AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY BOARD AND OTHER IMPROVEMENTS) BILL 2019

GENERAL OUTLINE

The Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019 (the Bill) will amend the Agricultural and Veterinary Chemicals (Administration) Act 1992 (the Administration Act), the Agricultural and Veterinary Chemicals Code Act 1994 (the Code Act) and the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994 (the Levy Act). The Bill will also repeal the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014 (the Removing Re-approval and Re-registration Act).

The Bill will improve the effectiveness and efficiency of the national system for regulating agricultural and veterinary (agvet) chemical products. The Bill will:

- provide the Australian Pesticides and Veterinary Medicines Authority (APVMA) and industry with more flexibility to deal with certain types of new information provided when the APVMA is considering an application
- enable the use of new, simpler regulatory processes for chemicals of low regulatory concern, to simplify the approval of active constituents and labels, and the registration of certain products
- provide for extensions to limitation periods and protection periods as an incentive for chemical companies to register certain new uses of chemical products—particularly those uses (minor uses) with insufficient commercial return for chemical companies to normally add to the product label
- reduce the regulatory burden on industry by simplifying reporting requirements for annual returns
- support computerised decision-making by the APVMA
- reduce the administrative burden on the APVMA and industry by increasing the flexibility of the APVMA to manage errors in an application at the preliminary assessment stage
- reduce the regulatory burden by enabling the APVMA to grant part of a variation application under section 27 of the Schedule to the Code Act
- enable a person to apply to vary an approval or registration that is suspended, to the extent that the variation relates to the grounds for suspension
- establish civil pecuniary penalties for contraventions of provisions in the Agvet Code and the Administration Act relating to providing false or misleading information to the APVMA
- provide the APVMA with more comprehensive grounds for suspending or cancelling approvals or registrations where information is provided in a variation application that is false or misleading
- optimise risk communication about chemical products by improving the transparency of voluntary recalls
- harmonise the need to inform the APVMA of new information (where it relates to the safety criteria) so that the same obligations apply to all holders and applicants
- simplify the APVMA’s corporate reporting requirements
- provide a more practical mechanism for dealing with minor variations in the constituents in a product, that normally occur in the manufacturing process
- clarify what information must be included on a label
- fix anomalies in the regulation-making powers for the labelling criteria
- amend the notification requirements in section 8E of the Agvet Code so that the APVMA and Food Standards Australia New Zealand (FSANZ) will have the flexibility to agree on appropriate timeframes for notifications and amend section 7A of the Administration Act to clarify the authority to make an APVMA legislative instrument for residues of chemical products in protected commodities
- amend the definition of expiry date in the Agvet Code to mean the date after which a chemical product 'must not' be used
- make minor and machinery changes including removal of unnecessary and redundant provisions and other changes to realise operational efficiencies, reduce unnecessary regulation and clarify ambiguities.

The Bill will also establish a governance Board for the APVMA and cease the existing APVMA Advisory Board. Establishing an APVMA Board will strengthen the APVMA’s governance arrangements and provide the necessary oversight to help the regulator manage operational, financial and performance matters. The Board will replace the Chief Executive Officer (CEO) as the accountable authority under the Public Governance, Performance and Accountability Act 2013 (PGPA Act), and will set the APVMA’s strategic direction, drive its operational performance, set an appropriate risk management framework and ensure greater accountability.

**National Registration Scheme**

Agvet chemicals are regulated through a cooperative National Registration Scheme. The scheme is a partnership between the Commonwealth and the states and territories with an agreed division of responsibilities. Assessment and registration of agvet chemicals, as well as control of supply activities (for example, retail sale) is undertaken by the APVMA. Regulating the control of agvet chemical use after supply is the responsibility of individual states and territories.

The National Registration Scheme is implemented, in part, through the Code Act. The Code Act contains, as a schedule, the Agricultural and Veterinary Chemicals Code (the Agvet Code). The Agvet Code operates in each state, the Northern Territory and each participating territory (the Australian Capital Territory and Norfolk Island) to constitute a single national Agvet Code applying throughout Australia.

The Administration Act, Levy Act and the Code Act, including the Agvet Code and any regulations or legislative instruments made under these laws, are collectively described as agvet legislation.
Consultation

The Bill comprises measures from two Bills that lapsed in April 2019—the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 (Operational Efficiency Bill)—including a government amendment—and the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (Streamlining Bill).

An exposure draft of the Operational Efficiency Bill was released for public consultation in June 2017. An exposure draft of the Streamlining Bill was released for public consultation in July 2018. Consultation on both lapsed Bills was also undertaken with relevant state and territory authorities and Commonwealth agencies and both were amended following consultation. The measures in the government amendment to the Operational Efficiency Bill were developed through a process of detailed targeted consultation with agvet chemical industry stakeholders from November 2017 to July 2018.

FINANCIAL IMPACT STATEMENT

The Bill will have no financial impact on the Australian Government Budget.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

This Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act 2011.

The full statement of compatibility with human rights is attached to this explanatory memorandum.
**ACRONYMS, ABBREVIATIONS AND COMMONLY USED TERMS**

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<thead>
<tr>
<th>Acronym or Term</th>
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<tr>
<td>AAT</td>
<td>Administrative Appeals Tribunal</td>
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<td>Administration Act</td>
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<td>Administration Regulations</td>
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<td>agvet</td>
<td>agricultural and veterinary</td>
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<td>Agvet Code (the Code)</td>
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<td>APVMA</td>
<td>Australian Pesticides and Veterinary Medicines Authority</td>
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<td>ARC</td>
<td>Administrative Review Council</td>
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<td>CEO</td>
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<td>Code Act</td>
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<td>FSANZ</td>
<td>Food Standards Australia New Zealand</td>
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<td>Guide to Framing Commonwealth Offences</td>
<td>the Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers published by the Attorney-General’s Department</td>
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<td>ICCPR</td>
<td>the International Covenant on Civil and Political Rights</td>
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<td>interested person</td>
<td>defined by subsection 3(1) of the Levy Act to mean, in relation to a registered chemical product: (a) subject to paragraphs (b), (c) and (d), 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, as the case may be, of the registration; or</td>
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(b) subject to paragraphs (c) and (d), if the original applicant has entered into a contract with another person in relation to the chemical product under which, or as a result of which, 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 chemical product, or to have a label approved in relation to containers for the chemical product, and the other person’s name is entered in those relevant particulars, or such a label is approved, on the application of the other person—the other person; or

(c) if the person who, apart from this paragraph, would be the interested person because of paragraph (a) or (b), was an individual who has died or is an individual whose affairs are being lawfully administered by another person—the legal representative of the individual or the person administering his or her affairs, as the case may be; or

if the person who, apart from this paragraph, would be the interested person because of paragraph (a) or (b), was a body corporate—a successor in law of that body corporate.

leviable disposal defined by subsection 3(1) of the Levy Act to mean:

(a) if the product is an Australian product:
   (i) if the product is disposed of in Australia by the manufacturer—that disposal of the product; or
   (ii) if the product is applied by the manufacturer to the manufacturer’s own use—that application of the product; or

(b) if the product is an imported product:
   (i) if the product is disposed of in Australia by the importer—that disposal of the product; or
   (ii) if the product is applied by the importer to the importer’s own use—that application of the product.

Levy Act Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994

MRL maximum residue limit

the minister the minister administering the Agricultural and Veterinary Chemicals (Administration) Act 1992

Operational Efficiency Bill Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017
Privacy Act 1988

the record

Record of Approved Active Constituents for Chemical Products kept under section 17 of the Agvet Code

Record of permits

the record of permits kept under section 113 of the Agvet Code

the register

Register of Agricultural and Veterinary Chemical Products kept under section 18 of the Agvet Code

Relevant APVMA file

the file in which information about approved labels is recorded as mentioned in paragraph 21(c) of the Agvet Code.

