislative instruments.
- The extension of data protection periods is viewed favourably, with stakeholders noting that the improved protection of data provides investment incentives. However, the provisions are still deemed to be complex and difficult for applicants to understand, and insufficient time has passed to evaluate the full impact of some of the reforms.
- The small number of stakeholders who provided submissions broadly opposed the suggestion to omit Part 3 of the Agvet Code from the legislation and leave stakeholders to rely on commercial arbitration legislation for persons to negotiate access to protected information and information with limits on its use.
- The amendments to reorganise and simplify the Agvet Code have improved its readability, nevertheless some stakeholders still consider it to be a complex document and some confusion and uncertainty remains.
- Stakeholders provided positive feedback on notifiable and prescribed variations and support further expansion of the variations to other application types and particulars. There was no support in the submissions, however, for the suggestion to deal with variations as a new registration.

4.1 Reconsiderations (chemical review)

The APVMA may undertake a formal reconsideration (also known as a chemical review) of an active constituent or label that has been approved or a product that has been registered in Australia to scientifically reassess whether the chemical can continue to be used safely and effectively without unduly prejudicing trade (as well as ensuring label instructions are adequate). This is a legislated process, which allows the APVMA to consider new information that may have emerged after the initial

approval which may change the risks to human health, the environment, animal or crop safety, or trade.⁷⁰

Prior to the 2014 reforms, industry had raised concerns about the time taken by the APVMA to complete reconsiderations. There were also concerns from APVMA arising from the ability of applicants to provide data for a reconsideration at any time, which further delayed the APVMA's finalisation of reconsiderations.

To address these issues the Amendment Act introduced the following measures to improve the transparency, predictability and timeliness of reconsiderations by prescribing time frames for reconsiderations:

- a requirement for the APVMA to develop and publish a work plan for the reconsideration⁷¹
- allowing for the legislation to prescribe time limits for requests for information, reports, samples and trial and experiments data⁷²
- focusing reconsiderations on specific matters to do with an approval or registration, and concluding reconsiderations after those matters have been addressed, with any additional concerns to be dealt with as a new reconsideration with a different work plan⁷³
- specifying the information the APVMA must take into account for a reconsideration to address the issue of stakeholders delaying finalisation by continually providing more information for the reconsideration⁷⁴
- introducing timeframes for reconsiderations, with a maximum period of 57 months.⁷⁵

As noted earlier in section 3.1.5 of this report, 'shut the gate' provisions were also introduced to reconsiderations to prevent applicants from 'drip feeding' information to the APVMA and unnecessarily delaying the finalisation of assessments.

Findings from previous reviews

Stakeholders who provided evidence to the 2019 Senate committee inquiry noted that timeframes for reconsiderations had not always been met, with one inquiry participant giving the example of the chemical chlorpyrifos which has been under review by the APVMA for 22 years.⁷⁶ However, it should be noted that these timeframes have only applied since 2014, and therefore the timeframe in the example given has only just expired.

The APVMA acknowledged that its chemical review program was behind schedule but told the Senate committee that the risks were being managed through interim regulatory action, undertaken during the early stages of a reconsideration. These include suspending registration, removing uses or adjusting label directions as a precaution, then reinstating the uses if the review deems the chemical safe for re-approval.⁷⁷

The committee expressed concern about the delay in the schedule of reconsiderations and encouraged the APVMA to ensure that reconsiderations were appropriately resourced.⁷⁸

⁷⁰ APVMA, *Chemical review*, available at <https://apvma.gov.au/node/10916> (accessed 5 April 2019).

⁷¹ Agvet Code, s 31.

⁷² Agvet Code, s 32.

⁷³ Agvet Code, s 34.

⁷⁴ Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, pp 38-39.

⁷⁵ APVMA, *Chemical review*, available at <https://apvma.gov.au/node/10916> (accessed 5 April 2019).

⁷⁶ 2019 Senate report, p 48.

⁷⁷ *ibid.*

⁷⁸ *ibid.*, p 88. The Senate report also examined risk versus schedule-based reviews and reconsiderations of particular chemicals, however these discussions were not outlined above as they are outside the scope of this review. Similarly, discussion from the ANAO audit regarding reconsiderations was also excluded as it concerned consultation on the prioritisation of chemicals for review, which was also out of scope.

Feedback from this review

Cotton Australia considered that the 2014 amendments for reconsiderations, including the published work-plans and statutory timeframes for the completion of reconsiderations, had improved the transparency and predictability of reconsiderations. It highlighted flow-on benefits of this to industry in terms of being made aware of upcoming chemical reviews and able to plan accordingly by considering the current use patterns of a chemical, or investigating alternatives to maintaining access or managing a product's withdrawal or change in registration.⁷⁹

CropLife Australia likewise viewed the introduction of work plans and timeframes favourably, concurring that these had improved transparency regarding the intent and progress of reconsiderations. It also stated that efficiency had been significantly improved as a result of reconsiderations focusing on specific areas of concern, and through the requirement for the APVMA to specify the information it must take into account for a reconsideration.⁸⁰

The GRDC welcomed the introduction of 'shut the gate' provisions to reconsiderations to increase timeliness and certainty. In regard to determining prescribed time limits for data submission, however, it was concerned that the APVMA may not take into account the seasonality of use patterns, pointing out that 'if additional data are required, there may be limited, if any, opportunity for the production industry to generate data for the reconsideration, due to the seasonality of crops.'⁸¹

In regard to completing reconsiderations on time, the Department advised that the APVMA has not yet met any of the newly imposed timeframes. No other information was received about this matter in submissions to this review

4.2 Compliance and enforcement

Prior to the 2014 reforms, the APVMA's compliance and enforcement powers consisted of warning letters and criminal prosecution, with no options in between. In addition, some legislative provisions prevented the APVMA from responding effectively when new information emerged.

