Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019

Paula Pyburne
Law and Bills Digest Section

This Bills Digest replaces an earlier version dated 2 December 2019 to include comments of the Senate Rural and Regional Affairs and Trade Committee in relation to the Bill.

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House: House of Representatives
Portfolio: Agriculture
Commencement: Various dates as set out in this Bills Digest

Links: The links to the Bill, its Explanatory Memorandum and second reading speech can be found on the Bill’s home page, or through the Australian Parliament website.
When Bills have been passed and have received Royal Assent, they become Acts, which can be found at the Federal Register of Legislation website.
All hyperlinks in this Bills Digest are correct as at January 2020.
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History of the Bill
The Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019 (the Bill) comprises measures from two Bills which were introduced during the 45th Parliament but which lapsed when the Parliament was prorogued in April 2019 being:

• the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 (Operational Efficiency Bill)—including a government amendment\(^1\) and
• the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (Streamlining Bill).\(^2\)

A Bills Digest was published in respect of each of the Bills.\(^3\)

The Bills Digest for this Bill replicates much of the information in the earlier Bills Digests and indicates whether the provisions are equivalent to, or depart from, the text of the earlier Bills.

Purpose of the Bill
The purpose of the Bill is:

• to amend various statutes to improve the effectiveness and efficiency of the national system for regulating agricultural and veterinary (agvet) chemical products and
• to establish a governance Board for the Australian Pesticides and Veterinary Medicines Authority Board (APVMA) and formally cease the existing APVMA Advisory Board.

Structure of the Bill
The Bill comprises two Schedules.

The amendments in Schedule 1 relates to the earlier Bills which are detailed above. Schedule 1 to the Bill has 20 Parts most of which amend the Agricultural and Veterinary Chemicals Code Act 1994 (the Code Act) as well as other statutes as set out below:

• Part 1 is about the information to be taken into account by the regulator—the APVMA—in determining applications
• Part 2 relates to the approval and registration for prescribed active constituents, chemical products or labels
• Part 3 details the limits on use of information
• Part 4 amends the Agricultural and Veterinary Chemical Products (Collection of Levy Act) 1994 (Collection of Levy Act) and the Agricultural and Veterinary Chemicals (Administration) Act 1992 (Administration Act) in relation to annual returns and record-keeping
• Part 5 relates to computerised decision-making
• Part 6 is about the preliminary assessment of applications for approval
• Part 7 allows for the variation or relevant particulars and conditions


• Part 8 provides for the variation of an approval or registration during suspension
• Part 9 amends the Administration Act and the Code Act to make the provision of false and misleading information in specified circumstances subject to a civil penalty
• Part 10 provides for the suspension or cancellation of approval or registration for provision of false or misleading information
• Part 11 is about voluntary recalls of chemical products
• Part 12 provides for the notification of new information
• Part 13 amends the Administration Act in relation to annual operational plans
• Part 14 contains a new definition of the term registered chemical product
• Part 15 relates to the supply of registered chemical products with an unapproved label
• Part 16 relates to the safety, efficacy, trade and labelling criteria
• Part 17 amends the Administration Act and the Code Act with respect to notification about variation to the Maximum Residue Limits Standard and
• Part 18 clarifies the expiry date of certain products
• Part 19 makes other amendments to the Administration Act and the Code Act
• Part 20 repeals the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014 (2014 Amending Act) in its entirety.

The amendments contained in Schedule 2 to the Bill were not included in the original form of the earlier Bills which are detailed above. Rather, they were Government amendments which were circulated to Senators prior to the debate on the Operational Efficiency Bill. Those amendments related to the functions and powers of the Board.

Schedule 2 amends the Administration Act in similar but not identical terms to the proposed Government amendments the Operational Efficiency Bill.

Schedule 1 of the Code Act contains the Agricultural and Veterinary Chemicals Code (Agvet Code). For the purposes of this Bills Digest, amendments to Acts are identified by way of section numbers. Amendments to the Agvet Code are identified by way of clause numbers.

Background

Regulation of chemical products

The regulatory framework for managing pesticides and veterinary medicines in Australia is collectively referred to as the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). The NRS is a partnership between the Commonwealth and the states and territories.\(^4\) Assessment and registration of agricultural and veterinary (agvet) chemicals, as well as control of supply activities up to the point of retail sale, is undertaken by the APVMA.\(^5\) Control of the use of agvet chemicals after sale is the responsibility of individual states and territories.\(^6\)

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4. Australian Pesticides and Veterinary Medicines Authority (APVMA), 'Overview of agvet chemical regulation', APVMA website, last updated 1 August 2017.
5. APVMA, 'The role of the APVMA', APVMA website, last updated 24 October 2018.
The Agvet Code is contained in a Schedule to the *Code Act*. Under the NRS, the Agvet Code operates, together with the Code of each participating jurisdiction (that is, each of the state and territories) to constitute a single national Code applying throughout Australia.  

### Functions of the APVMA

The *Administration Act* sets out the functions of the APVMA as follows:

- assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, registered chemical products, and labels for containers for chemical products
- ensure that approvals and registrations for active constituents for chemical products and labels for containers for chemical products comply with the Agvet Code and the Agvet Code Regulations
- provide information to the Australian Government and its agencies, and the states and territories, about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for such products, and cooperate with federal, state and territory governments on matters relating to the management and control of chemical products
- collect and publish relevant information and statistics on approvals and registrations granted, and permits and licences issued under the Agvet Code
- with the Australian Government and its agencies, and the states and participating territories, facilitate a consistent approach to the assessment and control of agvet chemicals
- exchange information relating to chemical products and their use with overseas and international bodies that have similar functions to those of the APVMA and
- report to or advise the Minister on matters relating to the performance of the APVMA’s functions.

Some of the agvet chemicals approved and registered by the APVMA are crop protection products (CPP). These include herbicides, insecticides, fungicides and other pesticides and chemical agents. The key reasons for use of CPP include:

- to decrease and control pests and diseases
- to reduce the need for crops and plants to compete with weeds and other invasive plants
- to increase the yield of crops or protect biodiversity and
- to protect and maintain infrastructure such as buildings and roads through pest or weed control.

Deloitte Access Economics has estimated the contribution of CPP to the Australian economy as:

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9. Deloitte Access Economics, *Economic activity attributable to crop protection products – commissioned by CropLife Australia*, Deloitte, n.p., February 2018, p. 2. These are products intended to prevent or reduce the growth of weeds. These can be either: selective (chemicals which kill weeds specifically without harming crops); or non-selective (chemicals which stop the growth of plants indiscriminately).
10. Ibid. These are chemicals which aim to control insects in plants and crops.
11. Ibid. These are products whose purpose is to prevent or manage fungal diseases in plants.
12. Ibid.
• the economic contribution was $2.3 billion, which is associated with 9,225 full-time equivalent jobs\textsuperscript{13} and
• $20.6 billion of Australian agricultural output in 2015–16.\textsuperscript{14}

**Early reviews of the APVMA**

The APVMA was the subject of reviews by the Australian National Audit Office in 2006\textsuperscript{15} and by the Productivity Commission in 2008.\textsuperscript{16} Both of those reviews made recommendations for improvement.

In response to the reviews and to complaints about the performance of the APVMA,\textsuperscript{17} the Government enacted the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (2013 Amendment Act).\textsuperscript{18} The 2013 Amendment Act represented a significant modernisation of the APVMA’s regulatory activities. The key reforms which were required to be implemented from 1 July 2014 included:

- new regulatory guidance to industry under the reformed legislative arrangements
- a structured, upfront pre-application assistance scheme for applicants
- a system to electronically receive all applications online
- stricter preliminary assessment arrangements that focus on basic application requirements (restricting the ability of the applicant to rectify a defect in their application during this phase of assessment)
- revised maximum assessment timeframes based on the type of application being made, with increased time for the assessment of certain products and chemical applications
- additional requirements for the review of registered products and chemicals (such as the development of work plans for each review) and statutory timeframes for completing chemical reviews and
- procedural, technical and transitional arrangements, including limiting the acceptance of additional material from applicants and introducing requirements to provide notices of certain proposed decisions to applicants.\textsuperscript{19}

The reforms in the 2013 Amendment Act were intended to:

> ... encourage the development of newer and safer chemicals by providing more flexible and streamlined regulatory processes with higher levels of transparency and predictability for business seeking approval for agvet chemicals to enter the market. The reforms should result in a more straightforward assessment process that is easier to understand and more cost effective to administer. In many cases, particularly for products of low regulatory concern, the reformed system as established by these

\textsuperscript{13} Ibid., p. ii.
\textsuperscript{14} Ibid., p. iii.
\textsuperscript{18} Parliament of Australia, ‘*Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013 homepage*’, Australian Parliament website.
amendments should be faster, deliver more predictable outcomes and result in improved health and environmental protection for the broader community.\(^{20}\)

In addition, amendments were made to the *Administration Act* to insert extensive monitoring and investigation powers, and include updates to entry, search and seizure provisions to bring them into line with contemporary standards.\(^{21}\) The purpose of these particular amendments was to create a graduated range of compliance and enforcement powers, such as infringement notices and enforceable undertakings, so that regulatory sanctions could be tailored to the seriousness of any non-compliance.\(^{22}\)

Despite the lengthy consultation which led to the *2013 Amendment Act*, it was not without its critics and it was unclear whether the relevant amendments would lead to the greater efficiencies which they were intended to create. Of greatest concern were the following:

- the potential for increased costs for registrants and applicants
- an increased complexity in the regulatory system which might result in the loss of existing agricultural chemical products and discourage the introduction of newer, modern chemistry and biological products and
- the potential loss from the Australian market of useful products that were safe and effective to use due to the need to obtain re-approval or re-registration of those products.\(^{23}\)

**2014 Amending Act**

The *2013 Amendment Act* received Royal Assent on 29 June 2013.\(^{24}\) One of the purposes of that Act was to insert into the *Code Act* a requirement that, first, existing approvals and registrations of active constituents and chemical products operate for a finite period and, second, when that period elapsed, a new application was to be lodged for re-approval or re-registration.\(^{25}\)

The primary purpose of the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* (*2014 Amending Act*) was to remove the requirement for re-approval or re-registration of active constituents and chemical products.

**Rationale for the 2014 Amending Act**

The originating Bill for the *2013 Amendment Act* was referred to the House of Representatives Standing Committee for Agriculture, Resources, Fisheries and Forestry (the House of Representatives Committee) for inquiry and report.\(^{26}\) Whilst the majority report of that Committee recommended that the Bill be passed,\(^{27}\) the Coalition Members provided a Dissenting Report which stated:

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21. The updated *investigative* powers are located in Part 7AA of the *Administration Act*.
22. The updated *enforcement* powers are located in Part 7AB of the *Administration Act*.
26. Details of the inquiry including the terms of reference, submissions from stakeholders and the Standing Committee for Agriculture, Resources, Fisheries and Forestry report are on the *inquiry homepage*.
... this Bill as is drafted provides a substantial increase in regulatory burden and costs that will have a negative impact on industry without significantly improving the efficiency of regulation and the re-registration process will slow down rather than increase the review of suspect chemistries. To achieve genuine efficiencies within the system that allow for a more timely review of suspect chemistries it is vital that the proposed re-registration process be removed from the Bill.28

The provisions of the originating Bill for the 2013 Amendment Act were also referred to the Senate Rural and Regional Affairs and Transport Legislation Committee (RRAT Committee) for inquiry and report.29 Whilst the majority of the RRAT Committee recommended that the Bill be passed, the Coalition Senators30 again provided a Dissenting Report recommending that it should not.31

In the lead up to the 2013 Federal election, the Coalition signalled its intention (if elected) to reform the agriculture and veterinary chemicals legislation to improve efficiencies by, amongst other things, removing re-registration.32

The 2014 Amending Act gave effect to that election promise.