Removing Re-approval and Re-registration Act

Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014

the Secretary

the Secretary of the Department administered by the Minister administering the Agricultural and Veterinary Chemicals (Administration) Act 1992

Streamlining Bill

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

Therapeutic Goods Act

Therapeutic Goods Act 1989
NOTES ON CLAUSES

Preliminary

Clause 1 Short Title
Clause 1 provides for the short title of the Act to be the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2019.

Clause 2 Commencement
Clause 2 provides for the commencement of each provision in the Bill, as set out in the table. The Bill provides for a staged introduction of measures. This will allow relevant subordinate laws to be developed and allow industry to be informed of new obligations. This approach will also allow the APVMA sufficient time to appropriately and incrementally implement necessary changes to policies, procedures and training protocols as a result of the amendments, while minimising any impact on its regulatory role.

Subclause 2(1) provides that each provision of the Bill specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Item 1 in the table provides that sections 1, 2 and 3, which concern the formal aspects of the Bill, as well as anything in the Bill not elsewhere covered by the table, will commence on the day on which the Bill receives the Royal Assent.

Item 2 in the table provides that Parts 1 and 2 of Schedule 1 to the Bill will commence on the day after the end of the period of six months beginning on the day the Bill receives the Royal Assent. Part 1 deals with giving industry and the APVMA more flexibility to deal with certain types of information provided during an application assessment. Part 2 deals with simplified processes for the approval of certain active constituents and labels and the registration of certain chemical products. Deferring commencement for six months is necessary to allow the associated regulations and other legislative instruments to be developed for these measures, including consultation on these instruments.

Item 3 in the table provides that Part 3 of Schedule 1 to the Bill (which deals with extending protection and limitation periods) will commence on a day to be fixed by Proclamation or three months after the Bill receives the Royal Assent (whichever is the earlier). This is necessary to allow the government to develop associated regulations and provide the APVMA with sufficient time to appropriately implement necessary changes to policies, procedures and training protocols as a result of implementing extended data protection.

Item 4 in the table provides that Part 4 of Schedule 1 to the Bill (which deals with annual returns and record-keeping) will commence on the day after the Bill receives the Royal Assent.

Item 5 in the table provides that Part 5 of Schedule 1 to the Bill (which deals with computerised decision-making) will commence on a day to be fixed by Proclamation or six months after the Bill receives the Royal Assent (whichever is the earlier). Deferring commencement is necessary to provide the APVMA with sufficient time to appropriately implement necessary changes to its systems, policies, procedures and training protocols as a result of implementing computerised decision-making.
Item 6 in the table provides that Part 6 of Schedule 1 to the Bill (which deals with preliminary assessments) will commence on the day after the end of the period of 12 months beginning on the day the Bill receives the Royal Assent. Deferring commencement for 12 months for Part 6 of Schedule 1 to the Bill is necessary to provide the APVMA with sufficient time to appropriately implement necessary changes to policies, procedures and training protocols as a result of amendments to preliminary assessment.

Item 7 in the table provides the Parts 7 to 12 of Schedule 1 to the Bill will commence on the day after the end of the period of three months beginning on the day the Bill receives the Royal Assent. Parts 7 to 12 of Schedule 1 to the Bill deal with:

- variation of relevant particulars and conditions
- variation of approval or registration during suspension
- false and misleading information
- suspension or cancellation of approval or registration for provision of false or misleading information
- voluntary recalls
- notification of new information.

Deferring commencement of these Parts is necessary to provide the APVMA with sufficient time to appropriately implement necessary changes to policies, procedures and training protocols as a result of these amendments.

Item 8 in the table provides that Part 13 of Schedule 1 to the Bill (removing annual operational plans) will commence on the first 1 January to occur after the day the Bill received the Royal Assent as this is the most practical day on which these measures can commence.

Item 9 in table provides that Parts 14 to 20 of Schedule 1 to the Bill will commence on the day after the Bill receives the Royal Assent. Parts 14 to 20 of Schedule 1 to the Bill deal with:

- the definition of registered chemical product
- supply of registered chemical products with unapproved label
- the safety, efficacy, trade and labelling criteria
- the maximum residue limits standard
- expiry dates
- other amendments
- repeals.

Item 10 in the table provides that Schedule 2 to the Bill will commence on the earlier of:

- a single day to be fixed by proclamation
- the day after the end of the period of 12 months beginning on the day the Bill receives the Royal Assent.

Schedule 2 to the Bill deals with the main amendments of the Bill to establish a governance Board for the APVMA and cease the existing APVMA Advisory Board. Deferring
commencement for 12 months is necessary to allow time for a robust recruitment process for members of the Board. This approach will also allow the APVMA sufficient time to appropriately and incrementally implement necessary changes to policies, procedures and training protocols as a result of the amendments, while minimising any impact on its regulatory functions.

Subclause 2(2) provides that any information in column 3 of the table is not part of the Bill. Information may be inserted in column 3 of the table, or information in it may be edited, in any published version of the Bill.

**Clause 3 Schedules**
Clause 3 provides that legislation that is specified in a Schedule to the Bill is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Bill has effect according to its terms. This is a technical provision to give operational effect to the amendments contained in the Schedules.
Schedule 1—Main improvements

PART 1—INFORMATION TO BE TAKEN INTO ACCOUNT IN DETERMINING APPLICATIONS

Overview

Part 1 of Schedule 1 to the Bill amends the Agvet Code to provide the APVMA and industry with more flexibility to deal with certain types of information given while the APVMA is determining an application. The kinds of information would be prescribed in the regulations.

Under section 8C of the Agvet Code, the APVMA is restricted from considering new information provided by, or on behalf of, the applicant during the assessment period for the application. Despite section 8C the APVMA may, at its discretion, issue a notice to an applicant under section 159 of the Agvet Code seeking additional clarifying information. The first such notice compulsorily triggers a one-off extension to the statutory time period in which the application must be assessed. This extension is typically equivalent to one third of the statutory assessment period for the original application (rounded up to the nearest whole month) plus an additional month. While the fixed extension period is intended to provide certainty to the applicant about when the application will be determined, this period may be excessive for requests for simple clarifying information (related to information that has already been provided in the original submission). The only alternative for an applicant to provide such information is to do so in a variation application made after the active constituent or label has been approved or the product has been registered. This can create inefficiencies for the APVMA and the applicant (adding costs, time and administrative burden).

Agricultural and Veterinary Chemicals Code Act 1994

Item 1 Subsection 8C(2) of the Code set out in the Schedule

Item 1 amends section 8C of the Agvet Code to provide that the operation of subsection 8C(2) is subject to new subsection 8C(2A) of the Agvet Code. Subsection 8C(2) currently prevents the APVMA from considering information provided by, or on behalf of, the applicant during the assessment period for an application. The amendment provides for the APVMA to be able to consider the kinds of information that would be prescribed in regulations for new subsection 8C(2A) (inserted by item 2) during the assessment period for an application.

Item 2 After subsection 8C(2) of the Code set out in the Schedule

Item 2 inserts new subsection 8C(2A) that allows the regulations to prescribe certain kinds of information (in certain circumstances) that the APVMA may consider during the assessment period for an application (for example, providing an updated good manufacturing practice certificate), removing the need for:

- a notice under section 159 of the Agvet Code, with the associated extension of the assessment period; or
- a variation application.