The reforms provided the APVMA with a modern, graduated range of compliance and enforcement powers. The new provisions improve the ability of the APVMA to efficiently administer its regulatory decisions by tailoring regulatory sanctions to the severity of the non-compliance, with the measures comparable to those available to other regulators under other Australian Government laws.⁸²

Some of the key amendments to compliance and enforcement measure made by the Amendment Act included:

- aligning the monitoring and investigation powers in the Agvet Code and Administration Act with regulatory powers in the subsequent *Regulatory Powers (Standard Provisions) Act 2014*, and allowing the powers in the Administration Act to be exercised for the purposes of the Levy Act.⁸³
- introducing civil penalty provisions (and the ability to apply to the court for a civil penalty order), which provide more proportionate and effective financial disincentives to misconduct⁸⁴
- the ability to issue:
 - infringement notices where civil penalty provisions have been contravened⁸⁵
 - substantiation notices requiring persons to provide information to support representations made about the import or export of a product⁸⁶
 - enforceable undertakings which formalise agreed remedial actions between the APVMA and parties seeking to address instances of non-compliance⁸⁷
 - enforceable directions where a person is not complying with the Code and action is necessary to protect human beings; or animals, plants, things or the environment; or trade or commerce⁸⁸

⁷⁹ Submission 7, Cotton Australia, p 2.

⁸⁰ Submission 5, CropLife Australia, p 6.

⁸¹ Submission 3, GRDC, p 3.

⁸² Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, p 58.

⁸³ *ibid*, p 12.

⁸⁴ *ibid*, p 4.

⁸⁵ *ibid*, p 6.

⁸⁶ *ibid*, p 69.

⁸⁷ *ibid*, p 88.

⁸⁸ *ibid* p 90.

- formal warnings which can be issued where the APVMA believes the non-compliant behaviour was inadvertent⁸⁹
- notices to produce information or documents or things, or attend before an inspector to answer questions.⁹⁰
- introducing a power to apply statutory conditions to registrations and approvals so the regulations could prescribe conditions, including an offence for contravening conditions of a permit⁹¹
- allowing the APVMA to suspend or cancel a registration or permit where there is imminent risk to persons of death, serious injury or illness,⁹² or suspend or cancel an approval or registration where false or misleading information is provided.⁹³ The amendments also introduce a procedural fairness mechanism where the APVMA is proposing such a suspension or cancellation.⁹⁴
- allowing the APVMA to apply to a court to have a person pay certain costs incurred in investigation of the offence or civil penalty provision, to avoid drains on the APVMA's resources⁹⁵
- increasing the penalty for some offences to align with contemporary standards
- introduction of the term 'holder' of approvals and registrations, replacing the previous and confusing expression 'interested person'⁹⁶
- updating the fit and proper person tests for permits and manufacturing licences so they reflected the Australian Government's Spent Conviction Scheme (which provides that only convictions or penalty orders in the previous ten years need to be declared).

Findings from previous reviews

The 2017 ANAO audit found that the APVMA had exercised its expanded enforcement powers since the reforms, issuing one statutory notice, six formal warnings, two infringement notices and one investigative warrant in 2015-16. However, the ANAO noted that the effectiveness of the APVMA's compliance and enforcement activities was limited due to a lack of a fit-for-purpose investigation case management system and procedures for the collection and use of compliance intelligence. This had resulted in the APVMA's investigations being largely reactive and dependent upon reports of non-compliance submitted by the public on its website. The ANAO stated that the development of appropriate intelligence collection and analysis arrangements would better place the APVMA to implement its graduated compliance and enforcement strategy.⁹⁷

Feedback from this review

According to Grain Producers Australia, the amendments to improve compliance and enforcement 'have had limited change in outcomes'. While acknowledging that the APVMA had been proactive with registrants in managing product safety and compliance for sale and use, it expressed concern about adverse spray drift events still occurring, despite industry compliance rates regarding pesticide use, chemical residue and food safety for trade and export still being high.⁹⁸

In response to one of the questions in the discussion paper regarding whether the Agvet Code should be simplified through greater use of conditions of registration to regulate the labelling of chemical products (with less reliance on specific labelling offences), Grain Producers Australia cautioned that there would be significant risks in doing so, which it said would be further complicated by the significant variance in state government control of use legislation across Australia.⁹⁹

⁸⁹ *ibid*, p 90.

⁹⁰ Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, p 90.

⁹¹ *ibid*, p 90.

⁹² *ibid*, p 5.

⁹³ *ibid*, p 90.

⁹⁴ *ibid*, p 71 and p 77.

⁹⁵ *ibid*, p 6.

⁹⁶ *ibid*, p 20.

⁹⁷ 2017 ANAO report, p 29.

⁹⁸ Submission 12, Grain Producers Australia, p 13.

⁹⁹ *ibid*.

CropLife Australia similarly expressed concern about replacing legislative offences with conditions of registration. It stated that while it supports efforts to simplify the legislation, 'replacing legislative offences with conditions of registration serves only to shorten the legislation and does not resolve its inherent complexity or simplify compliance activities.'¹⁰⁰

In contrast, the VMDA¹⁰¹ supported the greater use of conditions of registration to regulate the labelling of chemical products, as did Cotton Australia which commented:

The current labelling system can be inconsistent across chemicals and confusing for users. Any reforms that can simplify the label directions for end users, while ensuring responsible application of the product, is welcomed.

Submission 7, Cotton Australia, p 2.

In response to another question in the discussion paper as to whether agvet legislation should be further aligned¹⁰² with the *Regulatory Powers (Standard Provisions) Act 2014*, Grain Producers Australia felt that such an alignment could improve the current monitoring and investigation powers to search and seize evidential material; inspect items on premises; and enforce civil penalty provisions, infringement notices, enforceable undertakings and injunctions. However, it was concerned about whether there would be adequate resources to effectively implement these powers.¹⁰³

Grain Producers Australia supported a suggestion in the discussion paper for more measures to be included in disallowable legislative instruments on the basis that it would increase the APVMA's flexibility and responsiveness to rapidly evolving technologies such as digital and automation technologies.¹⁰⁴ Such a move was also supported by the VMDA.¹⁰⁵

The GRDC's feedback regarding the 2014 compliance and enforcement amendments concerned the fit and proper tests for permits, which the GRDC described as 'an anomaly'. It noted that while the holder of a permit is required to be assessed as fit and proper, the holder is rarely the user of the use pattern approved under the permit. The GRDC contended that the requirement for a permit holder to be aligned to the Spent Conviction Scheme 'appears to be over-governance and has no operational compliance on who uses a chemical under a permit.'¹⁰⁶

4.3 Improved consistency in protection provisions

Various protection provisions act to protect the owners of regulatory data from competitors who might otherwise gain an unfair commercial advantage from their information. Regulatory data can require significant research and investment, and the value of the data can also diminish in the time it takes to be collected and have it assessed by the APVMA. It is therefore important to protect owner data to encourage innovation and maintain investment in agvet chemicals.¹⁰⁷

The Agvet Code provides for two kinds of information protection during which information provided to the APVMA can be protected from unauthorised use: 'limitation periods' and 'data protection periods'.