**Agricultural Competitiveness White Paper**

On 4 July 2015, the Government released its Agricultural Competitiveness White Paper which promised ‘a fairer go for farm businesses by creating a better business environment with better regulation ....’33

The White Paper acknowledges that ‘Australian agricultural and veterinary (agvet) chemical regulation imposes a large regulatory burden’ that is ‘often disproportionate to the risks these products pose’.34 Accordingly it sets out the Government’s intention to lower the regulatory burden in the following ways:

The Government is putting in place 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.

Working with industry, the Government will limit pre-market assessments of low- and medium-risk products. The Government will focus its attention on products that pose the highest risk. The Government will recognise assessments from accredited third party suppliers and trusted chemical regulators to reduce the paper work. Where products are available in trusted overseas countries, the Government will examine risks that are different in the Australian market, such as where we have different human health requirements, agricultural practices or environmental assets. In collaboration with industry and the States and Territories, the Commonwealth will explore opportunities to improve post-market compliance and national control of chemical use.35

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28. Ibid., p. 52.
29. Details of the inquiry including the terms of reference, submissions from stakeholders and the Rural and Regional Affairs and Transport Legislation Committee report are on the inquiry homepage.
31. Ibid., p. 30.
33. T Abbott (Prime Minister) and B Joyce (Minister for Agriculture), *Agricultural Competitiveness White Paper—stronger farmers, stronger economy*, joint media release, 4 July 2015, p. 1.
35. Ibid., p. 38.
Further inquiries

Productivity Commission
In November 2015, the Treasurer requested the Productivity Commission to undertake an inquiry into the regulatory burden imposed on Australian farm businesses, focusing on regulation with a material impact on domestic and international competitiveness. 36

The Productivity Commission’s final report, published in March 201737 noted that, despite numerous reviews and subsequent reforms, concerns remain about:

• unnecessarily lengthy, complex and duplicative registration procedures and
• interjurisdictional inconsistencies, particularly in control-of-use regimes, 38 which can make it costly and confusing to comply with regulatory requirements. 39

ANAO report
In June 2017, the Australian National Audit Office (ANAO) published a performance audit report on the implementation of pesticide and veterinary medicine regulatory reform. 40 The report concluded that, amongst other things:

The Australian Pesticides and Veterinary Medicines Authority’s implementation of agvet chemical legislative reform has been mixed. While key legislative reforms were implemented by the legislated timeframe of July 2014, the full scope of the reform program is yet to be implemented more than four years since the legislative amendments were developed. Further, the Authority is not well placed to determine the extent to which reform objectives have been met in the absence of a robust set of performance measures. There is considerable scope for the APVMA to improve its management of major reform projects, particularly in the context of the Government’s decision to relocate the Authority over the next two years. 41 [emphasis added]

House of Representatives Committee inquiry
In May 2018, the House of Representatives Standing Committee on Agriculture and Water Resources published a report which was based on the ANAO report. 42 The Committee made a number of recommendations. Relevant to this Bills Digest, the Committee recommended

... the establishment of a Board of Directors for the Australian Pesticides and Veterinary Medicines Authority. The Committee recommends that, if a Board is to be established, the Minister for Agriculture should be consulted in relation to the appointment of Members to provide additional oversight and further links between the Minister and the APVMA. 43
As set out under the heading ‘History of the Bill’ above, the government subsequently introduced the Operational Efficiency Bill (which included a government amendment to establish a Board) and the Streamlining Bill.

However, both of the Bills lapsed when the 45th Parliament was prorogued.

**Committee consideration**

**Senate Rural and Regional Affairs and Transport Committee**

The Bill was referred to the RRAT Committee for inquiry and report by 28 November 2019. The RRAT Committee received ten submissions to its inquiry.

The majority view of the Committee was that the Bill should be passed. However, Australian Labor Party (ALP) Senators expressed their ‘deep concerns about the policy rationale for the implementation of a Governance Board’ because, amongst other things:

The APVMA Governance Board will not have the power to independently set the APVMA’s strategic direction, drive its operational performance, set an appropriate risk management framework and ensure greater accountability. Under the proposed legislation the Minister will continue to have the power to direct the APVMA and will be provided with the power to direct the board in the performance of its functions. Therefore, it appears the Governance Board will just be another layer of regulation which will add additional cost to Australian farmers.

The Australian Greens (the Greens) Senators did not agree that the Bill should be passed.

**What is not included in the Bill?**

A number of submitters to the first Committee’s inquiry into the Streamlining Bill, including the Western Australian Department of Primary Industries and Regional Development, the Grains Research and Development Corporation, and the Community and Public Sector Union, expressed concerns about amendments which would have allowed the APVMA to make a legislative instrument to prescribe a scheme in the future that would allow applicants and the APVMA to use accredited third party providers to undertake assessment services.

Both Australian Labor Party Senators and Australian Greens Senators who were members of the first Committee prepared Dissenting Reports in which they expressed concerns about that measure and recommended either that the Bill be passed without the measure or that the Bill be opposed. Importantly this measure has **not been replicated** in the current Bill.

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44. The terms of reference, submissions to the RRAT Committee and the Committee’s final report are available on the inquiry homepage.
As stakeholder comments about the amendments in Schedule 1 have been canvassed in an earlier Bills Digest, they have not been included in this Bills Digest.

Stakeholder comments in relation to the proposed APVMA Board are set out under the heading ‘Schedule 2’ below.

**Senate Standing Committee for the Scrutiny of Bills**

The Senate Standing Committee for the Scrutiny of Bills (Scrutiny of Bills Committee) made reference to an element in Part 5 of the Bill. This matter is discussed under the relevant heading below.

**Policy position of non-government parties/independents**

As stated above, the Greens Senators on the RRAT Committee inquiry into the Bill did not support it. They were particularly concerned about the proposed APVMA Board as they ‘believe greater detail is required to justify the need for the new Board, and appropriate provisions are required to ensure community engagement’.

**Position of major interest groups**

Submitters to the RRAT Committee were generally in support of the measures in Schedule 1 to the Bill. However, according to the Grains Research and Development Corporation (GRDC):

> Australia is missing out on productivity improvements through a lack of commercial investment in novel crop protection solutions including new or emerging chemical, biological and biochemical technologies. It is essential that Australian grain growers have access to the same pesticide technologies to remain internationally competitive with overseas producers.

Similarly Grain Producers Australia (GPA) expressed disappointment that the Bill addresses:

> … a small number of the issues identified, or in some cases created through previous rounds of legislative reforms. There is clearly a need for further legislative reform to deliver technology access outcomes for Australian agriculture including grains.

**Financial implications**

According to the Explanatory Memorandum, the Bill will ‘have no impact on the Australian Government Budget’.

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54. Grain Producers Australia (GPA), *Submission* to the RRAT Committee, *Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019 [Provisions]*, [Submission no. 3], 10 October 2019, p. 2.
55. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 3.
Statement of Compatibility with Human Rights
As required under Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011 (Cth), the Government has assessed the Bill’s compatibility with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of that Act. The Government considers that the Bill is compatible.56

Parliamentary Joint Committee on Human Rights
At the time of writing this Bills Digest the Parliamentary Joint Committee on Human Rights had not commented on the Bill.

Schedule 1—key issues and provisions

Part 1—information to be taken into account

Quick guide to Part 1
The provisions in Part 1 of Schedule 1 to the Bill amend existing rules which operate inefficiently where the APVMA is seeking simple clarifying information from an applicant during the assessment period.
The amendments allow Regulations to prescribe certain kinds of information that the APVMA may consider during the assessment period.
The amendments in Part 1 of the Bill are identical to those that were set out in Part 2 of Schedule 1 to the Streamlining Bill.

Commencement
The provisions in Part 1 of Schedule 1 to the Bill commence six months after Royal Assent.

Current law—seeking simple information
Currently, subclause 8C(1) of the Agvet Code sets out the information that must be taken into account in determining applications such as:

• information in, or accompanying, an application that is required under clause 8B or any other provision of the Code
• information given to the APVMA as required by clauses 157 (samples given for analysis), 159 (information, reports or samples) or 160A (new information) of the Code
• submissions made in response to an invitation given by the APVMA in relation to the application and
• any other matter that the APVMA thinks is relevant.

Subclause 8C(2) of the Agvet Code sets out the information that must not be taken into account in determining applications.

Together those provisions operate to restrict the APVMA’s ability to consider new information provided by an applicant during the assessment period for the application. The APVMA has the discretion to issue a notice to an applicant seeking additional clarifying information.57 However,

56. The Statement of Compatibility with Human Rights can be found at pages 83–125 of the Explanatory Memorandum to the Bill.
57. Agricultural and Veterinary Chemicals Code (Agvet Code), clause 159.
the notice compulsorily triggers a one-off extension to the statutory time period in which the application must be assessed.\textsuperscript{58} 

The rules may operate inefficiently where the APVMA is seeking simple clarifying information. 

**What the Bill does**

**Item 2** of Part 1 to the Bill inserts *proposed subclause 8C(2A)* into the Agvet Code. The new subclause operates so that Regulations may prescribe the type of information and/or the circumstances in which that information is given. Such information will not be subject to the prohibition in existing subclause 8C(2) of the Agvet Code.

Importantly, under the application provision in **item 3** of Part 1, the amendment will apply to applications lodged before the commencement of this item but not yet determined by the APVMA.

**Part 2—approval and registration**

**Quick guide to Part 2**

The amendments in Part 2 of Schedule 1 of the Bill establish a streamlined process for approvals and registrations where minimal or no assessment of technical information occurs.

The new processes will be set out in Regulations or other instruments made by the APVMA.

The changes are intended to better align regulatory effort with risk by:

- reducing red tape and
- reducing some of the costs associated with approval and registration.

The amendments are consistent with the commitments made in the Government’s *Agricultural Competitiveness White Paper of 2015*.\textsuperscript{59} 

The amendments in Part 2 of the Bill are identical to those that were set out in Part 1 of Schedule 1 to the Streamlining Bill.

**Commencement**

The amendments in Part 2 of Schedule 1 to the Bill commence on the day after the end of the period of 6 months beginning on the day this Act receives the Royal Assent.

**Current law**

Part 2 of the Agvet Code contains provisions relating to:

- the approval of active constituents for proposed or existing chemical products 
- registration of chemical products and 
- approval of labels for containers for chemical products.\textsuperscript{60} 

Within Part 2, Division 2 (comprising clauses 9A–26) relates to approving active constituents for chemical products, registering chemical products and approving labels for containers of chemical products. Essentially, the Division works as follows:

- clause 10 provides for applications to be made

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58. The relevant period is determined under **Division 9.3** of the *Agricultural and Veterinary Chemicals Code Regulations 1995*. 
60. Agvet Code, subclause 9(1).
• applications must meet the application requirements specified in clause 8A
• the APVMA must complete a preliminary assessment of an application. If the application passes preliminary assessment, the APVMA must notify the applicant and publish a summary of the application
• before determining certain applications that have passed preliminary assessment, the APVMA must publish a notice inviting public submissions
• the APVMA must approve an active constituent or label, or register a chemical product, if specified criteria are met
• clauses 14A–16 set out special rules about approvals and registrations
• the APVMA must keep a Record of Approved Active Constituents for Chemical Products and a Register of Agricultural and Veterinary Chemical Products
• clauses 19–21 set out how approvals and registrations take place
• clause 22 deals with dates of approval and registration
• approvals and registrations may be subject to conditions
• clause 26 provides for incorrect relevant particulars and conditions of a kind prescribed by the Regulations to be corrected.

What the Bill does
According to the Explanatory Memorandum to the Bill:

This change will introduce a system change to enable the use of new, simpler regulation processes for these approvals and regulations where minimal or no assessment of technical information occurs.

How this is achieved
The Bill operates to create new subdivisions within Division 2 as an aid to interpretation. Item 6 repeals and replaces subclauses 9A(2)–(5) of the Agvet Code to provide an updated explanation of the operation of Division 2 which is consistent with amendments outlined below.

Item 8 inserts proposed Subdivision C—Approval and registration for prescribed active constituents, chemical products or labels into the Agvet Code. It is new Subdivision C that introduces an additional streamlined pathway to the approval and registration process.