Item 3 Application provision

Item 3 provides that the amendments to section 8C made by Part 1 of Schedule 1 to the Bill will apply in relation to an application lodged on or after the commencement of this Part and
will also apply in relation to applications lodged before the commencement of this Part if those applications have not been determined by the APVMA before commencement.

Part 1 of Schedule 1 to the Bill will commence on the day after the end of the period of six months beginning on the day the Bill receives the Royal Assent.
PART 2—APPROVAL AND REGISTRATION FOR PRESCRIBED ACTIVE CONSTITUENTS, CHEMICAL PRODUCTS OR LABELS

Overview

Part 2 of Schedule 1 to the Bill amends the Agvet Code to provide the APVMA with greater flexibility to manage applications and to align regulatory effort with risk, similar to the APVMA’s existing streamlined options for prescribed variations to approvals or registrations. This will be achieved by providing for both:

- prescribed approvals of active constituents and labels
- prescribed registrations of chemical products.

Division 2A (prescribed variations of relevant particulars) of Part 2 of the Agvet Code provides for streamlined variations to the relevant particulars of approvals and registrations. These processes provide for variations with reduced information requirements and lighter-touch ‘assessments’ (for example there will be no requirement for a preliminary assessment), where the risks associated with a variation warrant such an approach. This reduces the time and effort for industry to make—and for the APVMA to deal with—these particular variations. The types of variations to approvals and registrations that can be made as prescribed variations are set out in a legislative instrument made by the APVMA.

The Agvet Code also provides for a person to apply for a new registration of a chemical product, or an approval of an active constituent or label for containers for a chemical product (section 10). However, there are currently no means to provide for approvals and registrations to be made by the APVMA through a simplified model, similar to prescribed variations.

The proposed amendments will enable both the Code Regulations and a disallowable legislative instrument made by the APVMA to specify kinds of approvals and registrations that the APVMA can determine as either prescribed approvals or prescribed registrations. This change will introduce a system change to enable the use of new, simpler regulation processes for these approvals and registrations where minimal or no assessment of technical information occurs. These changes would better align regulatory effort with risk and therefore improve access to safe and effective chemical products by reducing some of the red tape and reducing some of the costs associated with approval and registration.

The proposed amendments will be similar to the existing provisions for prescribed variations to approvals and registrations (including no requirement for a preliminary assessment), with safeguards to ensure that only safe and effective products continue to be available.

Agricultural and Veterinary Chemicals Code Act 1994

Item 4 Section 3 of the Code set out in the Schedule
Item 4 inserts provisions into section 3 of the Agvet Code for new definitions for ‘prescribed active constituent’, ‘prescribed chemical product’ and ‘prescribed label for containers for a chemical product’. These provisions are necessary to ensure that readers of the Agvet Code can easily locate these definitions.

Items 5 and 6 Section 9A of the Code set out in the Schedule
Item 5 inserts a new heading in the Agvet Code for the explanation of subdivision A of Division 2 of Part 2 of the Agvet Code. Subdivision A is an explanation of the approval of
active constituents and labels and registration of chemical products, including applications for approval and registration.

Item 6 repeals the existing subsections 9A(2) to (5) and inserts new subsections 9A(2) to (5B) and new headings. Section 9A explains the provisions in Division 2 of Part 2 of the Agvet Code that include existing sections 10, 11, 12, 13 and 14 of the Agvet Code and new sections 14C, 14D and 14E (which relate to prescribed active constituents and chemical products). These sections specify how persons apply for approval and registration (an application can be made under section 10 or 14C, 14D or 14E) and how the APVMA deals with these applications.

**Item 7 After section 9A of the Code set out in the Schedule**

Item 7 inserts a new heading in the Agvet Code to identify subdivision B of Division 2 of Part 2 of the Agvet Code. Subdivision B includes the current provisions that provide for the approval of active constituents and labels and registration of chemical products, including applications for approval and registration (sections 10 to 14B of the Agvet Code).

**Item 8 After section 14B of the Code set out in the Schedule**

Item 8 inserts a new subdivision C into Division 2 of Part 2 of the Agvet Code and a new subdivision D heading into Division 2 of Part 2 of the Agvet Code. Subdivision C includes the provisions that provide for the approval of prescribed active constituents and labels and the registration of prescribed chemical products (new sections 14C, 14D and 14E of the Agvet Code). This provides for a streamlined means of approving active constituents and labels and registering chemical products.

As a consequence of inserting new subdivision headings into Division 2 of Part 2 of the Agvet Code (items 5 to 8), item 8 also inserts a new subdivision D heading. This clarifies that the remaining sections of Division 2 of Part 2 of the Agvet Code (that is, sections 15 to 26) are common provisions.

**Applications for prescribed approvals and registrations**

New sections 14C, 14D and 14E provide for a person to apply for the approval of a prescribed active constituent, registration of a prescribed chemical product or approval of a prescribed label. These prescribed approvals and registrations represent a new approval or registration process that will be quicker and less costly than the current approval or registration process.

This prescribed approval or registration would only apply for an approval or registration that is of a kind determined by the APVMA in a disallowable legislative instrument or prescribed in the regulations (see paragraph 14C(4)(b), subsection 14D(4) and paragraph 14E(4)(b)). Each prescribed chemical product that is registered requires a label approval and therefore subsection 14E(7) also specifically provides that prescribed labels for containers for chemical products may be described by reference to a kind of chemical product.

The kinds of active constituents and chemical products subject to prescribed approvals and registrations are anticipated to be those that have sufficiently low associated regulatory risk as to warrant reduced supporting information requirements. Examples may include certain:

- applications involving well-characterised chemistry or existing active constituents described in pharmacopoeial monographs and standards
• consumer products with a history of safe use.

For these active constituents and chemical products, it is conceivable that no technical information may be required and, as such, this mechanism could support the introduction of a means of self-approval or self-registration (subject to the safeguard of the APVMA making a positive decision in relation to the application), where appropriate. This new process closely mirrors the existing process for prescribed variations—including there being no requirement for a preliminary assessment—where approvals and registrations are varied through a simplified process.

To ensure that active constituents, chemical products and labels continue to comply with the safety, efficacy, trade and labelling criteria, the APVMA can only include a kind of prescribed approval or registration in its legislative instrument if it is satisfied that:

• the prescribed active constituent would meet the safety criteria (subsection 14C(5))
• the prescribed chemical product would meet the safety, efficacy and trade criteria or comply with the established standard (subsection 14D(5))
• the prescribed label for the containers for the chemical product would meet the labelling criteria or comply with the established standard (subsection 14E(5)).

The application for a prescribed approval or registration would need to meet the application requirements (subsections 14C(2), 14D(2) and 14E(2)). If the application does not meet the application requirements then the APVMA would be required to notify the applicant of the reasons why before it refuses the application (current section 8S).

The APVMA may alter the application with the written consent of the applicant (subsections 14C(3), 14D(3) and 14E(3)). This provides a means for the APVMA to efficiently deal with simple discrepancies in an application. For this reason (and to reflect the existing provisions for prescribed variations) a preliminary assessment of applications for prescribed approvals or registrations is not required.

The APVMA may also, by legislative instrument, set out disqualifying criteria that apply to the applicant for prescribed approvals and registrations (subsections 14C(9), 14D(9) and 14E(10)). These 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 as is currently the case.

As required by new subsections 14C(7), 14D(7) and 14E(8) the APVMA must approve the active constituent, register the chemical product or approve the label for containers of a chemical product that is the subject of the application if it is satisfied that:

• the application meets the application requirements
• the active constituent is a prescribed active constituent (subsection 14C(7)), the chemical product is a prescribed chemical product (subsection 14D(7)), or the label is a prescribed label for containers of a chemical product (subsection 14E(8)); and
• none of the disqualifying criteria apply in relation to the applicant.
If the APVMA is not satisfied that these criteria are met then the APVMA must refuse the application (subsections 14C(8), 14D(8) and 14E(9)), subject to a notice of proposed refusal issued under existing section 8S of the Agvet Code.