For example, 'limitations on the use' of data by the APVMA apply as it assesses applications for new actives and products in order to protect the owners from unauthorised use of their data. During a limitation period, information provided to the APVMA as part of an application or under s 161 of the Agvet Code¹⁰⁸ that is relied on by the APVMA in making a decision cannot be used by the APVMA to assess or make a decision on another application. An exception may apply, however, if the authorising party consents to the use of this information.

¹⁰⁰ Submission 9, CropLife Australia, p 9.

¹⁰¹ Submission 13, Veterinary Manufacturers and Distributors Association, p 2.

¹⁰² There is currently already a high degree of alignment with the *Regulatory Powers (Standard Provisions) Act*, and any deviations are related to agvet-specific matters (e.g. time to present evidence delayed by distance of likely offence location).

¹⁰³ Submission 12, Grain Producers Australia, p 13.

¹⁰⁴ *ibid*, p 14.

¹⁰⁵ Submission 13, Veterinary Manufacturers and Distributors Association, p 2.

¹⁰⁶ Submission 3, GRDC, p 3.

¹⁰⁷ Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, p 6.

¹⁰⁸ Section 161 requires the holder of an active constituent approval or chemical product registration to provide certain new information to the APVMA that would affect the approval or registration as soon as they become aware of it.

In other situations, a 'protection period' from unauthorised use applies to 'protected information' when it is provided as part of a reconsideration. Part 3 of the Agvet Code also contains compensation provisions for such unauthorised use, that to date have never been used. These provisions entitle a person who has provided protected information in compliance with a requirement made by the APVMA, to receive compensation from anyone else who wishes the information to be used by the APVMA in connection with an application for an approval of another active constituent or the registration of another chemical product.¹⁰⁹

Previously, protected information provisions were overly complex and did not provide meaningful access to protection for information provided for a reconsideration. As such, the reforms aimed to simplify these provisions and make them more flexible, consistent and easier to administer.¹¹⁰ The reforms:

- removed disincentives for business to invest in innovative product development, thereby improving the productivity of Australia's agri-food industries
- extended eligibility for protection and compensation to a wider range of data
- extended the time that the data is protected
- improved the mechanism by which data owners can obtain compensation for information submitted in relation to a reconsideration
- maintained eligibility for protection where data is provided as part of an application and that application is withdrawn or refused, and where data is provided as part of a permit application and those data are provided in relation to a future application¹¹¹
- removed provisions relating to extensions of protection for minor uses, because these had not been used in the nearly ten years they had been included in the Agvet Code.

Feedback from this review

CropLife Australia supported the extension of data protection periods, nevertheless it submitted that the provisions were still complex and difficult for applicants to understand.¹¹²

One of the changes extended the protection period for protected information to eight years after the APVMA makes a reconsideration decision. CropLife noted that insufficient time had passed to evaluate the full impact of this change. Further, the Department noted that the impact has been difficult to evaluate since there has been little ensuing reconsideration activity since 2014, and therefore little need to activate these measures. Even so, CropLife considered that the extended protection period has provided a significant incentive for applicants to invest in trials to generate data to support the ongoing registration of a product.¹¹³

The investment incentives arising from the new provisions were also highlighted by the GRDC, which noted that the improved protection of data submitted through permit applications encourages registrants and industry to invest in minor use data generation.¹¹⁴ No comments on the other changes to information protection were received during this review.

In response to a suggestion in the discussion paper regarding whether Part 3 of the Agvet Code should be omitted (leaving stakeholders to rely on commercial arbitration legislation for persons to negotiate access to protected information), Grain Producers Australia strongly opposed such a move, warning that it could lead to uncertainty for registrants in maintaining confidential commercial information and data protection which may lower investment confidence in commercialising new agvet technology in Australia. Grain Producers Australia was also concerned that omitting Part 3 could result in increased legal costs for registrants (and ultimately end users) who may have to defend and

¹⁰⁹ Agvet Code, Part 3, Div 1, s 57.

¹¹⁰ Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, p 6.

¹¹¹ Commonwealth, *Parliamentary Debates*, House of Representatives, 28 November 2012, 13658 (Sid Sidebottom, Parliamentary Secretary for Agriculture, Fisheries and Forestry); Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, p 6 and p 93.

¹¹² Submission 3, CropLife Australia, p 10.

¹¹³ *ibid.*

¹¹⁴ Submission 3, GRDC, p 3. It should be noted that there is no data protection for data submitted with permits, but data is eligible for protection if re-submitted with a registration.

maintain labels to data protected products.¹¹⁵ It should, however, be noted that Part 3 compensation provisions have not been used to date.

CropLife was also opposed to removing Part 3 from the Agvet Code, submitting that the responsibility for determining the use of, and compensation for, the use of protected information or information with limits on its use should lie with the holder of that information, rather than with the APVMA.¹¹⁶ An issue with this argument though is that removing Part 3 of the AgVet Code would not remove responsibility from the APVMA since Part 3 requires the APVMA's involvement.

4.4 Legislation improvements

The Amendment Act simplified, reorganised and modernised the Agvet Code to reduce uncertainty and complexity in the legislation. The Amendment Act also removed redundant provisions and amended out of date provisions across agvet legislation, including provisions around applications, reconsiderations, suspensions and cancellations, notices and data protection.¹¹⁷

The revisions included:

- the insertion of explanation sections
- consolidation of existing 'legislative tests' for approval and registration, variation, reconsideration and elsewhere into four new tests (the 'meets the efficacy criteria', 'meets the labelling criteria', 'meets the safety criteria' and 'meets the trade criteria' tests) under subsection 3(1) of the Agvet Code¹¹⁸
- introducing a single set of general provisions relating to all applications except for licences
- consolidation of notice provisions
- simplification of provisions around 'interested persons', 'approved persons' and listed registrations to address some inconsistencies in the Agvet Code.¹¹⁹

Feedback from this review

CropLife Australia stated the view that the reorganisation and simplification of the Agvet Code had improved its readability but it remains a complex piece of legislation.¹²⁰

Similarly, Grain Producers Australia felt that even though the changes have attempted to improve legislative understanding and clarity, some uncertainty remains. It further submitted that the reforms made to the legislative tests had not addressed the key issue of a lack of investment in new active products to comply with safety, trade, efficacy and labelling criteria.¹²¹

4.5 Variations to relevant particulars and conditions

The Agvet Code provides that certain minor, low risk variations to relevant particulars of approval or registration (such as varying the name or address of an Australian manufacturer or a changing a company logo) may be made by 'notification' or as a 'prescribed variation'. Prior to the introduction of notifiable and prescribed variations, regulated entities were required to formally apply for low risk minor variations to certain particulars of an approval or registration.