Proposed clause 14C provides that a person may apply to the APVMA for approval of a prescribed active constituent—being an active constituent that is for a proposed or existing chemical product; and is of a kind that either is prescribed by the Regulations or determined by the APVMA.

61. Agvet Code, clause 11.
64. Agvet Code, clauses 17 and 18.
65. Agvet Code, clause 23.
66. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 12.
67. Agvet Code, proposed subclause 14C(4).
Instrument-making powers

A broad Regulation making power is contained in section 6 of the Code Act. Essentially it allows the Governor-General to make Regulations in relation to anything required or permitted by the Code to be so prescribed.

In addition to the existing Regulation making powers, the Bill empowers the APVMA to make two separate legislative instruments which relate to the approval of a prescribed active constituent. These instruments:

- determine a kind of active constituent which will be captured by proposed clause 14C. The APVMA must not make such a determination unless it is satisfied that the kind of active constituent meets the safety criteria and
- determine disqualifying criteria that apply to an application for approval under clause 14C.

According to the Explanatory Memorandum to the Bill:

These [disqualifying] criteria could, for example, set out the circumstances to allow the APVMA to have regard to the regulatory history of the applicant, or consider if applicants have been convicted of an offence, ordered to pay a civil pecuniary penalty or had a registration or approval cancelled or suspended for breaching a condition or providing false or misleading information. Applicants disqualified through this mechanism will still be able to apply for approvals and registrations under section 10 of the Agvet Code.

Decision-making process

In the event that such Regulations and determinations have been made, the decision-making process operates as follows:

- an application which meets the application requirements is received
- the APVMA must approve the active constituent if the application meets the application requirements, the active constituent is a prescribed active constituent and none of the circumstances which have been determined to be disqualifying circumstances apply
- otherwise the application must be refused.

Proposed clauses 14D and 14E of the Agvet Code relate to applications for registration of prescribed chemical products and applications for approval of prescribed labels for containers for chemical products respectively. They are set out in equivalent terms to proposed clause 14C in that they first, provide for the APVMA to make legislative instruments which prescribe certain kinds of chemical products and container labels and second, provide for the APVMA to determine the circumstances which would disqualify an application under the relevant clauses.

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68. Agvet Code, proposed subclause 14C(6).
69. Agvet Code, proposed subclause 14C(5).
70. Agvet Code, proposed subclause 14C(9).
72. Agvet Code, proposed subclause 14C(2).
73. Agvet Code, proposed subclause 14C(7).
74. Agvet Code, proposed subclause 14C(8).
Limits on use of information
Currently, Division 4A of Part 2 of the Agvet Code limits the use of information which has been given to the APVMA as part of the application process.

**Item 10** of Part 1 in Schedule 1 to the Bill inserts proposed subclause 34G(1AA) into the Agvet Code to limit the use of information given to the APVMA when it is making an assessment or decision under the streamlined approval and registration processes in proposed clauses 14C, 14D or 14E. According to the Explanatory Memorandum to the Bill:

> By limiting the use of information, the original producer of that information (the ‘innovator’) can prevent competitors (such as producers of generic products) from using the innovator’s data, or can seek compensation from the competitors for the information it has produced. This benefits the innovator, who has incurred the cost of generating this information and testing the market, and so promotes innovation.  

Review and appeal
**Item 12** amends subparagraph 166(1A)(b)(i) of the Code so that a decision to refuse an application under the abbreviated approval and registration process in proposed clauses 14C, 14D or 14E may be subject to an internal review. Consistent with that provision, **items 13 and 14** of Part 1 in Schedule 1 to the Bill amend subclause 167(1) of the Agvet Code so that a decision to refuse such an application, or approve it subject to conditions, may be subject to a review by the Administrative Appeals Tribunal.

**Part 3—limits on use of information**

*Quick guide to Part 3*

The amendments in Part 3 of Schedule 1 to the Bill extend the period of time (up to a maximum of five additional years) during which the APVMA must not use an innovator’s information to support the registration, variation or reconsideration of another chemical product or active constituent. The amendments in Part 3 of the Bill are in equivalent terms to those set out in Part 3 of Schedule 1 to the Streamlining Bill—with the exception of items 16 and 17 which are consequential amendments to the definitions of **protected active constituent** and **protected chemical product**.

Commencement
The amendments in Part 3 of Schedule 1 to the Bill commence on the earlier of a single day to be fixed by Proclamation or three months after Royal Assent.

*Current law*
Currently, Division 4A of Part 2 of the Agvet Code limits the use of information which has been given to the APVMA as part of the application process.

Existing clause 34J allows the APVMA to use information under certain conditions—for instance where the authorising party has given written consent to the use of the information or where the APVMA is satisfied that the use of the information is in the public interest.  

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75. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 15.
76. Agvet Code, subclause 34J(2).
Relevant to this Bills Digest, existing subclause 34J(5A) of the Agvet Code permits the APVMA to use information that is protected information where the relevant protection period has expired.

**What the Bill does**

**Item 22** of the Bill inserts proposed clause 34KA into Division 4A in Part 2 of the Code to extend the existing protection periods in certain circumstances. The clause allows Regulations to be made about extending the protection period for protected information and/or ending such an extension. The total length of all extensions of a protection period must not be more than five years.\(^7\)

No application for extension will be required.\(^7\) However, unless an application is made in accordance with the requirements of the Regulations at least three years before the protection period will end, an extension of a protection period must not occur.\(^8\)

Accordingly, **item 21** in Part 3 of Schedule 1 to the Bill repeals and replaces subclause 34J(5A) of the Agvet Code to permit the APVMA to use protected information where the protection period, or an extended protection period (in accordance with Regulations made under proposed clause 34K) has ended.

**Item 25** in Part 3 of Schedule 1 to the Bill inserts proposed clause 34MA into the Agvet Code to allow Regulations to be made to extend a limitation period or to end an extended limitation period.\(^8\) The terms of proposed clause 34MA are in near equivalent terms to those of proposed clause 34KA—that is:

- an application for extension is not required
- no extension of a limitation will occur unless an application is made at least three years before that limitation period will end and
- the maximum extension of a limitation period is five years.

Clarifying the reference to no application being required, the Explanatory Memorandum to the Bill states:

... an extension is a consequence that follows when particular applications (of a kind prescribed in regulations) are lodged and these applications also satisfy any requirements that may be prescribed by the regulations. It is anticipated that these applications would relate to products with new, desirable features. For example, products for priority uses (including minor uses), where the costs of registering these uses are not otherwise justified by the additional commercial returns to chemical manufacturers. In addition, the application must be lodged while there is at least three years of the existing protection period remaining. The purpose of this three year period is to reduce the impact on potential applicants, (whose applications would rely on the protected information), allowing them to have certainty as to when a protection period will end.\(^8\)

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77. Agvet Code, subclause 34J(3).
78. Agvet Code, proposed subclause 34KA(4).
79. Agvet Code, proposed subclause 34KA(2).
80. Agvet Code, proposed subclause 34KA(3).
81. Agvet Code, proposed subclause 34MA(1).
82. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 19.
Part 4—annual returns and record-keeping

Quick guide to Part 4
The provisions in Part 4 amend the Collection of Levy Act and the Administration Act to simplify reporting requirements for annual returns. They restrict mandatory reporting to total chemical product quantities supplied for the previous year.
The amendments in Part 4 are in near equivalent terms to the amendments in Part 1 of the Operational Efficiency Bill with some additional clarification of the Constitutional basis for the provisions.

Commencement
The amendments in Part 4 of Schedule 1 to the Bill commence on the day after Royal Assent.

Current law
Currently, levies under the agvet scheme are payable based on the dollar value of sales (known as leviable disposals) of registered products.\(^\text{83}\) The interested person in relation to the chemical product is liable to pay the levy.\(^\text{84}\)

For the purposes of the Collection of Levy Act, the interested person, in relation to a registered chemical product, is:

- the person (the original applicant) who applied for the registration or, in the case of a chemical product whose registration has been renewed, applied for the renewal, or the last renewal of the registration
- if the original applicant has entered into a contract with another person in relation to the product so that the other person will or may apply to the APVMA to have the other person’s name entered in the relevant particulars in relation to the product, or to have a label approved in relation to containers for the product—the other person
- if the person who would be the interested person was an individual who has died or is an individual whose affairs are being lawfully administered by another person— their legal personal representative or the person’s administrator or
- if the interested person was a body corporate—a successor in law of that body corporate.\(^\text{85}\)

Annual returns
The requirement for annual returns is contained in section 69E of the Administration Act. Under that section a person who imports into, manufactures in, or exports from Australia, chemical products or active constituents for proposed or existing chemical products during a financial year must give the APVMA a return, setting out the respective quantities of those active constituents, or of the active constituents contained in those products. The return must be provided to the APVMA within three months after the end of the year concerned.

Together, these provisions require companies to collate information on both quantities of active constituents contained in products and sales of product and to report those matters to the APVMA at different times.

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\(^{83}\) Collection of Levy Act, subsection 12B(1). Section 12C sets out the formula for calculating the amount of the levy based on the total leviable value in respect of the product for the financial year and the rate of the levy. The rate of the levy is set in section 6A of the Agricultural and Veterinary Products (Collection of Levy) Regulations 1995.

\(^{84}\) Collection of Levy Act, subsection 12B(2).

\(^{85}\) Collection of Levy Act, subsection 3(1).
What the Bill does

Lodging returns

Item 32 of Part 4 of the Bill repeals section 69E of the Administration Act.

Item 29 of Part 1 of the Bill inserts proposed section 35 into the Collection of Levy Act to align the requirement to lodge a return with the requirement to pay levies.

Proposed subsection 35(1) of the Collection of Levy Act requires the interested person in relation to a chemical product who is liable to pay a levy in respect of leviable disposals of the product to give the APVMA a return. The return must set out the total quantity of chemical product that was disposed of anywhere in Australia at any time during a financial year. The return must be provided before 30 November in the next financial year.

A failure to give the APVMA the required return gives rise to an offence of strict liability. The maximum penalty for the offence is 50 penalty units. In addition, proposed subsection 35(1) is a civil penalty provision. This is consistent with the APVMA’s existing power (and the position under section 69E of the Administration Act) to apply to a court of competent jurisdiction for an order that a person who is alleged to have contravened a civil penalty provision must pay the Commonwealth a pecuniary penalty.

There is an exception to the general rule about providing an annual return: a return is not required for a quantity of product that is less than the quantity prescribed by the Regulations or for a chemical product that is prescribed by the Regulations. This exception is in similar terms to the exception in existing subsection 69E(2), which is to be repealed. According to the Explanatory Memorandum to the Bill, the Regulation may:

... prescribe low quantities of chemical products for which an interested person is exempt from the requirements to provide an annual return... [and may also] ... prescribe a limited range of ‘low regulatory concern’ chemical products that could be exempted from the annual return reporting requirements.

The APVMA must give the Secretary of the Department a statement setting out the total quantities of each active constituent for each chemical product covered by those returns before

86. Collection of Levy Act, proposed subsection 35(3). The imposition of strict liability means that a fault element does not need to be satisfied, but the offence will not criminalise honest errors and a person cannot be held liable if he, or she, had an honest and reasonable belief that they were complying with relevant obligations.

87. Under section 4AA of the Crimes Act 1914 a penalty unit is equivalent to $210. This means that the maximum penalty is $10,500. Subsection 4B(3) of the Crimes Act provides that the maximum penalty that may be imposed on a body corporate is five times the maximum penalty that could be imposed on an individual convicted of the same offence. Accordingly, the maximum pecuniary penalty for a corporation is $52,500.

88. Collection of Levy Act, proposed subsection 35(4).

89. Administration Act, subsection 69E(1). Subsection 69EJA(1) of the Administration Act sets out the maximum amount of the penalty for a body corporate, which is five times the maximum monetary penalty that could be imposed if the body corporate was convicted of an offence constituted by the same conduct. As explained in footnote 34, the maximum penalty that could be imposed on a corporation for an offence against proposed subsection 35(1) is $262,500. Subsection 69EJA(2) of the Administration Act sets out the maximum amount of the penalty for an individual, which is three times the maximum monetary penalty that could be imposed if the individual was convicted of an offence constituted by the same conduct. This means that the maximum civil penalty that can be imposed on an individual is $31,500.


91. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 22.
the end of the next financial year. For the purposes of this requirement, item 28 of Part 4 in Schedule 1 to the Bill inserts the definition of the term active constituent into subsection 3(1) of the Collection of Levy Act.

**Keeping records**

Item 30 of Part 4 in Schedule 1 to the Bill inserts proposed section 37 into the Collection of Levy Act to require an interested person who is liable to pay a levy in respect of leviable disposals of the product to keep records. The relevant records are those that are reasonably necessary to enable the APVMA to find out whether the requirement to give an annual return has been complied with. The records are to be retained for six years.

A failure to comply with that requirement gives rise to an offence of strict liability. The maximum penalty for the offence is 50 penalty units. In addition, proposed subsection 37(1) is a civil penalty provision.

**Constitutional basis**

Item 30 also inserts proposed sections 37 and 37B into the Collection of Levies Act to set out the Constitutional basis for sections 35 and 37. These are:

- the census and statistics power: section 51(xi)
- the incidental matters power: section 51(xxxix)
- the trade and commerce power which relates to trade and commerce between Australia and places outside Australia; among the States; or within a Territory, between a State and a Territory or between two Territories: section 51(i)
- the corporations power in relation to a leviable disposal by a corporation: section 51(xx) and
- the Territories power in relation to a leviable disposal that occurs in a Territory: section 122.

**Part 5—computerised decision-making**

**Quick guide to Part 5**

The amendments in Part 5 of Schedule 1 to the Bill are intended to permit the APVMA to use computer programs which will make decisions.

Although other Commonwealth statutes allow the use of such computer programs, this is new for the APVMA.

In order to comply with the rules of natural justice, decisions which have been made using a computer program may be reviewed at first instance by an officer at the APVMA.

The amendments are identical to those set out in Part 4 of Schedule 1 to the Streamlining Bill.

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92. Collection of Levy Act, proposed subsection 35(5).
93. Active constituent, in relation to a proposed or existing agricultural chemical product or veterinary chemical product, means the substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the product as an agricultural chemical product or a veterinary chemical product, as the case may be. See section 3 of the Schedule to the Code Act.
94. Collection of Levy Act, proposed subsection 37(2). See footnote 34 for more information on penalties for individuals and corporations.
95. Collection of Levy Act, proposed subsection 37(3). This replicates the existing penalty which is imposed under section 69EA of the Administration Act in respect of annual returns that are required under section 69E of the Administration Act—which is to be repealed. See footnote 36 for more information on the quantum of the penalties.
Commencement
The provisions in Part 5 of Schedule 1 to the Bill commence on the earlier of a single day to be fixed by Proclamation or six months after Royal Assent.

Background
In 2004, the Administrative Review Council (ARC) prepared a report for the Attorney-General on *Automated Assistance in Administrative Decision Making*. The report acknowledged:

> Expert systems can play a significant and beneficial role in administrative decision making, particularly in areas where high volumes of decisions are made. Their potential to offer cost savings and improve efficiency and accuracy means it can be expected that the systems will become increasingly important tools of government.

To that end the ARC set out what it considered to be best-practice principles for computerised decision making.

Whilst other agencies have adopted computerised decision making, for instance the Therapeutic Good Administration, this has not been the case with the APVMA. However, the APVMA’s relocation to Armidale has presented an opportunity to create ‘a new business operating model, supported by modern technology’. According to the APVMA its

> ... present information and communication technology (ICT) environment is at the point of critical failure. Investment in the authority’s infrastructure, applications and core business systems is vital to support the transition to Armidale, New South Wales, and underpins future efficiencies in application assessment and registration.

This measure is consistent with the APVMA’s proposed digital strategy for the period 2018–22.

What the Bill does
Item 36 in Part 5 of Schedule 1 to the Bill inserts proposed clause 5F into the Agvet Code to authorise the APVMA to use computer programs to make decisions. Under proposed subclause 5F(1) the APVMA may arrange for the use of computer programs to make a decision, exercise a power or comply with any obligation under the Code or do anything else arising from those matters. In that case, the APVMA is deemed to have made the decision, exercised the power or complied with the obligation.

The APVMA may substitute a decision for a computer generated decision (the *initial decision*) if the APVMA is satisfied that the initial decision is incorrect—provided that the substituted decision is made within 60 days of the day the initial decision is made.

97. Ibid., p. vii.
98. Therapeutic Goods Act 1989, section 7C.
100. Ibid.
101. Agvet Code, proposed subclauses 5F(3) and (4).
Review and appeal

Items 37–41 of the Bill amend clause 166 of the Agvet Code to ensure that, where a decision has been made by a computer program, a person who is affected by the decision may request the APVMA to reconsider that initial decision.

Any subsequent decision made by a member of the staff of the APVMA will be a reviewable decision which will be able to be reviewed by the Administrative Appeals Tribunal.

This is consistent with the ARC best-practice principles which state that decisions made by, or with the assistance of, expert systems must comply with administrative law standards in order to be legally valid.102

Scrutiny of Bills Committee comments

The Scrutiny of Bills Committee noted that proposed clause 5F of the Agvet Code would allow the APVMA to arrange for the use of computer programs for any purpose for which it may make a decision, exercise a power or comply with an obligation, or do anything related to those matters.103

The Committee’s particular concern was that where decisions are made by computer rather than by a person there are risks that the process may operate as a fetter on discretionary power, by inflexibly applying predetermined criteria to decisions. This was considered to be especially relevant in the case of more complex or discretionary decisions. For example, the APVMA may be required to consider or take into account:

- any recommendations made by a co-ordinator
- whether there are reasonable grounds for issuing the permit pending determination of the application or
- whether there are exceptional circumstances that justify issuing the permit.

The Scrutiny of Bills Committee concluded that ‘it may be appropriate for more complex decisions to be made by a person, rather than by a computer’.104

As the Explanatory Memorandum did not address this matter in a manner that the Committee considered to be adequate, it requested Minister’s more detailed advice as to:

- why it is considered necessary and appropriate to permit the APVMA to arrange for the use of computer programs for any purpose for which the APVMA may or must take administrative action
- whether consideration has been given to how automated decision-making processes will comply with administrative law requirements (for example, the requirement to consider relevant matters and the rule against fettering of discretionary power) and
- whether consideration has been given to requiring that certain administrative actions (for example, complex or discretionary decisions) be taken by a person rather than by a computer.105

102. ARC, Automated assistance in administrative decision making, op. cit., p. viii.
104. Ibid., p. 3.
105. Ibid., pp. 3–4.
The Minister for Agriculture, Senator McKenzie, responded to the Scrutiny of Bills Committee stating:

The APVMA’s decisions about implementing computerised decision-making will be guided by the best practice principles developed by the Administrative Review Council.

This will ensure that decision-making done by or with the assistance of computer systems is consistent with the administrative law values of lawfulness, fairness, rationality, transparency and efficiency …

Decisions that require interpretation or evaluation of evidence—such as where fact finding or weighing evidence is required—would not be made by automated systems. Complex decisions such as these will continue to be determined by a human decision maker.106

The Scrutiny of Bills Committee noted the Minister’s advice but referred to the absence of ‘limitation on the types of decisions that will be subject to computerised decision-making on the face of the primary legislation’.107 Accordingly, the Committee recommended that the Bill be amended to limit the types of decisions that can be made by computers. The Committee also recommended amendments to the Bill to provide that the APVMA must, before determining that a type of decision can be made by computers, be satisfied that it is appropriate for the type of decision to be made by a computer rather than a person.

Given their concerns the Scrutiny of Bills Committee has requested further advice from the Minister as to whether the recommended amendments will be introduced.108

**Part 6—preliminary assessments**

**Quick guide to Part 6**

The measures in Part 6 of Schedule 1 to the Bill are intended to provide the APVMA with greater flexibility to manage application errors during the preliminary assessment of applications for:

- approval or registration and
- variation of approval of registration.

The amendments are in equivalent terms to those which were previously set out in Part 2 of the Operational Efficiency Bill.

**Commencement**

The measures in Part 6 of Schedule 1 to the Bill commence 12 months after Royal Assent.

**Current law—approvals and variations**

Prior to the enactment of the 2013 Amendment Act, the Department of Agriculture was concerned that the APVMA had to:

... go back to registrants with every small defect it finds with an application ... They have to continually do this and it takes an inordinate amount of time, and lots of letters back and forth to be able to accept the application, because of these small deficiencies.109

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107. Ibid., p. 41.
108. Ibid.
In order to remedy this perceived defect in the process, the 2013 Amendment Act did two things. **First**, it prescribed what it meant to *meet the application requirements*. **Second**, it gave the APVMA one month to complete a preliminary assessment of an application.

An application *meets the application requirements* if:

- it is lodged with the APVMA in the approved manner and form, is accompanied by the prescribed fee and contains the required information
- the constituent, product or label in relation to which the application is made complies with any requirement prescribed by the Regulations
- any requirement prescribed by another provision of the Agvet Code in relation to the application has been complied with and
- any amount (including an amount in respect of a tax or penalty) that is due and payable by the applicant to the APVMA has been paid.

Where the application appears to *meet the application requirements*, the APVMA must notify the applicant that the application has passed the preliminary assessment, in writing, within 14 days of making that preliminary assessment. The notice must state, amongst other things, that the application has passed preliminary assessment, and it must set out any matters prescribed by the Regulations. In addition, the APVMA must publish a summary of the application that includes any details prescribed by the Regulations.

Where the application does not appear to *meet the application requirements*, the APVMA must refuse the application.

The requirement for an application to undergo a preliminary assessment was a key feature of the 2013 Amendment Act—an application for a variation of an approval or registration is the subject of a preliminary assessment process in equivalent terms.

**What the Bill does**

The requirement that the APVMA complete a preliminary assessment of the application within one month after it is lodged remains. However, the Bill removes the requirement that the APVMA refuse an application at first instance if it does not appear to *meet the application requirements*.

**Application for approval**

**Item 46** of Part 6 repeals subclause 11(3) and inserts proposed subclauses 11(3) and 11(3A) into the Agvet Code. Under proposed subclause 11(3) where it appears to the APVMA, after completing a preliminary assessment of the application, that the application does not meet the application requirements but that the defects in the application can reasonably be rectified, the

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110. Agvet Code, clause 8A.
111. Agvet Code, subclause 11(1).
112. Agvet Code, paragraph 11(2)(a). Agvet Code, clause 156A operates so that if the APVMA is required to give a person information in writing, the requirement will be taken to have been met if the person consents to the information being given electronically and it is so given, the information includes the Chief Executive Officer’s electronic signature and, in the event of a breach of a civil penalty provision (arising from a person’s failure to do, or not do, a thing set out in the information), the APVMA has in place systems for proving the person received the information.
114. Agvet Code, subclause 11(3).
APVMA must give written notice to the applicant within 14 days setting out the relevant defects and requiring that they are rectified within one month.

**Item 45** of Part 6 of the Bill amends subclause 11(2) of the Agvet Code so that where an applicant who has been given a notice to rectify a defect does so within the specified time, the APVMA must give the applicant a written notice that the application has passed the preliminary assessment and will be determined under the relevant provisions of the Agvet Code.

**Proposed subclause 11(3A)** of the Agvet Code provides that where the APVMA is not satisfied that defects in the application can reasonably be rectified, or the defects are not rectified within the specified time, the APVMA must refuse the application.