The decision about the application must be made within the period prescribed in the regulations. If the decision is not made within this period, the applicant has the opportunity to have the application deemed to be refused and considered by the Administrative Appeals Tribunal (AAT). This process is the same process that currently applies for other applications not dealt with by the APVMA within the application timeframe (see section 165 of the Agvet Code).

**Item 9**  
**Paragraphs 17(3)(a) and (b) of the Code set out in the Schedule**  
Item 9 inserts the reference to new section 14C in paragraphs 17(3)(a) and (b) of the Agvet Code. This ensures that the relevant details for an active constituent approved under section 14C (a prescribed active constituent) are recorded in the Record of Approved Active Constituents for Chemical Products (the record). This requirement is the same as the existing requirements for active constituents approved under section 14 of the Agvet Code.

**Items 10 and 11**  
**Section 34G of the Code set out in the Schedule**  
Items 10 and 11 insert new subsection 34G(1AA), and a reference to subsection 34G(1AA) in subsection 34G(1B) of the Agvet Code. These amendments ensure that information that is subject to a limitation period (under Division 4A of Part 2 of the Agvet Code) cannot be used by the APVMA when determining an application made under section 14C, 14D or 14E. This reflects the restriction that currently applies to other applications for approval or registration. This limitation on use applies to information given to the APVMA in an application made under sections 10 or 27 or information provided as required by section 161 of the Agvet Code (for example, the results of field trials or laboratory experiments).

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.

**Item 12**  
**Subparagraph 166(1A)(b)(i) of the Code set out in the Schedule**  
Item 12 inserts references to new subsections 14C(8), 14D(8) and 14E(9) in subparagraph 166(1A)(b)(i) of the Agvet Code. This provides for persons to apply for an internal review of a decision by the APVMA to refuse an application for approval of either a prescribed active constituent or prescribed labels for containers for chemical products or for registration of a prescribed chemical product.

This mirrors the internal review available for the existing processes for approvals and registrations when an application is refused by the APVMA for not meeting the application requirements set out in paragraphs 8A(a) and (b) of the Agvet Code.

**Item 13**  
**Paragraph 167(1)(a) of the Code set out in the Schedule**  
Item 13 inserts references to new paragraphs 14C(7), 14D(7) and 14E(8) in paragraph 167(1)(a) of the Agvet Code. This provides for review by the AAT of a decision to approve a prescribed active constituent or prescribed labels for containers for chemical products or to register a prescribed chemical product. This mirrors the AAT review available for the existing processes for approvals and registrations where that approval or registration is
made with an instruction or relevant particular other than that set out in the application, or where the approval or registration is subject to particular conditions.

**Item 14  Paragraph 167(1)(b) of the Code set out in the Schedule**

Item 14 inserts references to new paragraphs 14C(8), 14D(8) and 14E(9) in paragraph 167(1)(b) of the Agvet Code. This provides for review by the AAT of a decision by the APVMA to refuse an application for approval of either a prescribed active constituent or prescribed labels for containers for chemical products or for registration of a prescribed chemical product.

However, a review by the AAT is not available when a decision to refuse was based only on not meeting the application requirements set out in paragraphs 8A(a) and (b) of the Agvet Code (such decisions are limited to internal review; see item 12).

These grounds for AAT review mirror that available for the existing processes for approvals and registrations.
PART 3—LIMITS ON USE OF INFORMATION

Overview

An innovator funds the production of information (such as through field trials or laboratory experiments) to support a new active constituent (or improved characteristics for an existing active constituent) or a new use of a chemical product. Restricting the use of this information prevents competitors from using innovators’ data or allows innovators to seek compensation from the competitors for use of the innovators’ information. This benefits the innovator, who has incurred the cost of generating this information, and promotes innovation.

Part 3 of Schedule 1 to the Bill amends the Agvet Code to provide incentives for the chemicals industry to seek approval of certain kinds of active constituents with new, desirable features (such as new modes of action to manage resistance) or to register certain uses (priority uses) of chemical products. This involves extending 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 Agvet Code provides for two kinds of data restriction:

- ‘Protected information’ is certain kinds of information (that relate to either an active constituent that has been approved or a chemical product that has been registered) provided in response to a request from the APVMA as part of a reconsideration (sometimes referred to as a chemical review). It also includes certain information provided under section 159 of the Agvet Code to assist the APVMA in deciding whether to suspend or cancel an approval or registration. A protection period of eight years applies to this information (when provided in relation to a reconsideration), commencing from the time the APVMA makes its decision on the reconsideration. During the protection period, the APVMA must not use the information to assess or make a decision on a reconsideration of another chemical product or active constituent, or on an application for a product or active, unless an exception applies (for example, the authorising party has provided consent for the information to be used).

- ‘Limits on use of information’ (Division 4A of Part 2) relates to information provided to the APVMA as part of an application made under sections 10 or 27 of the Agvet Code or as relevant information under section 161 of the Agvet Code. If the information is relied on by the APVMA in making a decision, it receives a ‘limitation period’. The limitation periods for this information are set out in section 34M of the Agvet Code and range from three years to a maximum of 10 years depending on the application. During the limitation period, the APVMA must not use the information to assess or make a decision on another application or on a reconsideration unless an exception applies (for example, the authorising party has provided consent for the information to be used).

The period during which any information (whether protected or with limits on use) cannot be used is often referred to as a ‘data restriction period’.

The APVMA’s existing data restriction period is insufficient for some new active constituents or product uses to be brought to market. This is especially true for those active constituents and uses (minor uses) that are not expected to produce sufficient economic return to offset the cost of approval or registration (including costs associated with data generation). Some active constituents or uses that are unlikely to be introduced into Australia in a timely fashion under the existing market dynamics may be particularly important to Australia and
could include those needed to support agricultural productivity or to control weeds and pests of national significance. The amendments in Part 3 of the Bill help overcome this barrier.

Encouraging the inclusion of more priority uses on product labels is also anticipated to reduce the regulatory burden on product users who may otherwise need to seek permits under Part 7 of the Agvet Code.

The requirements for extending these periods will include technical detail. For this reason, Part 3 of the Bill also provides (through amendments to the Agvet Code) that the regulations will specify most of the details for extending limitation and protection periods. Consistent with international practice the main application of these measures will be for information for agricultural chemical products and it is anticipated that regulations for these products will be the priority.

**Agricultural and Veterinary Chemicals Code Act 1994**

**Items 15 and 18**  
Section 3 of the Code set out in the Schedule  
Items 15 and 18 are consequential amendments to the definitions of ‘limitation period’ and ‘protection period’ in section 3 of the Agvet Code. The amendments insert notes after these definitions to reflect the insertion of new sections 34MA and 34KA (in, respectively, amending items 22 and 25).

**Items 16 and 17**  
Section 3 of the Code set out in the Schedule  
Items 16 and 17 are consequential amendments to the definitions of ‘protected active constituent’ and ‘protected chemical product’ in section 3 of the Agvet Code. The amendments reflect that the protection period in these definitions would include any period that is extended as a result of an extension under new section 34KA (in amending item 22).

**Items 19 and 20**  
Section 34F of the Code set out in the Schedule  
Items 19 and 20 are consequential amendments to section 34F of the Agvet Code. Section 34F is a section that explains the provisions in Division 4A of Part 2 of the Agvet Code (which deals with information with limits on its use). The amendments update section 34F so that it reflects the insertion of new sections 34KA and 34MA (in, respectively, amending items 22 and 25).