Prescribed variations were introduced in the *Agricultural and Veterinary Chemicals Code Amendment Act 2010* and allow the APVMA to develop a legislative instrument which sets out relevant particulars which can be varied by an application to notify.¹²²

Notifiable variations were introduced in the *Removing Re-approval and Re-registration Act* and allow certain changes to registrations or approvals to be made by notifying the APVMA. Notifiable variations are deemed to be granted when they are lodged with the APVMA after checks have been conducted.

¹¹⁵ Submission 15, Grain Producers Australia, p 15.

¹¹⁶ Submission 5, CropLife Australia, p 10.

¹¹⁷ Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, p 2.

¹¹⁸ n.b. while s 3 provides definitions for meeting these and other various criteria, the statutory tests themselves are provided in ss 5A-5D.

¹¹⁹ Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013, p 2.

¹²⁰ Submission 5, CropLife Australia, p 11.

¹²¹ Submission 12, Grain Producers Australia, p 16.

¹²² Revised Explanatory Memorandum, Agricultural and Veterinary Chemicals Code Amendment Bill 2010, p 2.

The amendments aimed to reduce red tape by allowing for simpler variations to low risk approvals and registrations.

The 2013 Amendment Act added:

- a new option for 'prescribed variations' to be prescribed in regulation as an alternative to the previously specified APVMA legislative instrument¹²³
- a requirement that a prescribed variation take effect within a period prescribed in the regulations (currently one month).

The current notifiable variations and prescribed variations only allow some relevant particulars to be varied and do not authorise conditions to be varied as notifiable or prescribed variations.

As noted in chapter 1, the Minister requested that this review include consideration of notifiable and prescribed variations – particularly the extent to which these have been successful and could be expanded.

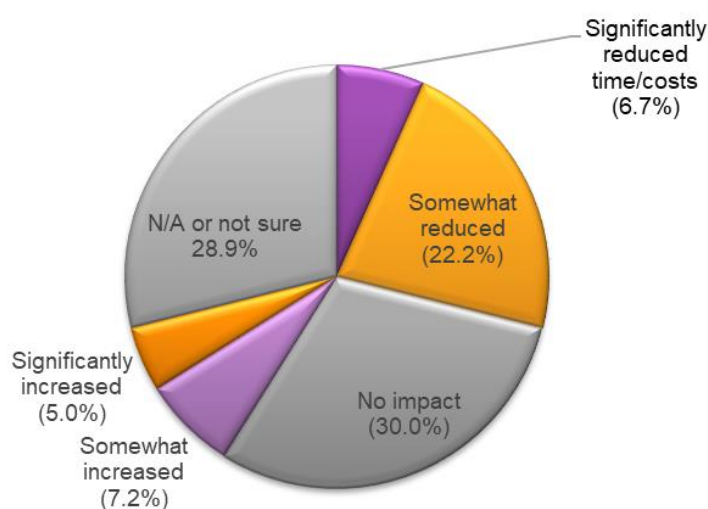
Findings from previous reviews

The ANAO reported that in 2015-16, 736 variation notices were lodged with the APVMA and 696 variations were issued.

The ANAO stated there had been a decline in the overall number of applications to the APVMA, and that one of the contributing factors for the decline was the introduction of the Notifiable Variations Scheme on 1 January 2015, which would likely have resulted in time and cost savings, given that under the pre-reform system these variations would have been lodged and processed as applications. It noted, however, that the APVMA had not retained data to enable the assessment of the extent of any efficiency improvements.¹²⁴

The ANAO surveyed regulated entities as to how much prescribed/notifiable variations have impacted compliance time and costs (see **Figure 4.1**). The majority of respondents (58.9 per cent) stated that there had been no impact or they were not sure of any impact, while around 29 per cent said that the variations had significantly or somewhat reduced time/costs. A small proportion (12.2 per cent) of respondents reported that the variations had somewhat or significantly increased their costs.

FIGURE 4.1 IMPACT OF PRESCRIBED / NOTIFIABLE VARIATIONS ON COMPLIANCE TIME/COSTS



SOURCE: AUSTRALIAN NATIONAL AUDIT OFFICE, PESTICIDE AND VETERINARY MEDICINE REGULATORY REFORM, REPORT NO. 56, 2016-17, P 46

¹²³ However, to prevent any ambiguity or possible duplication of requirements, a list of prescribed variations was removed from the regulations in 2019 thus facilitating the sole use of the APVMA legislative instrument.

¹²⁴ 2017 ANAO report, pp 41-42.

Feedback from this review

CropLife Australia was highly supportive of notifiable and prescribed variations, commenting that they been very effective for the Australian plant science industry and had reduced regulatory burden on agvet industries and the APVMA. It supported further expansion of the variations to other application types and particulars, however urged that there be sufficient time and consultation with industry in doing so.¹²⁵

Similarly, Grain Producers Australia considered there to be value and practical effects from having multiple processes for varying relevant particulars, which it said had led to positive outcomes for the grains industry. It supported expanding the concept to enable label holders to make reasonable variations to chemical product constituents to help reduce the regulatory burden on industry and the APVMA.¹²⁶

The VMDA also supported the 2014 reforms regarding notifiable variations. In response to a question in the discussion paper as to whether there should be a streamlined means to vary conditions, it commented that more clarity would be required before it could reach a view on the matter, although submitted that while conditions requiring significant technical assessment would not be able to be varied by notification, perhaps conditions requiring 'supporting information' for technical changes could.¹²⁷

4.6 Conclusion

Overall, stakeholder feedback in relation to the operation of amendments discussed in Themes 2 to 6 of the discussion paper was broadly that there have been some improvements but there is scope for even more legislative clarity, or that it is still too soon to evaluate the full impact of some of the amendments.

For example, there was support for the amendments to simplify and modernise the legislation and improve consistency in protection provisions, however some stakeholders still find the provisions to be confusing and complex. Similarly, stakeholders of the 2017 ANAO audit and this review were supportive of the amendments made in relation to compliance and enforcement activities yet felt that there had been limited effects on organisational outcomes.