**Application for variation**

The Agvet Code allows a *holder*\(^{116}\) to apply to the APVMA for a variation of the relevant particulars or conditions of:

- the approval of an active constituent
- the registration of a chemical product or
- the approval of a label for containers for a chemical product.\(^{117}\)

An application for such a variation must meet the application requirements.\(^ {118}\)

Clause 28 of the Agvet Code sets out the requirement for a preliminary assessment of such an application in equivalent terms to clause 11. **Items 47 and 48** of Part 6 in Schedule 1 to the Bill amend subclauses 28(2) and 28(3) in equivalent terms to items 45 and 46, as discussed above, where a holder makes an application for a variation, and the application contains defects that can reasonably be rectified.

**Current law—permits**

All agricultural and veterinary chemical products sold in Australia must be registered by the APVMA. In addition:

> The APVMA administers a permits scheme that allows for the legal use of chemicals in certain ways that are contrary to the label instructions or, in certain circumstances allows for the limited use of an unregistered chemical product.\(^ {119}\)

A person may apply to the APVMA for a permit in respect of an active constituent for a proposed or existing chemical product, or in respect of the chemical product.\(^ {120}\) The application must meet the application requirements.\(^ {121}\)

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116. Agvet Code, subclause 3(1) defines a *holder* as (a) in relation to an approval or registration: the person entered in the Record, Register or relevant APVMA file as the holder of the approval or registration; if the holder was an individual who has died or is an individual whose affairs are being lawfully administered by another person—the legal personal representative of the individual or the person administering the individual’s affairs or if the holder was a body corporate—a successor in law of the body corporate or (b) in relation to a permit or licence: the person to whom the permit or licence was issued.

117. Agvet Code, subclause 27(1).

118. Agvet Code, subclause 27(3).

119. Australian Pesticides and Veterinary Medicines Authority (APVMA), ‘Permits’, APVMA website, last updated 1 July 2014.

120. Agvet Code, clause 110.

121. Agvet Code, clause 110A.
Like approvals and variations, applications for permits are subject to a preliminary assessment process. However, the process differs because it already contains the right for the APVMA to give notice to an applicant to rectify defects.\textsuperscript{122}

**What the Bill does**

Items 49 and 50 of Part 6 in Schedule 1 to the Bill make minor amendments to the wording in existing subclauses 110A(2) and 110A(3) of the Agvet Code so that they are in equivalent terms to the preliminary assessment provisions for applications for approval which are discussed above.

**Part 7—variation of relevant particulars and conditions**

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| The amendments in Part 7 of Schedule 1 to the Bill amend the Agvet Code to enable the APVMA to vary the relevant particulars or conditions of an approval of an active constituent, a registration of a chemical product, or an approval of a label for containers for a chemical so that they are different from the original application. The amendments are in equivalent terms to those which were previously in Part 3 of the Operational Efficiency Bill.

**Commencement**

The provisions of Part 7 of Schedule 1 to the Bill commence on the day after the end of the period of three months after Royal Assent.

**Current law**

A stated above, a holder may apply to the APVMA for a variation of the relevant particulars or conditions of:

- the approval of an active constituent
- the registration of a chemical product or
- the approval of a label for containers for a chemical product.\textsuperscript{123}

Under existing subclause 29(1) of the Agvet Code, the APVMA must vary the relevant particulars or conditions if it is satisfied that the application meets the application requirements and that the variation would meet applicable statutory criteria and established standards as required by paragraphs 29(1)(b)–(d) of the Agvet Code. If the application does not satisfy those provisions, the APVMA must refuse the application.\textsuperscript{124}

Essentially those paragraphs only give the APVMA the authority to approve the variation precisely as it is set out in the relevant application.

**What the Bill does**

Item 54 of Part 7 in Schedule 1 to the Bill amends paragraphs 29(1)(b)–(d) of the Agvet Code by deleting references to a variation ‘in accordance with the application’ and substituting references to a variation of particulars or conditions ‘in a particular way (which may not be the same way as

\textsuperscript{122}. Agvet Code, subclauses 110A(3) and (4).
\textsuperscript{123}. Agvet Code, subclause 27(1).
\textsuperscript{124}. Agvet Code, subclause 29(2).
set out in the application). This will allow the APVMA to vary an approval or registration in a way which differs from the application.

**Items 52 and 53** of Part 7 of the Bill make consequential amendments to the notice provisions in existing clause 85 to require the APVMA to give an applicant a written notice of its intention—prior to approving a variation of an approval or registration in a way other than that set out in the application. The effect of the amendments is to provide the applicant with the opportunity to make submissions to the APVMA about the proposal.

**Item 55** of Part 7 of the Bill is also a consequential amendment. It inserts proposed paragraph 167(1)(ca) into the Agvet Code so that a decision to vary relevant particulars or conditions in a way other than set out in the application for variation is subject to review by the Administrative Appeals Tribunal.

**Part 8—variation of approval or registration during suspension**

**Quick guide to Part 8**

The provisions of Part 8 in Schedule 1 to the Bill amend the Agvet Code so that the APVMA may implement practical measures to deal with suspended label approvals or registrations and address the reason for that suspension.

The amendments in items 60–63 are in equivalent terms to those which were previously set out in Part 4 of the Operational Efficiency Bill. The amendments in items 57–59 and items 64–65 are in equivalent terms to those which were previously in Part 11 of Schedule 1 to the Streamlining Bill.

**Commencement**

The provisions of Part 8 of Schedule 1 to the Bill commence on the day after the end of the period of three months after Royal Assent.

**Current law**

The Agvet Code provides for both:

- the making, and assessment of, applications for approval of an active constituent for a proposed, or existing, chemical product, the registration of a chemical product and approval of a label for the containers of a chemical product.

Clause 15 of the Agvet Code provides that the APVMA must not register a chemical product unless each active constituent of the product, as well as a label for the container of the product, have been approved. The APVMA must not approve a label for the container of a chemical product unless it also registers the product.

Division 5 of Part 2 of the Agvet Code provides for suspending and cancelling approvals and registrations. It sets out the procedure to be followed by the APVMA before it takes action to suspend and the circumstances in which it may exercise that power.

In particular, the APVMA may suspend an approval for a label for containers for a chemical product. This may be because, amongst other things, there has been a contravention of a condition of the approval, the label does not meet the labelling criteria, or it does not comply

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125. Agvet Code, clause 36.
with a requirement prescribed by the Regulations. The Agvet Code provides that an approval is taken not to be in force during any period in which it is suspended. The suspension is made by entering the information, including the period of the suspension, into the APVMA file.

The effect of these provisions is that where the problem with the label may be addressed by an amendment to or variation of the label, the APVMA must first revoke the suspension.

What the Bill does

Items 57–59 of Part 8 of Schedule 1 to the Bill amend clause 42 of the Agvet Code. The amendments allow the holder of a product registration that is suspended to apply to the APVMA to vary relevant particulars and conditions of that registration, while the registration is suspended (rather than requiring the suspension to be revoked before any variations to the registration can be made, as is the case at present). It will also enable a holder to have their approval or registration suspended while they deal with any issues with that approval or registration.

Item 61 of Part 8 of Schedule 1 to the Bill inserts proposed subclauses 43(4) and (5) into the Agvet Code to address this problem.

In particular, proposed subclause 43(4) provides that the suspension of an approval of a label for containers for a chemical product does not prevent a person from requesting a variation of the relevant particulars of the approval, provided that the variation relates to the reasons for the suspension of the approval. This means that suspended label approvals may be rectified without first revoking the suspension.

Part 9—false and misleading information

Quick guide to Part 9
The provisions in Part 9 of Schedule 1 to the Bill amend both the Administration Act and the Agvet Code to establish civil pecuniary penalties for contraventions of the prohibition against giving false or misleading information.

The amendments are in equivalent terms to those which were previously set out in Part 5 of the Operational Efficiency Bill.

Commencement
The provisions of Part 9 in Schedule 1 to the Bill commence three months after Royal Assent.

Current law

Importation offence
Subsection 69B(1) of the Administration Act prohibits a person from importing into Australia:

- an active constituent for a proposed or existing chemical product that is not approved or
- a chemical product that is not a registered chemical product, a reserved chemical product or an exempt chemical product.

126. Agvet Code, subclause 41(2).
127. Agvet Code, subclause 43(2).
128. Agvet Code, clause 45. Agvet Code, clause 21 sets out how approval of a label takes place.
129. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 19.
130. Agvet Code, suspension of an approval or a registration may be made under clause 36, subclause 41(2) or subclause 44(2).
Similarly, a person is prohibited from arranging such importation into Australia, on behalf of another person who, at the time of the arrangements, is neither a resident of, nor carrying on business in, Australia.

Subsection 69B(1AA) of the Administration Act provides that a person who contravenes these prohibitions commits an offence (known as an importation offence)—the maximum penalty for which is 300 penalty units. However, an offence will not be committed if the person has the APVMA’s written consent for the relevant importation.

**False and misleading information**

Subsection 69ER(1) of the Administration Act provides that where a person who has applied to the APVMA for written consent (as above) gives information (whether orally or in writing) that the person knows to be false or misleading in a material particular, the person commits an offence. In the alternative, the offence arises if the person produces a document that the person knows to be false or misleading in a material particular without:

- indicating to the person to whom the document is produced that it is false or misleading and
- providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

Similarly to the importation offence, the maximum penalty for the offence is 300 penalty units.

**Lesser offence**

Subsection 69ER(2) of the Administration Act provides that a person commits an offence if, when complying with a requirement made by an inspector under, or for the purposes of, or in connection with any provision of Part 7A, Part 7AA or Part 7AB of the Administration Act the person gives information that the person knows to be false or misleading in a material particular. An offence is also committed if the person produces a document that the person knows to be false or misleading in a material particular without:

- indicating to the person to whom the document is produced that it is false or misleading and
- providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

In this case, the maximum penalty for the offence is 60 penalty units.

**What the Bill does**

The 2013 Amendment Act introduced a range of enforcement options for the APVMA which included seeking civil penalty orders, issuing infringement notices, accepting and enforcing

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131. Under section 4AA of the Crimes Act 1914, a penalty unit is equivalent to $210. This means that the maximum penalty for the offence is $63,000. Subsection 48(3) of the Crimes Act provides that the maximum penalty that may be imposed on a body corporate is five times the maximum penalty that could be imposed on an individual convicted of the same offence. Accordingly, the maximum pecuniary penalty for a corporation is $315,000.

132. Administration Act, subsection 69B(1B).

133. Administration Act, subsection 69ER(1). See footnote 73 for more information on penalties for individuals and corporations.

134. Other than section 69B, which is covered by subsection 69ER(1).

135. Administration Act, subsection 69ER(2). The maximum penalty is equivalent to $12,600 for an individual and $63,000 for a corporation.
undertakings, seeking injunctions, requiring claims to be substantiated and issuing formal warnings.

However, while it created two offences in section 69ER of the Administration Act, it did not create equivalent rights to seek civil penalty orders.

**Item 68** of Part 5 of the Bill addresses this problem by inserting *proposed subsections 69ER(3)–(5)* into the Administration Act.

**Proposed subsections 69ER(3) and (4)** are in equivalent terms to existing subsections 69ER(1) and (2) respectively. **Proposed subsection 69ER(5) of the Administration Act** specifies that those subsections are civil penalty provisions. Accordingly if they are breached, the APVMA may apply to a court of competent jurisdiction for an order that a person pay the Commonwealth a pecuniary penalty.  

**Item 70** of Part 9 in Schedule 1 to the Bill amends the equivalent offences for false and misleading information in the Agvet Code by inserting *proposed subclauses 146(3)–(5)* which are in similar terms to *proposed subsections 69ER(3)–(5)* being inserted into the Administration Act. The difference between the provisions is that proposed subsection 146(3) makes reference to matters referred to in clause 5A, 5B, 5C or 5D or subclause 123(1) of the Agvet Code rather than to Part 7A, Part 7AA or Part 7AB of the Administration Act.

### Amount of civil penalty

The amount of the pecuniary penalty is worked out under section 69EJA of the Administration Act. Importantly, it applies not only to persons but to bodies corporate.