**Item 21**  
Subsection 34J(5A) of the Code set out in the Schedule  
Item 21 repeals and substitutes subsection 34J(5A) of the Agvet Code. Section 34J of the Agvet Code deals with conditions where the APVMA may use information to determine an application where there is either protected information or information with limits on its use. The amendment is a consequential amendment to subsection 34J(5A) so that it reflects where a protection period is extended under new section 34KA (in amending item 22).

**Item 22**  
After section 34K of the Code set out in the Schedule  
Item 22 inserts new section 34KA into the Agvet Code. Protected information is certain kinds of information (that relate to either an active constituent that has been approved or a chemical product that has been registered) provided in response to a request from the APVMA as part of a reconsideration or to assist the APVMA in deciding whether to suspend or cancel an approval or registration. A protection period of eight years applies to this information (when provided in relation to a reconsideration), commencing from the time the APVMA makes its decision on the reconsideration.
Section 34KA provides for the regulations to extend the protection period for protected information (and end such an extension), as a result of a prescribed application that is made to the APVMA. For example, an application to:

- approve an active constituent that is of a kind prescribed in the regulations
- register, or vary a registration of, a chemical product for a kind of use that is prescribed in the regulations.

If there are multiple kinds of information that are protected information then it is anticipated that the protection period for each of these kinds of information can be extended if the information is eligible for extension.

Section 34KA includes restrictions on when the protection period can be extended and how long this period can be extended:

- New subsections 34KA(2) and (3) provide that an application for an extension of a protection period is not required. Instead, 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. This approach mirrors similar practices used in other countries.

- New subsection 34KA(4) provides that a protection period can only be extended for a maximum of five years. This extension is consistent with the approach used in other countries and provides a balance between providing incentives to innovators through increased periods of data restriction, while allowing competitors to access protected information at a suitable time.

**Items 23 and 24  Subsection 34M(1) of the Code set out in the Schedule**

Items 23 and 24 are consequential amendments to subsection 34M(1) of the Agvet Code to reflect the insertion of new section 34MA in amending item 25.

**Item 25  At the end of Division 4A of Part 2 of the Code set out in the Schedule**

Item 25 inserts new section 34MA into the Agvet Code. Section 34MA mirrors new section 34KA but applies extensions to information subject to a limitation period (and ending such an extension).

Information has limits on its use if it is information provided as part of certain applications (set out in the table to subsection 34M(1)) and the APVMA relies on the information to approve an active constituent or label, register a product or vary an approval or registration. The limitation periods that apply to this information depend upon the nature of the application made to the APVMA. These limitation periods commence from the time the APVMA approves an active constituent or label, registers a product or varies an approval or registration.
Section 34MA provides for the regulations to extend the limitation period for information, as a result of a prescribed application that is made to the APVMA. For example, an application to:

- approve a particular kind of active constituent that is prescribed in the regulations; or
- register, or vary a registration of, a chemical product and approve a label for a chemical product for a kind of use that is prescribed in the regulations.

If there are multiple kinds of information that are limited information, then section 34MA provides that the limitation period for each of these kinds of information can be extended if the information is eligible for extension.

Similar to new section 34KA, section 34MA provides for regulations to prescribe when limitation periods can be extended and for how long. Specifically, section 34MA provides:

- for restrictions on when the limitation period can be extended and for how long
- that an application for an extension of a limitation period is not required—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
- that the application must be lodged while there is at least three years of the existing limitation period remaining
- that a limitation period can only be extended for a maximum of five years.

**Item 26 Paragraph 59(2)(c) of the Code set out in the Schedule**

Item 26 is a consequential amendment to paragraph 59(2)(c) of the Agvet Code to reflect that the protection period for information can be extended. Section 59 of the Agvet Code deals with when the APVMA must not use protected information and it is appropriate that this reflects the extension under new section 34KA.

**Item 27 Application provisions**

Item 27 provides that new sections 34KA and 34MA of the Agvet Code apply in relation to a protection period or limitation period that begins before, on or after the Part commences and means that currently protected or limited information is eligible for extension.

Part 3 of Schedule 1 to the Bill will commence on the earlier of either three months after the Bill receives the Royal Assent or by Proclamation.
PART 4—ANNUAL RETURNS AND RECORD-KEEPING

Overview

Part 4 of Schedule 1 to the Bill amends the Levy Act and the Administration Act to simplify reporting requirements for annual returns, by restricting mandatory reporting to total chemical product quantities supplied for the previous financial year. The proposed amendments reduce the regulatory burden on industry for reporting requirements, while ensuring sufficient data is provided to the Australian Government to assist with functions such as policy development and meeting international reporting requirements.

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994

Item 28 Subsection 3(1)
Item 28 amends subsection 3(1) of the Levy Act to insert a definition of active constituent to provide that the term has the same meaning as it does in the Agvet Code. The insertion of a definition of active constituent in subsection 3(1) of the Levy Act is necessary to complement the insertion of a new section 35 of the Levy Act by item 29.

Item 29 After section 34
Item 29 inserts a new section 35 after section 34 of the Levy Act. The new section 35 of the Levy Act requires interested persons (defined by subsection 3(1) of the Levy Act) with a levy liability to provide annual returns to the APVMA about the total quantity of chemical products covered by leviable disposals during a financial year. The term leviable disposal, in relation to a chemical product, is defined by subsection 3(1) of the Levy Act.

The new section 35 of the Levy Act will provide for a more simplified annual return reporting system than current section 69E of the Administration Act, which is repealed by item 32 below. New section 35 establishes an annual return reporting system based on the leviable disposals of chemical products. Section 69E of the Administration Act currently provides for annual returns that must be given to the APVMA by persons who import, manufacture, or export active constituents for proposed or existing chemical products or in chemical products.

New subsection 35(1) of the Levy Act provides that an interested person in relation to a chemical product who is liable to pay a levy in respect of leviable disposals of that product that took place anywhere in Australia at any time during a financial year, must give to the APVMA, before 30 November in the next financial year, a return setting out the total quantity of the chemical product covered by those leviable disposals. Reporting on chemical product quantities will provide the APVMA with information necessary to perform its functions and powers, and is much less complex and burdensome for industry than the current annual returns required under section 69E of the Administration Act. The new simplified reporting requirements will also reduce the returns to one single element instead of the possible six annual return elements that are currently required.

New subsection 35(1) of the Levy Act also aligns the annual reporting of quantities of active constituents with existing reporting on the financial value of leviable disposals of chemical products.

New subsection 35(1) of the Levy Act ensures that the APVMA can continue to collect information about agvet chemicals in the marketplace. This information is used by the Australian Government for policy development and to meet international reporting requirements.
requirements under international conventions and arrangements. For example, the data collected will provide the government with information as to the amount of active constituent that is supplied in Australia, and will allow the government to determine the effect of any restrictions or conditions that other countries may propose on agvet chemicals. The data will also provide the APVMA with information necessary to perform its functions and powers.

*Note at the end of the new subsection 35(1) of the Levy Act.*

Item 29 also inserts a note at the end of the new subsection 35(1) of the Levy Act. See Item 30 which inserts new sections 37A and 37B that address the constitutional basis of sections 35 and 37.

*Status of information provided*

New subsection 35(1) will require the interested person to provide the quantity of chemical products disposed of during a financial year, in addition to the existing requirement to report the financial value of this quantity of chemical products. The new requirement to provide the APVMA with information on the quantity of chemical products may mean that interested persons need to provide personal information to the APVMA. However, this information will be no different to that already collected for the leviable disposal financial value. For this reason, the new annual return reporting requirement will not result in the collection of any new personal information. The APVMA will manage this information in the same manner as it manages personal information now.