In regard to evaluating the impact of the amendments, some of the measures have not operated long enough (or even at all) to assess their full effect. For instance, CropLife Australia noted that insufficient time has passed to enable a complete consideration of the eight year protection period amendment. It was also not possible to evaluate the operation of some of the compliance and enforcement measures as they have not yet been used.

Positive feedback was received about the operation of amendments to reconsiderations (including published work-plans, statutory timeframes for completion and shut the gate provisions), which stakeholders considered had improved efficiency, transparency and predictability; and the amendments to improve consistency in protection provisions, which stakeholders noted had created investment incentives for registrants and industry.

Review participants were also positive about the introduction of prescribed and notifiable variations, and generally supported the suggestion to expand the variations to certain other application types and conditions.

Other suggestions that gained support included further alignment of agvet legislation with the *Regulatory Powers (Standard Provisions) Act 2014* and inclusion of more measures in disallowable instruments.

Mixed views were received in response to the suggestion to increase the use of conditions of registration to regulate the labelling of chemical products, and the suggestion relating to the expansion of certain measures from the 2014 reforms. The Department may wish to consider this feedback during the development and implementation of any future reforms to agvet regulation.

¹²⁵ Submission 5, CropLife Australia, p 11.

¹²⁶ Submission 12, Grain Producers Australia, p 17.

¹²⁷ Submission 13, Veterinary Manufacturers and Distributors Association, p 2.

A suggestion opposed by stakeholders was to omit Part 3 of the Agvet Code and rely on commercial arbitration legislation for persons to negotiate access to protected information in a reconsideration.

In conclusion, stakeholders welcomed the 2014 reforms to simplify, modernise and improve the effectiveness of agvet chemical regulation. In some areas the operation of the amendments has led to tangible improvements, whereas in others the impact of amendments has been limited or yet to be seen. There are two primary reasons for this. The first concerns the use of certain provisions by the APVMA. However, this relates to implementation, which is out of scope for this review. The second is that insufficient time has passed to see the full impact of some of the amendments, or some measures have not been used as the need for them has not yet arisen. For these amendments, more time is needed before an assessment can be made.

While the 2014 reforms have delivered some efficiencies, more reform is required to simplify the legislation. ACIL Allen maintains its view from the 2017 review of *International IP & Registration Arrangements for the Regulation of AgVet Chemicals* that the legislation and regulations need to be simplified and rewritten. It may therefore be beneficial to include a comprehensive examination of the entire agvet framework in the near future.



Submissions were received from the following stakeholders:

1. Infopest
2. Name suppressed
3. Grains Research & Development Corporation (GRDC)
4. Confidential
5. CropLife Australia
6. Andrew Johnston and Robyn Wood
7. Cotton Australia
8. Australian Food Sovereignty Alliance
9. Aerial Application Association of Australia (AAAA)
10. Name suppressed
11. Animal Medicines Australia
12. Grain Producers Australia
13. Veterinary Manufacturers and Distributors Association (VMDA)
14. Dairy Australia / Aglign Ag



B

DISCUSSION
PAPER

18 FEBRUARY 2019

DISCUSSION PAPER



OPERATION OF THE AMENDMENTS IN THE AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT ACT 2013

**CONSULTATION ON BEHALF OF THE
DEPARTMENT OF AGRICULTURE AND WATER RESOURCES**





INVITATION FOR SUBMISSIONS

ACIL Allen Consulting (ACIL Allen) is seeking submissions on the operation of amendments to legislation made by the [Agricultural and Veterinary Chemicals Legislation Amendment Act 2013](#) (Amendment Act).

Section 4 of the Amendment Act specifies that the Minister must cause a review of the operation of the amendments made by the Amendment Act and a written report of the review to be laid before each House of the Parliament within 15 sitting days of that House after 1 July 2019:

4 Review of operation of amendments

- (1) *The Minister must cause a review to be conducted of:*
 - (a) *the operation of the amendments made by this Act; and*
 - (b) *any other related matter that the Minister specifies.*
- (2) *At least one of the persons conducting the review must be a person who is not otherwise appointed, employed or engaged by the Commonwealth.*
- (3) *The review must include a request for, and consideration of, submissions from members of the public.*
- (4) *The Minister must cause a written report of the review to be laid before each House of the Parliament within 15 sitting days of that House after 1 July 2019.*

The submissions will inform the review and will be used to develop the report to be tabled in Parliament.

1.1 Background

The National Registration Scheme regulates agricultural and veterinary (agvet) chemicals. The legislation that gives effect to the scheme includes the [Agricultural and Veterinary Chemicals \(Administration\) Act 1992](#) (Administration Act) and the [Agricultural and Veterinary Chemicals Code Act 1994](#) (Code Act).

The Administration Act establishes the Australian Pesticides and Veterinary Medicines Authority (APVMA) and sets out its role as an independent regulator of agvet chemical products. The provisions in the Code Act and the Schedule to it (the Agvet Code) allow the APVMA to evaluate, approve, register or review active constituents and chemical products (and their labels), and issue permits and licences for the manufacture of chemical products. Other provisions in the Agvet Code provide for controls to regulate the supply of chemical products, and ensure compliance with, and enforcement of, the Agvet Code including suspending and cancelling registration of chemical products.

The Amendment Act amended the Administration Act, Code Act, [Agricultural and Veterinary Chemicals Act 1994](#) (Agvet Act) and the [Agricultural and Veterinary Chemical Products \(Collection of Levy\) Act 1994](#) (Levy Act).

The term “agvet legislation” refers to these laws and to any regulations or legislative instruments made under them.

The Amendment Act aimed to simplify, re-organise and modernise the Agvet Code, and reform the approval, registration and reconsideration of agvet chemicals to improve the efficiency and effectiveness of the existing regulatory arrangements.

In general terms the purpose of the amendments in the Amendment Act included:

- enhancing the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations through development, publication and implementation of a risk framework, to which the APVMA must have regard, and legislative amendments to align regulatory effort with chemical risk
- ensuring the ongoing safety of agvet chemicals and improving the effectiveness and efficiency of then current agvet chemical reconsideration arrangements by implementing a mandatory re-approval and re-registration scheme, designed to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses
- improving the efficiency and effectiveness of assessment processes for agvet chemicals applications for approval, registration and variation, and improving the timeliness of agvet chemical approvals, registrations and reconsiderations
- improving the ability of the APVMA to enforce compliance with its regulatory decisions by providing the APVMA with a graduated range of compliance enforcement powers and introducing a power to apply statutory conditions to registrations and approvals
- improving consistency in data protection provisions and removing disincentives for industry to provide data in support of ongoing registration of agricultural and veterinary chemicals
- addressing perceptions of a conflict of interest by providing for an agency other than the APVMA to collect the chemical products levy, should it be cost effective to do so
- providing greater certainty to the Australian public that agvet chemicals approved for use in Australia are safe by clarifying that the first priority of the regulatory system is the health and safety of human beings, animals and the environment.