**By a body corporate**

Subsection 69EJA(1) of that Act provides that the pecuniary penalty for a contravention of a civil penalty provision by a body corporate must not exceed five times the amount of the maximum monetary penalty that could be imposed by a court if the body corporate were convicted of an offence constituted by the same conduct. Subclause 145AA(1) of the Agvet Code is in equivalent terms.

This means that for a contravention of *proposed subsection 69ER(3)* of the Administration Act or *proposed subclause 146(3)* of the Agvet Code, a body corporate would be liable for a maximum penalty of 1,500 penalty units—being $315,000. For a contravention of *proposed subsection* 

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136. *Administration Act*, subsection 69EJ(1). The amount of the pecuniary penalty is worked out under section 69EJA of the *Administration Act* (as discussed further below).

137. Clause 5A of the Agvet Code sets out the matters to be considered in determining whether an active constituent or chemical product *meets the safety criteria*.

138. Clause 5B of the Agvet Code sets out the matters to be considered in determining whether a chemical product *meets the efficacy criteria*.

139. Clause 5C of the Agvet Code sets out the matters to be considered in determining whether a chemical product *meets the trade criteria*.

140. Clause 5D of the Agvet Code sets out the matters to be considered in determining whether a label for containers of a chemical product *meets the labelling criteria*.

141. Subclause 123(1) of the Agvet Code sets out the matters to be considered in determining whether a licence to carry out steps in the manufacture of chemical products at particular premises must be issued.

142. Subsection 4B(3) of the Crimes Act states that, where a body corporate is convicted of an offence against a law of the Commonwealth, a court may, if the contrary intention does not appear and the court thinks fit, impose a pecuniary penalty not exceeding an amount equal to five times the amount of the maximum pecuniary penalty that could be imposed by the court on a natural personal convicted of the same offence.
Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019

69ER(4) of the Administration Act or proposed subclause 146(4) of the Agvet Code, a body corporate would be liable for a maximum penalty of 300 penalty units—being $63,000.

By an individual

Subsection 69EJA(2) of the Administration Act and subclause 145AA(2) of the Agvet Code provide that the penalty for an individual for contravening a civil penalty provision must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court on an individual convicted of an offence constituted by the same conduct.

This means that for a contravention of proposed subsection 69ER(3) of the Administration Act or proposed subclause 146(3) of the Agvet Code, an individual would be liable for a maximum penalty of 900 penalty units—being $189,000. For a contravention of proposed subsection 69ER(4) of the Administration Act or proposed subclause 146(4) of the Agvet Code, an individual would be liable for a maximum penalty of 180 penalty units—being $37,800.

Problems that are addressed by civil penalties

Prior to the enactment of the 2013 Amendment Act all of the offences in the Agvet Code were criminal offences—most (but not all) of which were strict liability offences. The standard of proof in a criminal case is ‘beyond a reasonable doubt’. To establish an offence of strict liability it is only necessary to prove that the relevant conduct or event took place. However the defence of ‘mistake of fact’ (honest and reasonable mistake) is open to those who mistakenly but reasonably believe certain facts to exist which, if true, would have shielded them from liability. Those offences, if proven, generally allowed for financial penalties to be paid rather than imposing a term of imprisonment.

Unfortunately, the APVMA had limited success in prosecuting holders of registrations and approvals in circumstances where alleged breaches of the Agvet Code had occurred.143 That being the case, the 2013 Amendment Act provided for existing offence provisions to also be civil penalty provisions to enable the APVMA to apply to the court for a civil penalty order against a person who has contravened a civil penalty provision. In that case, the standard of proof is lower being ‘on the balance of probabilities’.

The tension within the Agvet statutes, then, is that a pecuniary penalty may be higher than an amount payable as a fine were the person prosecuted under a criminal offence, even though the conduct is essentially the same.144

Part 10—suspension or cancellation of approval or registration

Quick guide to Part 10

The amendments in Part 10 of Schedule 1 to the Bill create more comprehensive grounds for suspending or cancelling approvals or registrations where information is provided that is false or misleading in a material particular.

The amendments are in equivalent terms to those which were previously set out in Part 9 of Schedule 1 to the Streamlining Bill.


144. Although additional, non-monetary consequences, such as a criminal record, flow from conviction for a criminal offence.
Commencement
The amendments in Part 10 of Schedule 1 to the Bill commence three months after Royal Assent.

Current law
At present, clause 38A of the Agvet Code provides for the APVMA to suspend or cancel an active constituent approval, or a product registration, where false or misleading information has been provided. However, clause 38A does not currently apply if the false or misleading information was provided:

- in an application for variation of an approval of an active constituent or variation of a registration of a chemical product
- in an application for approval, or variation of an approval, of a label for containers for a chemical product
- by a person other than the holder, such as through subclause 27(2) of the Code.145

What the Bill does
Part 10 of Schedule 1 to the Bill introduces more comprehensive grounds for suspending or cancelling approvals or registrations where information is provided that is false or misleading in a material particular.

Item 73 of the Bill repeals and replaces clause 38A of the Code. Proposed clause 38A addresses the deficiencies outlined above and improves the capability of the APVMA to respond to false or misleading information after a product has been registered or a label or active constituent has been approved. Specifically, it broadens the circumstances where a more proportionate APVMA response (suspension or cancellation) is available, rather than the APVMA only being able to rely on the offences and civil penalty provisions in clause 146 of the Agvet Code for providing false or misleading information.

Part 11—voluntary recalls

Quick guide to Part 11
The amendments in Part 11 of Schedule 1 to the Bill establish a voluntary recall scheme for persons who have stocks of chemical product in their possession. The Scheme will specify notification and publication requirements in respect of a chemical product that is being voluntarily recalled. This is not currently required.

The recall scheme will be in addition to the product recall scheme which is set out in Part 3-3 of the Australian Consumer Law (which is contained in Schedule 2 to the Competition and Consumer Act 2010).

The amendments are in equivalent terms to those which were previously contained in Part 6 of Schedule 1 to the Streamlining Bill.

Commencement
The amendments in Part 11 of Schedule 1 to the Bill commence three months after Royal Assent.

145. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 46.
**Current law**

Currently Part 6 of the Agvet Code sets out various circumstances in which the APVMA may issue recall notices requiring persons who have, or have had, stocks of chemical products in their possession to stop supplying the products and to take action in relation to the products as directed by the APVMA. These powers are said to be ‘in addition to the recall powers conferred on the Australian Competition and Consumer Commission under the *Competition and Consumer Act*.’

Existing clause 106 of the Agvet Code cross references those powers.

**What the Bill does**

**Items 75 and 76** of the Bill amend clause 100 of the Agvet Code to provide for the voluntary recall of chemical products.

**Item 77** repeals and replaces clause 106 to set out in detail the manner in which the voluntary recall power will operate. In particular, the new provisions apply if a person voluntary recalls a chemical product on the grounds that:

- the chemical product does not meet the safety criteria, trade criteria or the efficacy criteria or a label for the container of a chemical product does not meet the labelling criteria and/or
- the chemical product is not registered.

In particular, where a person takes voluntary action to recall a chemical product in specified circumstances, the person must notify the APVMA within two days, in the appropriate manner and form, of the recall action.

The APVMA is to publish a copy of that notice on its website within three days of its receipt and publish an additional copy in the Gazette within 14 days of its receipt.

**Proposed subclause 106(4)** provides that where a person is required to give such a notice to the APVMA, the person commits an offence of strict liability if he, or she, refuses or fails to give the notice. This is also a civil penalty provision.

**Part 12—notification of new information**

**Quick guide to Part 12**

The amendments in Part 12 of Schedule 1 to the Bill extend the obligations to provide relevant information to the APVMA by persons in respect of applications lodged but not yet determined for:

- label approvals and
- variations to approvals and registrations.

These requirements already apply to holders of active constituent approvals and product registrations.

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146. Agvet Code, clause 100.
147. Agvet Code, proposed subclause 106(1).
148. Agvet Code, proposed subclause 106(2).
149. Agvet Code, proposed subclause 106(6).
150. The imposition of strict liability means that a fault element does not need to be satisfied, but the offence will not criminalise honest errors and a person cannot be held liable if he, or she, had an honest and reasonable belief that they were complying with relevant obligations.
The amendments are in equivalent terms to those which were previously contained in Part 7 of Schedule 1 to the Streamlining Bill.

Commencement
The amendments in Part 12 of Schedule 1 to the Bill commence three months after Royal Assent.

Current law
Existing subclause 160A(1) of the Agvet Code applies if an application has been lodged with the APVMA for:

• approval of an active constituent for a proposed or existing chemical product
• registration of a chemical product
• a permit in respect of such an active constituent or in respect of a chemical product or
• a licence in respect of the manufacture of a chemical product.

If the APVMA has not determined the application and the applicant becomes aware of any relevant information in relation to the constituent, or in relation to the product or any of its constituents then he, or she, must give the information to the APVMA as soon as the applicant becomes aware of it.151

Under existing clause 161 of the Agvet Code, the requirement to give new information to the APVMA also applies to:

• the holder of an approval of an active constituent and
• the holder of a permit in relation to an active constituent of a chemical product.

What the Bill does
Item 80 of Part 12 in Schedule 1 to the Bill inserts proposed subparagraphs 160A(1)(a)(vi) and 160A(1)(a)(vii) into paragraph 160A(1)(a) of the Agvet Code to expand the requirement to give relevant information to applicants for label approvals and applicants for variations of approvals or registrations.

Item 84 of Part 12 in Schedule 1 to the Bill inserts proposed paragraph 161(1)(c) into the Agvet Code to extend the requirements of clause 161 to the holder of the approval of a label for containers for a chemical product.

These amendments address minor inconsistencies in the Agvet Code.

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151. Agvet Code, subclause 160A(2). Subclause 160A(4) states that information is relevant information if it: (a) contradicts any information that was given to the APVMA by the applicant in an application and relates to particulars prescribed by the Regulations; or (b) shows that the constituent or product may not meet the safety criteria, the trade criteria or the efficacy criteria.
Part 13—annual operational plans

Quick guide to Part 13

The amendments in Part 13 of Schedule 1 to the Bill amend the Administration Act to remove the need for the APVMA to develop and seek approval of an annual operational plan in addition to a corporate plan.

The amendments are in equivalent terms to those which were previously contained in Part 13 of Schedule 1 to the Streamlining Bill.

Commencement

The amendments in Part 13 of Schedule 1 to the Bill commence on the first 1 January to occur after the day this Act receives the Royal Assent.

Current law

Currently Part 6 of the Administration Act requires the Chief Executive Officer of the APVMA to give a corporate plan to the Minister for approval on or before 1 June of each year, or such other date that the Minister allows. That report must be prepared in accordance with the requirements of section 35 of the Public Governance, Performance and Accountability Act 2013 (PGPA Act). The Corporate Plan must include, amongst other things:

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

In addition, Part 6 of the Administration Act requires that an annual operational plan must be prepared and approved by the Minister. The operational plan must:

• set out particulars of the action that the APVMA intends to take in order to give effect to the objectives set out in the corporate plan
• include such performance indicators as the Chief Executive Officer considers appropriate against which the APVMA’s performance can be assessed during the period to which the plan relates and
• include such other information (if any) as is prescribed by the Regulations.

What the Bill does

Item 91 of Part 13 of Schedule 1 to the Bill repeals sections 55–57 of the Administration Act so that there will no longer be a requirement to provide an annual operational plan. The requirement for a corporate plan, prepared in accordance with the PGPA Act, is unchanged.

152. Administration Act, section 51.
154. Ibid.
155. Ibid., table item 5.
156. Ibid., table item 6.
157. Administration Act, sections 55 and 56.
**Items 92–94** amend section 61 of the *Administration Act* to make consequential amendments to the matters which are to be included in the APVMA’s Annual Report.

According to the Explanatory Memorandum to the Bill:

Removing the requirement for the APVMA to prepare an annual operational plan would remove duplicative reporting that is required by the *Public Governance, Performance and Accountability Act 2013.*

**Part 14—Definition of registered chemical product**

### Quick guide to Part 14

The amendments in Part 14 of Schedule 1 to the Bill address an inconsistency in the Agvet Code. The amendments are in equivalent terms to those which were previously set out in Part 8 of Schedule 1 to the Streamlining Bill.