Information on the quantity of chemical products disposed during a financial year may be commercially sensitive information. The APVMA would manage this information in the same manner as it manages the financial value of disposals during a financial year, which is of equivalent commercial sensitivity.

From the information provided to it by interested persons, the APVMA will use the information it holds about concentrations of active constituents in chemical products to prepare a statement for the department administered by the minister administering the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Department) setting out the quantities of each active constituent disposed of during the financial year. This statement will not include personal information.

*Exemptions in regulations*

The new subsection 35(2) of the Levy Act enables regulations made under that Act to exempt certain quantities of chemical products or certain chemical products from the obligation in new subsection 35(1) of that Act.

It is necessary to include new subsection 35(2) of the Levy Act because it will allow the regulations to prescribe low quantities of chemical products for which an interested person is exempt from the requirement to provide an annual return. It will also allow the regulations to prescribe a limited range of ‘low regulatory concern’ chemical products that could be exempted from the annual return reporting requirements. Information about disposals of low quantities of chemical products or chemical products of low regulatory concern is of limited value to government and therefore it may be unnecessary to require annual returns in these instances.
Strict liability offence

The new subsection 35(3) of the Levy Act provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty of 50 penalty units, if that person contravenes the new subsection 35(1) of the Levy Act. See ‘Items 29 and 30 – general matters’ below for more information on this strict liability offence.

Civil penalty provision

The new subsection 35(4) of the Levy Act provides that new subsection 35(1) of the Levy Act is also a civil penalty provision. See ‘Items 29 and 30 – general matters’ below for more information on this civil penalty provision.

Notes at the end of the new subsection 35(4) of the Levy Act.

Item 29 also inserts notes at the end of the new subsection 35(4) of the Levy Act. See ‘Items 29 and 30 – general matters’ below for more information on these notes.

APVMA statement to the Department about annual returns

New subsection 35(5) of the Levy Act provides that, from the returns given to the APVMA in relation to a financial year, the APVMA must give the Secretary of the Department, before the end of the next financial year, a statement or statements setting out the total quantities of each active constituent for each chemical product covered by those returns. This new subsection preserves the effect of current subsection 69E(3) of the Administration Act, which is repealed by item 32 below.

New subsection 35(5) of the Levy Act is necessary to ensure that the Department receives information from the APVMA that relates to total quantities of active constituents for chemical products covered by leviable disposals in a timely manner. This information assists the Department with ongoing policy development and enables it to meet international reporting requirements under international conventions and arrangements.

Item 30 After section 36

Item 30 inserts new sections 37, 37A and 37B after section 36 of the Levy Act.

New section 37

New section 37 of the Levy Act creates record-keeping requirements for those interested persons (as defined by subsection 3(1) of the Levy Act) to which new section 35 of the Levy Act will apply. New section 35 of the Levy Act is inserted by item 29 above. The obligation to keep and retain records in new subsection 37(1) of the Levy Act applies to an interested person who is liable to pay levy.

New section 37 of the Levy Act is necessary to complement new section 35 of the Levy Act (which is inserted by item 29 above), and broadly preserves the effect of current subsection 69EA(1) of the Administration Act (which included a requirement that records need to be retained for 6 years), which is amended by items 33 and 34 below.

It is appropriate that the obligation on interested persons to keep records in relation to leviable disposals of chemical products is inserted into the Levy Act, and repealed from the Administration Act. This is because it will place interested persons on notice to guard against the possibility of any contravention of the Levy Act by keeping the relevant records for the
specified period of time so the APVMA can, if necessary, verify information in annual returns provided under new subsection 35(1) of the Levy Act.

Note at the end of the new subsection 37(1) of the Levy Act

Item 30 also inserts a note at the end of the new subsection 37(1) of the Levy Act. This note refers to new sections 37A and 37B (also inserted by item 30) that address the constitutional basis of sections 35 and 37. This is discussed in more detail below.

Strict liability offence

The new subsection 37(2) of the Levy Act provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty of 50 penalty units, if that person contravenes the new subsection 37(1) of the Levy Act. See ‘Items 29 and 30 – general matters’ below for more information on this strict liability offence.

Civil penalty provision

The new subsection 37(3) of the Levy Act provides that new subsection 37(1) of the Levy Act is also a civil penalty provision. See ‘Items 29 and 30 – general matters’ below for more information on this civil penalty provision.

Notes at the end of the new subsection 37(3) of the Levy Act

Item 30 also inserts notes at the end of the new subsection 37(3) of the Levy Act. See ‘Items 29 and 30 – general matters’ below for more information on these notes.

New sections 37A and 37B

New section 37A and 37B of the Levy Act provide for the main constitutional basis of sections 35 and 37 and other constitutional bases of those provisions.

General matters for Items 29 and 30

The strict liability offences, civil penalty provisions and notes that are inserted by these amending items are similar for both items. For this reason, these general matters for both new sections have been combined and are described below.

Strict liability offence

The new subsections 35(3) and 37(2) of the Levy Act provide that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty of 50 penalty units, if that person contravenes, respectively, the new subsection 35(1) or subsection 37(1) of the Levy Act.

The applicable pecuniary penalty of 50 penalty units in new subsections 35(3) and 37(2) of the Levy Act is the maximum criminal pecuniary penalty that a relevant court could impose on an individual. The maximum criminal pecuniary penalty that a relevant court could impose on a body corporate for a contravention of new subsections 35(1) or 37(1) of the Levy Act will be 250 penalty units, due to the application of subsection 4B(3) of the Crimes Act 1914 to new subsections 35(3) and 37(2) of the Levy Act.

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.

It is necessary to prescribe the conduct in new subsections 35(1) and 37(1) of the Levy Act as an offence of strict liability. This is because it will place interested persons on notice to guard against the possibility of any contravention of the Levy Act by providing their annual returns about chemical products at the required time and to keep the relevant records for the specified time period so the information in annual returns can be verified.

Further, the proposed penalties in new subsections 35(3) and 37(2) are consistent with the current penalty in section 36 of the Levy Act and the current penalties in sections 69E and 69EA of the Administration Act. The application of strict liability in new subsections 35(3) and 37(2) of the Levy Act is appropriate because:

- a contravention of new subsections 35(1) and 37(1) of the Levy Act is not punishable by imprisonment
- the applicable penalty for the strict liability offence is 50 penalty units for an individual and 250 penalty units for a body corporate (consistent with subsection 4B(3) of the Crimes Act, where no contrary intention exists)
- the punishment of the strict liability offence prescribed by new subsections 35(3) and 37(2) of the Levy Act is likely to significantly enhance the effectiveness of the enforcement regime of the Levy Act in deterring interested persons from either not providing annual returns to the APVMA or not keeping records for the specified period of time.

**Civil penalty provision**

The new subsections 35(4) and 37(3) of the Levy Act provide that, respectively, new subsections 35(1) and 37(1) of the Levy Act are also civil penalty provisions.

Subsection 69EJA(1) of the Administration 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 conduct that is the same as the conduct constituting the contravention. Subsection 69EJA(2) of the Administration Act provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

By virtue of section 69EJA of the Administration Act, and the matters prescribed by new subsections 35(3) and 37(2) of the Levy Act (including the application of subsection 4B(3) of the Crimes Act to the new subsections), the civil pecuniary penalty for a contravention of new subsections 35(1) and 37(1) of the Levy Act will be 150 penalty units for individuals and 1250 penalty units for bodies corporate.