1.2 Purpose of this discussion paper

This discussion paper describes the amendments made by the Amendment Act and invites submissions from interested parties on the operation of these amendments and other related matters. To assist stakeholders, this paper groups the amendments into six key themes and seeks comment on the operation of these amendments.

Complicating factors

The operation of some of the amendments made by the Amendment Act may be difficult to review due to the following factors:

- The provisions establishing the re-approval and re-registration scheme only operated for a short time until they were repealed by the [Agricultural and Veterinary Chemicals Legislation Amendment \(Removing Re-approval and Re-registration\) Act 2014](#) (Removing Re-approval and Re-registration Act), therefore it is not possible to assess the operation of these provisions.
- Some measures have not been in effect long enough to allow a complete consideration of their operation. This is particularly relevant for some data protection measures and compliance and enforcement measures, which only apply in certain circumstances such as where certain information is provided or where non-compliance is detected. The operation of these types of amendments is difficult to assess until enough time has passed to allow the circumstances to manifest in a sufficient number of cases.
- Some measures, such as the levy collection arrangements, have never operated because the additional steps needed to bring them into effect were never implemented. It is therefore not possible to assess the operation of these amendments.

Operation versus implementation

This review is focused on the *operation* of the amendments in the Amendment Act, rather than the *implementation* of the amendments, which has already been comprehensively considered by the Australian National Audit Office in its 2017 report [Pesticide and Veterinary Medicine Regulatory Reform](#), and the House of Representatives Standing Committee on Agriculture and Water Resources in its 2018 report, [APVMA Regulatory Reforms](#).

Stakeholders should therefore limit their comments to the operation of the amendments since they commenced on 1 July 2014.

Notifiable and prescribed variations

In addition to the amendments made by the Amendment Act, we also invite you to comment on the extent to which notifiable and prescribed variations (as amended by the Removing Re-approval and Re-registration Act) have or have not been successful and whether or not stakeholders see scope for expanding the concept to other types of applications.

1.3 How to have your say

The deadline for receipt of all submissions is **5:00 pm on Friday 29 March 2019**.

ACIL Allen will consider all relevant material provided in submissions. While there is no set format for a submission, please make sure you include your name and title, your organisation's name (if applicable) and your contact details.

We would appreciate your assistance by identifying the relevant section of this document when making a comment on that specific section. Please note that the discussion points in this document are a guide only. They do not all need to be addressed, and stakeholders are welcome to raise other matters relating to the operation of the amendments.

Submissions can be emailed to agvetreview@acilallen.com.au.

Questions about the review or the submission process can be directed to Teresa McMichael at the email address above, or on (02) 6103 8216.

1.4 Publishing of submissions

Unless requested otherwise, submissions will be published on ACIL Allen's website. All personal contact details will be removed before publication.

Please advise if you would like some or all of your submission to be kept confidential and indicate your reasons for withholding the information.

We reserve the right not to publish submissions or to redact parts of submissions, for example, if they contain defamatory comments.

Privacy: We will only use the personal information collected to contact you about your submission and may (where the disclosure is consistent with relevant laws, in particular the *Privacy Act 1988*) disclose it to the Department of Agriculture and Water Resources (the Department). Confidential submissions will not be disclosed to the Department.

We will use and store all personal information in accordance with the National Privacy Principles as outlined in ACIL Allen's privacy policy available on our website.

5

DISCUSSION THEMES

Theme 1: Application assessment efficiency and effectiveness

The Amendment Act included measures aimed at improving assessment efficiency and effectiveness.

Amendments were included to address concerns about the time taken by the APVMA to complete applications. The (then) timeframes for applications did not take into account the total time that had elapsed for considering an application. The timeframes for applications operated on a 'stop the clock' model, whereby the timeframe paused if the APVMA sought additional information from the applicant. This model did not provide for certainty and predictability in assessment timeframes for either the applicants or the APVMA.

In addition, applicants could lodge an incomplete application, and provide data for the APVMA's consideration at any time during the assessment process. These arrangements unnecessarily delayed the finalisation of assessments for applications, as whenever the applicant provided new information, the APVMA would need to reassess the application based on that information.

Before the Amendment Act commenced, the APVMA conducted preliminary assessments of applications, which included an assessment of the adequacy of the technical information provided. This meant that the APVMA had to consider the technical information twice – once at preliminary assessment stage and again at the assessment stage of the application.

The Amendment Act (and regulations amendments) introduced:

- timeframes for assessments based on total elapsed time, including the time taken to provide more information (elapsed time model)
- amendments requiring the APVMA to refuse inferior or deficient applications so that it was only required to assess applications that were complete and of the required standard at the time of lodgement (refusal of applications)
- amendments that specified the information the APVMA must take into account for an application, to prevent the practice of some applicants submitting incomplete applications, and 'drip-feeding' information to the APVMA as it became available, thereby lengthening assessment timeframes and consuming more regulatory resources than warranted
- the "shut the gate provisions", being the provisions above, used in combination with the operation of section 159 notices¹²⁸, which are mirrored for reconsiderations (discussed in Theme 2)
- amendments to preliminary assessment so that it dealt only with administrative matters concerning applications and did not include a technical assessment (preliminary assessment)
- amendments to ensure that there was no undue impediment to the APVMA's use of overseas data and assessments conducted by comparable regulatory agencies, while recognising differences in national approaches (overseas data and assessments)
- amendments that enabled the APVMA to require electronic communication between it and applicants to improve efficiency in providing applications and information (electronic communication)
- guidelines for the APVMA to make, publish, and have regard to, as part of an overarching risk-based compendium that would be developed, maintained and published by the APVMA (guidelines)

¹²⁸ Under section 159 of the Agvet Code, the APVMA can require an applicant to do specified things, such as clarify aspects of an application, or provide specified information, such as reports or samples. The APVMA may issue a section 159 notice where an application is deficient and they are unable to assess the application against the statutory requirements.

- pre-application assistance so prospective applicants could obtain information on making a quality application.