### Commencement

The amendments in Part 14 of the Bill commence on the day after this Act receives the Royal Assent.

### Current law

Currently clause 3 of the Agvet Code defines a **registered chemical product** as a chemical product that is registered and complies with the relevant particulars entered in the Register for the product.

### What the Bill does

**Item 96** of Part 14 in Schedule 1 to the Bill repeals that definition and inserts a new cross reference to **proposed clause 5AA.**

**Item 97** inserts **proposed clause 5AA** into the Code to provide a fuller definition of the term **registered chemical product.** The new definition reiterates the contents of the current definition and adds additional requirements about:

- the constituents of the chemical product
- the concentration of the constituents of the chemical product
- the composition of the constituents of the chemical product and
- the purity of the constituents of the chemical product.

The updated definition is consistent with variations which may be authorised under clause 83 of the Agvet Code and which currently interact in an inconsistent way with the offences and civil penalties which relate to possessing with the intention of supply, or supplying an unregistered chemical product.

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159. Agvet Code, **proposed subclause 5AA(1).**
160. Agvet Code, clauses 75 and 78.
Part 15—supply of registered chemical products with unapproved label

Quick guide to Part 15

The amendments in Part 15 of Schedule 1 to the Bill address an inconsistency in the Agvet Code by clarifying what information must be included in a label attached to the container for a chemical product.

The amendments are in equivalent terms to those which were previously contained in Part 10 of Schedule 1 to the Streamlining Bill.

Commencement

The amendments in Part 15 of Schedule 1 to the Bill commence on the day after Royal Assent.

Current law

Currently clause 21 of the Agvet Code sets out how approval of a label takes place. The clause provides that approval of a label takes place when the APVMA does all of the following:

(a) determines the particulars prescribed by the regulations that are appropriate to be contained on the label
(b) gives a distinguishing number to the label
(c) records the following information in the relevant APVMA file:
   (i) the name of the person who applied for the approval as the holder of the approval
   (ii) the name of any nominated agent for the approval
   (iii) the distinguishing number
   (iv) the instructions and any particulars that are to be contained on the label
   (iva) any other particulars prescribed by the Regulations and
   (v) any conditions of the approval imposed by the APVMA.

The Bill recognises that stating all of the relevant particulars in a label is not necessary, for instance, the name of the nominated agent and the holder of the approval.

However, under clause 81 of the Agvet Code, a person commits an offence if he, or she, supplies a registered chemical product in a container if the label attached to the container does not state the relevant particulars.

The term relevant particulars is defined in clause 3 of the Agvet Code as meaning, in relation to the approval of a label—the information required to be recorded in the relevant APVMA file by subparagraphs 21(c)(i) to (iva) (as set out above) and includes particulars of variations of relevant particulars.

What the Bill does

Items 98–101 in Part 15 of Schedule 1 to the Bill substitute existing references to relevant particulars in clause 81 with references to minimum information.

Item 103 inserts proposed subclause 81(5) into the Agvet Code which states that the term minimum information means the information covered by subparagraphs 21(c)(iii) and (iv) (including that information as varied under Part 2).

Item 102 in Part 15 repeals and replaces paragraphs 81(3)(a), (b) and (c) of the Agvet Code. The new provisions allow a registered chemical product to be supplied for a limited period of two years (or another period allowed by the APVMA) if the information on the label is different from
that required when supply occurs, but is information that was required to be on the label at a time before supply took place.

The Explanatory Memorandum provides the following rationale for the change:

Information required on a label may change. It is therefore necessary to enable the APVMA to deal with products containing information that was previously required but is different from the information that is currently required (that is, to allow trade out of a product with previously required information in the label). The amendments ... allow the APVMA to deal with this by allowing a product (with the previously required information in the label) to be supplied, where the APVMA considers that is appropriate.161

**Part 16—safety, efficacy, trade and labelling criteria**

**Quick guide to Part 16**

The amendments in Part 16 of Schedule 1 to the Bill address existing anomalies in the Agvet Code in relation to the safety, efficacy, trade and labelling criteria.

The amendments are in equivalent terms to those which were previously set out in Part 12 of Schedule 1 to the Streamlining Bill.

**Commencement**

The amendments in Part 16 commence on the day after Royal Assent.

**Current law**

Each of clauses 5A, 5B and 5C of the Agvet Code operate so that in working out whether a product meets the safety criteria, the efficacy criteria and the trade criteria respectively the APVMA must have regard to matters prescribed in Regulations.

Currently clause 5D of the Agvet Code, which relates to whether a label meets the labelling criteria, is different. Subclause 5D(1) provides that a label must contain adequate instructions for use and sets out those matters which will satisfy that requirement. In particular a label will contain adequate instructions for use—and thereby meet the labelling criteria—if the label also contains instructions about matters that are prescribed by Regulations. Under subclause 5D(2) of the Agvet Code, the APVMA must have regard to certain specified matters in making a determination about whether a label meets the labelling criteria.

Unlike clauses 5A, 5B and 5C, there is no overt requirement for the APVMA to make its decision on a label by having regard to matters prescribed in Regulations.

**What the Bill does**

Item 105 in Part 16 inserts proposed paragraph 5D(2)(d) into the Agvet Code to address that anomaly.

Subclause 160(2) (which is not amended by the Bill) provides that in determining matters about active constituents and/or chemical products (including their label) the APVMA may take into account the following information:

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

(b) any decisions or evaluations made by regulators of agricultural or veterinary chemicals in a foreign country and

(c) any information on which a decision or evaluation mentioned in paragraph (b) is based to the extent that those results, decisions or evaluations are, or that information is, relevant having regard to any matters the APVMA thinks appropriate.

Item 106 in Part 16 inserts proposed clause 5E into the Agvet Code. Essentially it ties the provisions of clause 160 into the decision-making processes in clauses 5A–5D by allowing Regulations to prescribe that the APVMA must have regard to the matters in paragraphs 160(2)(a), (b) or (c) of the Agvet Code.

**Part 17—Maximum Residue Limits Standard**

**Quick guide to Part 17**

The provisions in Part 17:

- amend the Agvet Code to simplify and provide flexibility in the timing of the notification that must be provided to Food Standards Australia New Zealand (FSANZ) by the APVMA in relation to an approval, registration, variation or person under the Agvet Code that would require a corresponding variation to the Maximum Residue Limits Standard
- make a consequential amendment to the Administration Act.

**Items 110 and 111** are in equivalent terms to those contained in Part 6 of Schedule 1 to the Operational Efficiency Bill. The amendments to the Administration Act were not contained in either the Streamlining Bill or the Operational Efficiency Bill.

**Commencement**

The provisions of Part 17 in Schedule 1 to the Bill commence on the day after Royal Assent.

**Background**

The APVMA registers and approves all agvet chemicals in Australia and sets maximum residue limits (MRLs) for these chemicals. Levels are set based on how much of the chemical is needed to control pests and/or diseases. The product's chemistry, metabolism, analytical methodology and residue trial data are also assessed.\(^{162}\)

The MRLs apply to agvet chemicals in agricultural produce—particularly produce entering the food chain. They are set at levels that are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions.\(^ {163}\)

**Current law**

Existing subsection 8E(1) of the Agvet Code requires the APVMA to notify FSANZ if an approval, registration, variation or permit proposed under the Code would be likely to require a variation to

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162. Food Standards Australia New Zealand (FSANZ), ‘Chemicals in food—maximum residue limits’, FSANZ website, April 2018.
the Maximum Residue Limits Standard. Currently the notice must be given to FSANZ within 28 days after the APVMA completes a preliminary assessment of the application.

That notification triggers the process to be carried out by FSANZ including the preparation of a dietary exposure assessment of the proposed variation, any relevant consultation about the dietary exposure assessment and the eventual publication of the variation.

**What the Bill does**

**Item 111** of Part 17 in Schedule 1 to the Bill repeals and replaces paragraph 8E(2)(c) of the Agvet Code so that the notice is to be given to FSANZ before the approval, registration, variation or permit is given, made or issued.

According to the *Explanatory Memorandum* to the Bill this will ‘provide the APVMA and FSANZ with the flexibility to agree on appropriate timeframes for notification’.

**Item 109** of Part 17 in Schedule 1 to the Bill repeals and replaces subsection 7A(1) of the *Administration Act*. **Proposed subsection 7A(1)** specifies that the APVMA is authorised to approve standards for residues of chemical products in protected commodities. Currently, the subsection merely provides that the APVMA is to publish such standards.

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**Part 18—expiry date**

**Quick guide to Part 18**

The amendment in Part 18 of Schedule 1 to the Bill amends the definition of *expiry date* in the Agvet Code to make clear that is a reference to the date after which a chemical product must not be used.

The amendment is in equivalent terms to that in Part 7 of the Operational Efficiency Bill.

**Commencement**

The provision in Part 18 of Schedule 1 to the Bill commences on the day after Royal Assent.

**What the Bill does**

**Item 33** of Part 7 of the Bill amends the definition of *expiry date* in section 3 of the Agvet Code to omit the reference to ‘should’ and substitute a reference to ‘must’. This is intended to ensure that the definition ‘reflects the timeframe in which the use of a chemical product is safe, effective and does not cause unmanageable risks’.

**Other amendments in Schedule 1**

The provisions in Part 19 of Schedule 1 the Bill are minor consequential amendments to the *Administration Act* and the Agvet Code. The amendment in Part 20 of Schedule 1 to the Bill repeals the 2014 Amending Act.

The relevant amendments in Parts 19 and 20 commence on the day after Royal Assent.

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164. Subsection 82(3) of the *Food Standards Australia New Zealand Act 1991* contains equivalent similar requirement.
166. *FSANZ Act*, section 82.
168. Ibid., p. 64.
Schedule 2—key issues and provisions

Commencement
The amendments in Schedule 2 commence on the earlier of a single day to be fixed by Proclamation or 12 months after Royal Assent.

Background
As stated above, the House of Representatives Standing Committee on Agriculture and Water Resources published a report in 2018 in which it recommended:

... the establishment of a Board of Directors for the Australian Pesticides and Veterinary Medicines Authority. The Committee recommends that, if a Board is to be established, the Minister for Agriculture should be consulted in relation to the appointment of Members to provide additional oversight and further links between the Minister and the APVMA. 169

The amendments in Schedule 2 to the Bill are consistent with that recommendation.

Current law
Currently, Part 3 of the Administration Act establishes an Advisory Board, the function of which is to provide advice and make recommendations to the Chief Executive Officer in relation to the performance of a function or the exercise of a power of the APVMA. 170

Advisory Board members did not represent particular interests, and were appointed by the minister based on experience in the regulation of chemical products, the agricultural chemical industry, primary production, environmental toxicology, consumer interests, public health, and work health and safety. 171

However, there are currently no members appointed to the Advisory Board. Previous appointments expired in November 2015. 172

Establishing the Board
Item 11 of Schedule 2 to the Bill repeals Divisions 2, 3 and 4 of Part 3 of the Administration Act which currently provide for the Advisory Board, the appointment of its members and the Advisory Board’s procedures respectively.

Item 11 also inserts proposed Division 2—Board of the APVMA.

Within new Division 2, proposed section 14 establishes the Board of the APVMA. Items 1–3 of Schedule 2 to the Bill make consequential amendments to the definitions in section 4 of the Administration Act to ensure that references to the Board are not references to the former Advisory Board but to the Board established under proposed section 14.