New subsections 35(4) and 37(3) of the Levy Act are necessary to achieve the legitimate objective of placing interested persons on notice to guard against the possibility of any contravention of the Levy Act by providing their annual returns about chemical products at the required time and keeping relevant records for the specified period of time. Subjecting the conduct in new subsections 35(1) and 37(1) of the Levy Act to a civil pecuniary penalty of 150 penalty units for individuals and 1250 penalty units for bodies corporate provides a
necessary and proportionate deterrent to non-compliance with the obligation in those new subsections. Furthermore, the proposed penalties are consistent with the penalty in current section 36 of the Levy Act and current sections 69E and 69EA of the Administration Act.

Civil penalty provisions have been introduced as one component of differentiated enforcement provisions, which give greater flexibility and more opportunity to encourage non-compliant persons to become compliant.

Notes at the end of the new subsections 35(4) and 37(3) of the Levy Act.

Items 29 and 30 also insert notes at the end of the new subsections 35(4) and 37(3) of the Levy Act.

Note 1 to the new subsections 35(4) and 37(3) of the Levy Act directs the reader to Part 7AA of the Administration Act, which provides for the monitoring and investigation powers of inspectors (as defined by section 4 of the Administration Act). This will apply to the Levy Act due to subsection 69EAB(1), sections 69EAH and 69EB and the definition of evidential material in section 4 of the Administration Act. It is appropriate that the powers and functions in Part 7AA of the Administration Act apply to the new sections 35 and 37 of the Levy Act, as that Part currently applies those powers and functions to other civil penalty provisions of the Levy Act. Note 1 to new subsections 35(4) and 37(3) of the Levy Act is merely included to assist the reader.

Note 2 to new subsections 35(4) and 37(3) of the Levy Act directs the reader to Division 1 of Part 7AB of the Administration Act, which creates a framework for the use of civil penalties to enforce the civil penalty provisions of the Administration Act and the Levy Act (see the definition of civil penalty provision in section 4 of the Administration Act). Note 2 to new subsections 35(4) and 37(3) of the Levy Act is merely included to assist the reader.

Note 3 to new subsections 35(4) and 37(3) of the Levy Act directs the reader to Divisions 2, 3 and 6 of Part 7AB of the Administration Act, which provide for matters in relation to infringement notices, enforceable undertakings and formal warnings that may be used in relation to a contravention of new subsections 35(1) and 37(1) of the Levy Act. Divisions 3 and 6 of Part 7AB of the Administration Act will apply to new subsections 35(1) and 37(1) of the Levy Act due to subsections 69EL(1) and 69EO(1) of the Administration Act.

It is appropriate that the powers and functions in Divisions 3 and 6 of Part 7AB of the Administration Act apply to new sections 35 and 37 of the Levy Act as those Divisions currently apply those powers and functions to other civil penalty provisions of the Levy Act. The references to Divisions 3 and 6 of Part 7AB of the Administration Act in note 3 to new subsections 35(4) and 37(3) of the Levy Act are merely included to assist the reader.

Division 2 of Part 7AB of the Administration Act relates to the giving of infringement notices where an inspector (as defined by section 4 of the Administration Act) has reasonable grounds to believe that a person has contravened a prescribed civil penalty provision. Section 4 of the Administration Act defines prescribed civil penalty provision to mean a civil penalty provision that is prescribed by the Administration Regulations. Regulation 3A.01 of the Administration Regulations states that, for the definition of prescribed civil penalty provision in section 4 of the Administration Act, each civil penalty provision mentioned in Schedule 5 to the Administration Regulations is prescribed. New sections 35 and 37 of the Levy Act are not mentioned in Schedule 5 to the Administration Regulations. Division 2 of Part 7AB of the Administration Act will not apply to new sections 35 and 37 of the Levy Act.
unless Schedule 5 to the Administration Regulations is amended to list new sections 35 and 37 of the Levy Act. It is intended that Schedule 5 to the Administration Regulations will be amended at a later date to list new sections 35 and 37 of the Levy Act. The reference to Division 2 of Part 7AB of the Administration Act in note 3 to new subsections 35(4) and 37(3) of the Levy Act, is merely included to assist the reader.

**Item 31 Application provisions**

Sub-item 31(1) provides that new section 35 of the Levy Act, as inserted by item 29 above, applies in relation to leviable disposals that take place in the financial year in which this item commences or in a later financial year.

Sub-item 31(2) provides that new section 37 of the Levy Act, as inserted by item 30 above, applies in relation to leviable disposals that take place on or after the commencement of Part 4 of Schedule 1 to the Bill. Part 4 of Schedule 1 to the Bill will commence on the day after the Bill receives the Royal Assent. This will ensure that there is no retrospective application of the requirement to keep records required by section 37. The records that are required to be kept for new section 37 will be similar to those currently required to be kept for section 69E of the Administration Act and sub-item 35(2) of the Bill allows the current form of records to be kept until the new record keeping requirements apply.

**Agricultural and Veterinary Chemicals (Administration) Act 1992**

**Item 32 Section 69E**

Item 32 repeals section 69E of the Administration Act, which currently provides for matters in relation to annual returns required from persons who import into, manufacture in, or export active constituents for proposed or existing chemical products or in chemical products from Australia.

It is appropriate that the obligation on interested persons to provide annual returns in relation to leviable disposals of chemical products is inserted into the Levy Act and repealed from the Administration Act, because this will give effect to the new simplified annual return reporting system. The repeal of section 69E of the Administration Act is therefore consequential to the insertion of new section 35 of the Levy Act by item 29 above.

**Item 33 Subsection 69EA(1) (heading)**

Item 33 repeals the current subheading “Records relating to compliance with sections 69B, 69C and 69E” to subsection 69EA(1) of the Administration Act, and inserts the new subheading “Records relating to compliance with sections 69B and 69C” to that subsection.

Item 33 is consequential to the amendments made by item 32 above, which repeals section 69E of the Administration Act, and removes the redundant reference to section 69E.

**Item 34 Paragraph 69EA(1)(a)**

Item 34 omits the reference to “69B, 69C and 69E” in paragraph 69EA(1)(a) of the Administration Act and substitutes that reference with a reference to “69B and 69C”.

Item 34 is consequential to the amendments made by item 32 above, which repeals section 69E of the Administration Act and removes the redundant reference to section 69E.
**Item 35 Saving provisions**

Sub-items 35(1) and 35(2) provide that, despite the repeal of section 69E and amendment to section 69EA of the Administration Act by items 33 and 34 respectively, those sections, as in force immediately before the commencement of Part 4 of Schedule 1 to the Bill, continue to apply on and after that commencement for the purposes of active constituents and chemical products that were imported, manufactured or exported in a financial year that ended before the commencement of this item.

Item 35 provides that the current annual return reporting requirements in section 69E of the Administration Act would continue to apply for current and earlier financial years. The obligation in existing section 69EA to keep records which arises where there is an obligation to be complied with under 69E, will also continue to apply.

Part 4 of Schedule 1 to the Bill will commence on the day after the Bill receives the Royal Assent.
PART 5—COMPUTERISED DECISION-MAKING

Overview

Part 5 of Schedule 1 to the Bill amends the Agvet Code to provide that the APVMA may choose to use computerised decision-making as part of its processes, thereby increasing efficiency. For example, computerised decision-making might be used for decisions involving an administrative check of an application.

While the Agvet Code deals with electronic transactions, it does not currently provide for the use of computer programs to make decisions. Accordingly, all decisions, including those of a largely administrative nature, require an APVMA staff member to turn their minds to the matter at hand. The proposed amendments address this deficiency by allowing computerised decision-making.