BOX 2.1 DISCUSSION THEME 1: ASSESSMENT EFFICIENCY AND EFFECTIVENESS

Stakeholders may wish to comment on the following:

1. The effectiveness of the 'elapsed time' model versus the 'stop the clock' model, and whether the elapsed time model can be made more flexible through broadening the scope of 'time-shift' applications.
2. Whether the amendments have assisted stakeholders with the application process.
3. Whether there should be more flexibility in the time period used to rectify defects in applications.
4. Whether the preliminary assessment step should be retained.
5. The value and practical effects of the APVMA's use of international assessments and data for assessing applications.
6. Any other issues (caused by the amendments) relating to the efficiency and effectiveness of assessments.

Theme 2: Reconsiderations (chemical review)

The Amendment Act introduced measures to improve the transparency and predictability of reconsiderations of an active constituent, label approval, or product registration in response to concerns about the time taken by the APVMA to complete reconsiderations (chemical reviews). In addition, persons could provide data for the reconsideration at any time. These arrangements unnecessarily delayed the APVMA's finalisation of reconsiderations.

The Amendment Act also introduced the following changes:

- a requirement for the development and publication of a work plan for the reconsideration to provide transparency and predictability
- allowing for the legislation to prescribe time limits for requests for information, reports, samples and trial and experiments data, to provide predictability
- focusing reconsiderations on specific matters to do with an approval or registration, and concluding reconsiderations after those matters have been addressed, with any additional concerns identified in the course of reconsideration to be dealt with as the subject of a new reconsideration with a different work plan
- specifying the information the APVMA must take into account for a reconsideration to address an incentive for affected stakeholders to frustrate the reconsideration process by continually providing reconsideration information to the APVMA and thereby delaying final action
- introduced timeframes for reconsiderations to provide for a more predictable completion of the reconsideration.

BOX 2.2 DISCUSSION THEME 2: RECONSIDERATIONS

Stakeholders may wish to comment on the following:

7. Whether the amendments, including the published work-plans and timeframes, have improved the transparency and predictability of reconsiderations.

Theme 3: Compliance and enforcement

The Amendment Act improved the ability of the APVMA to enforce compliance with its regulatory decisions by providing it with a graduated range of compliance and enforcement powers.

The amendments aimed to improve the APVMA's ability to administer its regulatory decisions efficiently by tailoring regulatory sanctions to the severity of the non-compliance, to enhance protection of public health and safety and the environment. The measures are similar to those available to other regulators under Commonwealth laws and modernised current investigation and enforcement provisions, consistent with contemporary standards.

The largest schedule of amendments in the Amendment Act encompasses compliance and enforcement measures. Some of the most significant amendments included:

- aligning the monitoring and investigation powers in the Agvet Code and the Administration Act, with regulatory powers in the later [Regulatory Powers \(Standard Provisions\) Act 2014](#), including applying the powers in the Administration Act for the Levy Act (so the Levy Act did not need to mirror the monitoring, investigative and enforcement powers in the Administration Act)
- introducing civil penalty provisions (and the ability for civil penalty orders), the ability to issue infringement notices, substantiation notices, enforceable undertakings, enforceable directions, warnings and notices to attend, give information or produce documents or things
- introducing a power to apply statutory conditions to registrations and approvals so the regulations could prescribe conditions, including an offence for contravening conditions of a permit
- improving suspension and cancellation powers to include where there is imminent risk to persons of death, serious injury or illness, or where false or misleading information is provided, as well as providing for a procedural fairness mechanism where the APVMA is proposing to suspend or cancel an approval, registration or licence
- providing for costs of investigations to be offset in particular situations to avoid drains on the APVMA resources
- increasing the penalty for some offences to align with contemporary standards
- introduction of the term 'holder' to replace the expression 'interested person'
- introduction of a procedural fairness mechanism if the APVMA proposes to suspend or cancel a permit
- updating the fit and proper person tests for permits and manufacturing licences so they reflected the Australian Government's Spent Conviction Scheme (which provides that only convictions or penalty orders in the previous ten years need to be declared)

There is scope in the future to simplify the Agvet Code further, with a greater use of conditions of registration to regulate the labelling of chemical products, and less reliance on specific labelling offences. For example, the current labelling of a restricted chemical product could become a condition of registration, and non-compliance dealt with as a contravention of a condition of registration rather than a separate offence. This would simplify the Agvet Code and may assist compliance with labelling requirements by co-locating the labelling requirements in one place as conditions of registration.

There is also future scope to include more measures in the disallowable legislative instruments made by the APVMA. For example, conditions of registration could be set out in an APVMA legislative instrument instead of in regulation. Another option could be to authorise the APVMA to set out a licensing scheme for the manufacture of chemical products, thereby allowing the existing Good Manufacturing Practice licensing scheme to be in a legislative instrument the APVMA would make, instead of the prescriptive requirements in the Agvet Code or the [Agricultural and Veterinary Chemicals Code Regulations 1995](#).

While the examples given in the latter two paragraphs were not changes made by the Amendment Act, stakeholders may wish to comment on whether these matters should be considered in any future changes to agvet legislation.

BOX 2.3 DISCUSSION THEME 3: COMPLIANCE AND ENFORCEMENT

Stakeholders may wish to comment on the following:

8. Whether the amendments have improved compliance and enforcement.
9. Whether, as a legislative priority, agvet legislation should be aligned with the Regulatory Powers (Standard Provisions) Act 2014.
10. Whether the Agvet Code should be simplified through greater use of conditions of registration to regulate the labelling of chemical products, and less reliance on specific labelling offences.
11. Whether more measures should be included in disallowable legislative instruments made by the APVMA.

Theme 4: Improve consistency in data protection provisions

The Amendment Act improved consistency in data protection provisions and removed disincentives for industry to provide data in support of ongoing registration of agricultural and veterinary chemicals.

The Agvet Code provides for two kinds of 'periods' during which information provided to the APVMA can be protected from unauthorised use. These are known as 'limitation periods' and 'data protection periods'.

'Limits on use of information' relates to information provided to the APVMA as part of an application or as relevant information under section 161 of the Agvet Code. Section 161 requires the holder of an active constituent approval or chemical product registration to provide certain new information to the APVMA that would affect the approval or registration as soon as they become aware of it. If the APVMA relies on this information in making a decision, it receives a 'limitation period'. Limitation periods for this

information are set out in Division 4A of Part 2 of the Agvet Code. During the limitation period, the APVMA may not use the information to assess or make a decision on another application or on information given under section 161 unless an exception applies (for example, the authorising party has provided consent for the APVMA to use the information).