The functions of the Board are:

• to ensure the proper, efficient and effective performance of the APVMA’s functions which are contained in section 7 of the Administration Act

170. Administration Act, sections 14 and 16.
172. Ibid., p. 13.
• to determine objectives, strategies and policies to be followed by the APVMA and
• to do anything incidental to or conducive to the performance of those functions.\textsuperscript{173}

\textbf{Board members}

The Board is to consist of the Chair, the Chief Executive Officer and three other members.\textsuperscript{174} To assist in its work, the Board may establish committees which may consist of those persons that it determines. Committee members may also be Board members.\textsuperscript{175}

Board members are to be appointed by the Minister, in writing, on a part-time basis\textsuperscript{176} for a period not exceeding four years.\textsuperscript{177} A person who is appointed to the Board is eligible to be reappointed on one further occasion.\textsuperscript{178}

A person must not be appointed as a Board member unless the Minister is satisfied that the person has appropriate qualifications, skills or experience in one or more of the following fields:
• financial management
• law
• risk management
• public sector governance
• science (including agricultural science and veterinary science)
• public health or occupational health and safety.\textsuperscript{179}

The Remuneration Tribunal is to determine the remuneration to be paid to an appointed Board member.\textsuperscript{180} In the absence of such a determination the member is to be paid the remuneration that is prescribed by the Regulations.

The Minister may terminate the appointment of a Board member, amongst other things:
• for misbehaviour
• an inability to perform his or her duties because of physical or mental incapacity
• where the member becomes bankrupt or applies to take the benefit of any law for the relief of bankrupt or insolvent debtors
• if the person engages in paid work that conflicts or could conflict with the performance of his or her member’s duties or
• if the Minister is satisfied that the appointed Board member’s performance has been unsatisfactory.\textsuperscript{181}

\textsuperscript{173} \textit{Administration Act}, proposed subsection 15(1).
\textsuperscript{174} \textit{Administration Act}, proposed section 17.
\textsuperscript{175} \textit{Administration Act}, proposed subsections 27(1) and (2).
\textsuperscript{176} \textit{Administration Act}, proposed subsection 18(1).
\textsuperscript{177} \textit{Administration Act}, proposed subsection 19(1).
\textsuperscript{178} \textit{Administration Act}, proposed subsection 19(2).
\textsuperscript{179} \textit{Administration Act}, proposed subsection 18(2).
\textsuperscript{180} \textit{Administration Act}, proposed section 21.
\textsuperscript{181} \textit{Administration Act}, proposed section 25.
Meetings of the Board
The Chair may convene a meeting at any time but must convene at least four meetings each calendar year.182 A quorum is constituted by a majority of Board members.183 The person presiding at the meeting of the Board has a deliberative vote and, if the votes are equal, a casting vote.184 The Board must give the Secretary of the Department a copy of the minutes and the Board papers within 20 business days of the date of the meeting.185 In addition the Board must give the Secretary of the Department a copy of any other document he, or she, has requested within 20 business days of the date that the request was made.

Ministerial directions
The Bill empowers the Minister to give written directions to the Board about the performance of its functions or the exercise of its powers,186 provided that the Minister:

• has first given the Board a written notice that the Minister is considering giving the direction and
• has given the Board an adequate opportunity to discuss with the Minister the need for the proposed direction.

In that case, the Board must comply with the direction.187 A copy of any direction given by the Minister to the Board in accordance with proposed subsection 27G(1) of the Administration Act is to be laid before each House of the Parliament within 15 sitting days of giving the direction.188

Other matters relating to the Board
Under the Bill, the Board replaces the CEO as the accountable authority under the PGPA Act.189 As a result the PGPA Act will impose general duties on Board members (other than the CEO).190

Stakeholder comments
Independence of the Board
The NSW Farmers Association stated the ‘need for members of the APVMA Board to be selected on a skills basis and continue to allow the organisation to operate independently.’191 Similarly, the National Farmers’ Federation (NFF) stated that it:

... is not opposed to the establishment of a skills-based APVMA governance Board, on the understanding that establishment of such a Board has been recommended as the best mechanism to strengthen the

182. Administration Act, proposed section 27.
183. Administration Act, proposed section 27B.
184. Administration Act, proposed subsection 27C(2).
185. Administration Act, proposed section 27E.
186. Administration Act, proposed subsection 27G(5) provides that the direction is a notifiable instrument. This means that it will not be subject to disallowance under the Legislation Act 2003.
187. Administration Act, proposed subsections 27G(1) and (2).
188. Administration Act, proposed subsection 27G(6).
189. Administration Act, proposed subsections 27G(3), inserted by item 11 of Schedule 2 to the Bill.
190. PGPA Act, sections 15–19.
191. NSW Farmers’ Association, Submission to the Rural and Senate Rural and Regional Affairs and Transport Committee, Inquiry into the provisions of the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, 10 October 2019, p. 1.
APVMA’s governance arrangements and assist the regulator to manage operational, financial and performance matters—and drive improvement in those areas.\(^\text{192}\)

However, it should be noted that this is a small Board. Essentially, it has four members plus the CEO. If for some reason the CEO has to recuse him, or herself, from voting on a matter, the person presiding, probably the Chair, will have the casting vote. Whilst the Bill provides for persons with a range of skills to be members, it remains to be seen what the skill set of the Board in its final form will be; and whether the Board will ‘be effective and protect the independent evidence- and science-based decision-making of the APVMA’.\(^\text{193}\)

According to the Explanatory Memorandum to the Bill, ‘a five member Board is appropriate as it balances the need to provide the necessary skills to effectively govern the APVMA with the cost of maintaining the Board’.\(^\text{194}\) The issue of cost was raised by some submitters to the RRAT Committee.

### Cost of the Board

Grain Producers Australia (GPA) expressed support for the establishment of a governance board for the APVMA. However, it stressed that it should be:

> ... a skills based board and independence of directors will be essential. To ensure absolute public confidence in the independence of a skills based APVMA board, the costs associated with the appointment and operation of this board should be fully funded by the Australian Government in annual appropriation budgets rather than funded through the APVMA by registrant levies which are indirectly supported by producers through pesticide sales.\(^\text{195}\)

CropLife Australia was also critical of the expected costs of the Board stating:

> The direct and associated costs of a Board should be fully funded by government as an appropriate contribution to the effective operations of the Regulator. Without government funding, the cost of a Governing Board would be an additional direct cost to the farming sector, further limiting access to crucial crop protection products by farmers. The $600,000 a year cost attributed to the APVMA Governing Board, as referenced in Senate Estimates in May 2018, is an exorbitant and unnecessary cost to what is already one of the world’s most expensive agricultural chemical regulators for industry.\(^\text{196}\)

### Role of the Chief Executive Officer

Currently, Part 4 of the Administration Act sets out the terms and conditions of the Chief Executive Officer (CEO). The Bill amends subsection 32(1) so that the CEO is ‘responsible for the day-to-day management and decision making of the APVMA’. In carrying out his, or her, duties the CEO is to

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192. NFF, Submission to the Rural and Senate Rural and Regional Affairs and Transport Committee, Inquiry into the provisions of the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, 10 October 2019, p. 2.
193. GPA, Submission to the Rural and Senate Rural and Regional Affairs and Transport Committee, Inquiry into the provisions of the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, 10 October 2019, p. 2.
194. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 72.
195. CropLife Australia, Submission to the Rural and Senate Rural and Regional Affairs and Transport Committee, Inquiry into the provisions of the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, 10 October 2019, p. 8.
196. CropLife Australia, Submission to the Rural and Senate Rural and Regional Affairs and Transport Committee, Inquiry into the provisions of the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, 10 October 2019, p. 2. See, Senate Rural and Regional Affairs and Transport Legislation Committee, Official Committee Hansard, 23 May 2018, p. 95.
act in accordance with the objectives, strategies and policies determined by the Board as part of its functions.\textsuperscript{197}

Importantly, the Board may give written directions to the CEO about the performance of the CEO’s duties. However, the Board must not give such a direction unless the Board has first:

- given the CEO a written notice stating that the Board is considering giving the direction and
- given the CEO an adequate opportunity to discuss with the Board the need for the proposed direction.\textsuperscript{198}

\textbf{Items 16–26, 28 and 30} make consequential amendments to Part 4 of the \textit{Administration Act} to substitute references to Minister with references to the Board to make clear that it is the Board who appoints the CEO. However, the Board must consult the Minister before appointing the CEO\textsuperscript{199} or terminating that appointment.\textsuperscript{200}

According to the Explanatory Memorandum:

The Bill will also establish a governance Board for the APVMA and cease the existing APVMA Advisory Board. Establishing an APVMA Board will \textbf{strengthen the APVMA’s governance arrangements} and provide the necessary oversight to help the regulator manage operational, financial and performance matters.\textsuperscript{201}

\begin{quote}
\textbf{About corporate governance}

In general terms, corporate governance encompasses the arrangements by which the power of those who implement the strategy and direction of an organisation is both delegated and limited to ensure the organisation’s success, taking into account the environment in which the organisation is operating …

Generally, governance arrangements for statutory authorities should strike a balance between providing flexibility to enable authorities to undertake their legislated functions and the policies of the government of the day … the ability of an authority to act independently of government is drawn by the authority’s legislative framework. The greater an organisation’s independence, the greater is the need for robust governance mechanisms as a means of ensuring that it is discharging its delegation appropriately. To the extent that independence is combined with power, that need is heightened. Given the independence of statutory authorities, this is a critical factor for the public sector. Robust governance provides assurance, not only to government, but also to the Parliament and the public, that those in the community affected by the activities of an authority are protected from the inappropriate exercise of power.

Governance should establish appropriate structures and behaviour to enhance the capacity of government and statutory authorities to achieve greater clarity in their relationship and in aligning expectations with performance. Good governance structures also establish appropriate processes to resolve any tensions which may emerge between the manner in which authorities perform their legislated functions and the policies of the Government of the day. They should also provide a mechanism for that part of the community upon which an authority has impact to have input through consultation of some kind. The benefits include greater openness in
\end{quote}

\textsuperscript{197} \textit{Administration Act}, proposed subsection 32(4), inserted by item 14 of Schedule 2 to the Bill.

\textsuperscript{198} \textit{Administration Act}, proposed subsections 32(5) and (8), inserted by item 14 of Schedule 2 to the Bill.

\textsuperscript{199} \textit{Administration Act}, proposed subsection 33(1A), inserted by item 17 of Schedule 2 to the Bill.

\textsuperscript{200} \textit{Administration Act}, proposed subsection 41A(2), inserted by item 31 of Schedule 2 to the Bill.

\textsuperscript{201} \textit{Explanatory Memorandum}, Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019, p. 2.
The APVMA has extensive functions including providing information to the Governments and authorities of the Commonwealth, the States and the participating Territories about approved active constituents for proposed or existing chemical products, registered chemical products, reserved chemical products and approved labels for containers for chemical products and to co-operate with those Governments and authorities on matters relating to the management and control of chemical products.\(^{203}\)

Given the amount of legislative change in relation to agvet chemicals over the last six years, and the criticisms of the effectiveness of those changes, it is appropriate that a Board is established to ensure the proper, efficient and effective performance of the APVMA. The rationale for creating a Board is as valid today as it was when the House of Representatives Standing Committee on Agriculture and Water Resources made its recommendation in May 2018.\(^{204}\)

The Bill imposes a high level of scrutiny by the Minister and the Secretary on the activities of the Board. On the one hand this may give the appearance of undermining the independence of the Board. However, this needs to be balanced against the need to ensure that the APVMA is operating optimally and that the Minister is fully informed if it is not.

On 5 September 2019 Minister for Agriculture, Senator McKenzie, announced that there would be a review of ‘every facet of agricultural and veterinary chemical regulation’ stating:

> The independent review will tell us a lot about how we can modernise our agricultural and veterinary chemical regulatory framework—and how we can safely improve farmer and community access to agvet chemical products.\(^{205}\)

It would be prudent to have the proposed Board in place to assist in providing information to that review.

**Concluding comments**

The Bill contains most of the measures included in two previous Bills—the Operational Efficiency Bill) and the Streamlining Bill. The measures mostly have been widely welcomed by stakeholders.

The Bill establishes the APVMA Board. However, the size of the Board and the oversight of the Board’s activities by the Government may not deliver the level of independence that some stakeholders would prefer.

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203. *Administration Act*, paragraph 7(1A)(b).


Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019

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