'Protected information' refers to certain kinds of information provided as part of a reconsideration (chemical review) that relates either to an active constituent that has been approved or a chemical product that has been registered. The protection period commences from the time the APVMA receives the information and ends eight years after its reconsideration decision.

Such limitations on the use of information are sometimes called 'data protection', and the period during which the information cannot be used is often called a 'data protection period'.

Data protection is a common feature of agvet regulation in countries with regulatory systems comparable to Australia's. Since investment in regulatory data can require significant resources, and given that the time taken to collect such data and have it assessed by the regulator also diminishes its value, the protection of data encourages innovation in agvet chemicals.

Where data protection applies, the APVMA is prevented from using data generated or owned by a person or company when determining (including assessing) an application from another person or company. This restriction on the use of data is for a specific period and protects the data owner's investment from competitors gaining an unfair commercial advantage over those who have been involved in the generation of that data.

Prior to their amendment, the data protection provisions were complex and did not provide meaningful access to data protection for information provided to a reconsideration. By enhancing these provisions, the Amendment Act removed disincentives to invest in innovative product development and improve the productivity of Australia's agri-food industries.

The Amendment Act included amendments to improve the mechanism by which data owners could obtain compensation for information submitted in relation to a reconsideration. These amendments aligned the data protection for new products and reconsiderations. Other amendments included:

- consolidating data protection provisions into a more contemporary format without changing their effect
- extending data protection eligibility to efficacy data, and data relating to the use of products on non-food-producing animals (for example, companion animals), therefore removing disincentives to generating and providing data for these situations
- maintaining data protection eligibility where data is provided as part of an application and that application is withdrawn or refused, and where data is provided as part of a permit application and those data are provided in relation to a future application
- partially addressing 'spring-boarding' by preventing the APVMA from using protected information when assessing and making a decision on the second application
- removing provisions relating to data protection extensions for minor uses because they had never been used in the nearly ten years they had been included in the Agvet Code.

An option for future consideration may be to consolidate 'protected information' and 'information with limits on its use' so that the information used for applications and reconsiderations is considered equitably and consistently throughout the Code. This would essentially treat 'protected information' like information currently provided under section 161 of the Agvet Code but with eight years instead of the three to five years protection given to section 161 information. Stakeholders may wish to comment on whether this consolidation should be considered in any future changes to agvet legislation.

BOX 2.4 DISCUSSION THEME 4: DATA PROTECTION

Stakeholders may wish to comment on the following:

12. Whether the amendments have improved data protection and made the associated provisions easier to understand.
13. Whether stakeholders have experienced benefits from using data contained in withdrawn and refused applications, or permit applications, for a subsequent product registration.
14. Whether Part 3 of the Agvet Code should be omitted to allow stakeholders to rely on commercial arbitration legislation for persons to negotiate access to both protected information and information with limits on its use.
15. Whether 'protected information' and 'information with limits on its use' should be consolidated.

Theme 5: Legislation improvements

The Amendment Act simplified, reorganised and modernised the Agvet Code to reduce uncertainty and complexity in the legislation. The Act also removed redundant provisions and amended out of date provisions in all Commonwealth agvet legislation.

The Office of Parliamentary Counsel made extensive technical revisions to the Agvet Code, amending provisions around applications, reconsiderations, suspensions and cancellations, notices and data protection.

The revisions brought the Agvet Code up to contemporary standards for legislative drafting. The revisions included:

- the insertion of explanation sections
- consolidation of existing 'legislative tests' for approval and registration, variation, reconsideration and elsewhere into four new tests (the 'meets the efficacy criteria', 'meets the labelling criteria', 'meets the safety criteria' and 'meets the trade criteria' tests) under subsection 3(1)
- a single set of general provisions relating to all applications except those for licences
- consolidating notice provisions
- simplification of provisions around 'interested persons', 'approved persons' and listed registration to address some inconsistencies in the Agvet Code.

BOX 2.5 DISCUSSION THEME 5: LEGISLATIVE DRAFTING

Stakeholders may wish to comment on the following:

16. Whether the simplification and re-organisation of provisions has helped them to better understand the legislation.
17. Whether the redrafting of existing 'legislative tests' into the four 'meets the X criteria' tests in subsection 3(1) of the Agvet Code has assisted them to comply with safety, trade, efficacy and labelling criteria.

Theme 6: Variations to relevant particulars and conditions

The Agvet Code currently provides for the variation of relevant particulars and conditions of an approval or registration (Division 3 of Part 2 of the Agvet Code – sections 27 to 29B). The Agvet Code also provides that some variations to relevant particulars of approval or registration may be made by 'notification' (Division 2AA of Part 2 of the Agvet Code – sections 26AA to 26AD) or as a 'prescribed variation' (Division 2A of Part 2 of the Agvet Code – sections 26A to 26D). These notifiable variations and prescribed variations only allow some relevant particulars to be varied and do not authorise conditions to be varied as notifiable variations and prescribed variations.

The notifiable variations were introduced in the Removing Re-approval and Re-registration Act. Prescribed variations were introduced in the [Agricultural and Veterinary Chemicals Code Amendment Act 2010](#). The Amendment Act did not introduce the policy for these variations but the Amendment Act did include prescribed variations to further the policy developed for the *Agricultural and Veterinary Chemicals Code Amendment Act 2010*. The Amendment Act also included:

- the new option for regulation to prescribe 'prescribed variations' as an alternative to the previously specified APVMA legislative instrument
- the requirement that a prescribed variation take effect within a period prescribed in the regulations (currently one month).

It is noted that notifiable variations and prescribed variations can contain incorrect information. Stakeholders may wish to comment on what mechanisms could be introduced for the APVMA to deal with this situation in a cost-effective manner. For example, an option may be for the APVMA to apply specific fees to deal with these circumstances instead of rejecting the variation.

BOX 2.6**DISCUSSION THEME 6: NOTIFIABLE AND PRESCRIBED VARIATIONS**

Stakeholders may wish to comment on the following:

18. The value and practical effects of having multiple processes for varying relevant particulars.
19. The effectiveness of existing processes for varying conditions, and whether there should be a streamlined means of varying conditions (recognising the technical assessment that can be required).
20. Whether agvet legislation could be simplified by dealing with variations to approval and registration as new approvals and registrations.
21. What mechanisms would stakeholders support for dealing cost-effectively with incorrect information in notifiable variations and prescribed variations?

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