The proposed amendments align the Agvet Code with other Commonwealth legislation that also authorises computerised decision-making (for example the therapeutic goods legislation).

The APVMA’s decisions about implementing computerised decision-making will be guided by the best practice principles developed by the Administrative Review Council (ARC), as outlined in the ARC report Automated Decision Making (ARC Report No. 46, 2004), available from the website of the Attorney-General’s Department.

The Bill provides for a specific commencement provision (by Proclamation) for Part 5 to allow procedures and guidance to be developed in line with these best practice principles.

Agricultural and Veterinary Chemicals Code Act 1994

Item 36 Before section 6 of the Code set out in the Schedule

Item 36 inserts new section 5F into the Agvet Code. This allows the APVMA to introduce computerised decision-making where the APVMA considers that this is appropriate, and is intended to establish a flexible legislative regime that will support future developments in information technology and business processing. This provision does not require the APVMA to use computerised decision-making, but rather provides it as an option.

New subsection 5F(1) provides for the APVMA to arrange for the use of computer programs for any purpose for which the APVMA may or must make a decision, exercise a power, comply with an obligation or anything else related to these actions.

New subsection 5F(2) provides that the decision made by the computer program is taken to be a decision made by the APVMA with all the consequences that would flow from this. This is consistent with Principle 5 of the best practice principles developed by the ARC, as outlined in the ARC Report No. 46, 2004. This principle states that the use of an expert system to make a decision—as opposed to helping a decision-maker make a decision—should be legislatively sanctioned to ensure that it is compatible with the legal principles of authorised decision-making.

New subsection 5F(3) allows the APVMA to substitute a decision for a decision made by a computer program if the APVMA is satisfied that the decision made by the computer program is incorrect. This allows the APVMA to fix an error and minimise the impact on the persons affected by any incorrect decision made by the computer program. This provides a
safeguard to ensure that if a computer program is not operating correctly, or has produced a
decision that the APVMA considers is wrong, the action can be substituted by the APVMA
without the need for formal administrative review. This is consistent with Principle 6 of the
best practice principles developed by the ARC, as outlined in ARC Report No. 46, 2004. This
principle states that if decisions made by or with the assistance of expert systems can be
overridden only by a senior officer, it might be advantageous for this to be legislatively
clarified.

New subsection 5F(4) specifies that the APVMA may only substitute a decision for a
decision made by a computer program within 60 days of the day the decision is made by the
computer program. This provision ensures that there is a clear ‘window’ in which the
APVMA may substitute a decision.

**Items 37, 39 and 41  Paragraphs 166(1)(a) and (1A)(a) and after subsection 166(1A) of
the Code set out in the Schedule**

Items 37 and 39 amend paragraphs 166(1)(a) and 166(1A)(a) of the Agvet Code to provide
that a decision made under paragraph 5F(2)(a) by a computer program may be reconsidered
by the APVMA. This will mean that a decision made by a computer program will be subject
to the same opportunity for internal reconsideration as if that decision were made by an
APVMA staff member. In addition, amended paragraph 166(1)(a) and new
subsection 166(1B), inserted by item 41, provide the same opportunity for internal
reconsideration that applies if the decision by a computer program is substituted by an
APVMA decision under subsection 5F(3) of the Agvet Code.

Items 37 and 39 also replace the existing definition of ‘original decision’ with ‘reviewable
decision’ for clarity.

**Items 38, 40 and 42  Paragraphs 166(1)(b), 166(1A)(b) and (c) and subsections 166(2)
to (4A) and (5) to (7) of the Code set out in the Schedule**

Items 38, 40 and 42 amend paragraphs 166(1)(b), 166(1A)(b) and (c), and
subsections 166(2) to (4A) and (5) to (7) of the Agvet Code to replace all occurrences of
‘original decision’ with ‘reviewable decision’ as a consequential amendment to items 37
and 39.

**Item 43  After subsection 167(2A) of the Code set out in the Schedule**

Item 43 inserts new subsection 167(2B) into the Agvet Code to provide that where the
APVMA substitutes a decision under subsection 5F(3) then that decision may be reviewed on
application to the AAT.

**Item 44  Application and saving provisions**

Item 44 provides that the amendments to section 166 of the Agvet Code made by Part 5 of
Schedule 1 to the Bill will apply in relation to reviewable decisions made on or after the
commencement of this Part. It also provides that section 166 as in force before
commencement of this item is preserved in relation to original decisions made before
commencement of the item.

Part 5 of Schedule 1 to the Bill will commence on the earlier of either six months after
the Bill receives the Royal Assent or by Proclamation.
PART 6—PRELIMINARY ASSESSMENTS

Overview

Part 6 of Schedule 1 to the Bill amends the Agvet Code to provide the APVMA with greater flexibility to manage application errors during the preliminary assessment of those applications, which relate to:

- approval or registration (see sections 10 and 11 of the Agvet Code)
- variation of approval or registration (see sections 27 and 28 of the Agvet Code).

Currently, the APVMA must refuse an application if it does not meet the application requirements, including minor errors. The applicant must then make a new application, which is administratively burdensome for industry and time consuming for the APVMA.

The proposed amendments will enable the APVMA to, following preliminary assessment of an application, notify an applicant of minor errors in their application, and provide them with one opportunity to address those errors or submit missing information, where this can be reasonably rectified. This flexibility is also consistent with the flexibility currently available for the preliminary assessment of permit applications under section 110A of the Agvet Code. Providing applicants with an opportunity to address errors or submit missing information will, for example, overcome situations where the applicant simply failed to attach the information, or attached the wrong piece of information, to the application.

The amendments proposed by Part 6 of Schedule 1 to the Bill are not intended to provide applicants with the ability to rectify major errors in their applications or to provide more than one opportunity to rectify the defects.

Agricultural and Veterinary Chemicals Code Act 1994

Item 45  Subsection 11(2) of the Code set out in the Schedule

Item 45 omits the reference to “from the preliminary assessment” in subsection 11(2) of the Agvet Code, and substitutes that reference with “to the APVMA, after completing a preliminary assessment of the application or after defects in the application have been rectified in response to a notice under subsection (3),”.

Subsection 11(2) of the Agvet Code currently specifies notices that must be provided to the applicant and publication requirements for applications that meet the application requirements.

Item 45 clarifies that the notice and publication requirements in subsection 11(2) of the Agvet Code apply to applications that meet the application requirements and applications that had minor defects and that have since been rectified. Item 45 is consequential to the amendments made by item 46.

Item 46  Subsection 11(3) of the Code set out in the Schedule

Item 46 repeals subsection 11(3) of the Agvet Code and substitutes new subsections 11(3) and (3A) into the Agvet Code.

Subsection 11(3) of the Agvet Code currently provides that if subsection 11(2) of the Agvet Code does not apply to the application, the APVMA must refuse the application. New subsections 11(3) and (3A) of the Agvet Code provide an applicant with one opportunity to
rectify minor defects in their application. This will ensure both the APVMA and the applicant are provided with more flexibility during the assessment of an application.

New subsection 11(3A) of the Agvet Code is necessary to preserve the integrity of the application process and provides that the APVMA must refuse the application if:

- the APVMA is not satisfied that defects in the application can reasonably be rectified; or
- the defects are not rectified to the satisfaction of the APVMA within the period mentioned in new paragraph 11(3)(c) of the Agvet Code.

Item 46 also inserts a note at the end of new subsection 11(3A) of the Agvet Code to direct the reader to section 8G of the Agvet Code, which outlines the process the APVMA must follow when notifying an applicant of an application refusal.

**Item 47 Subsection 28(2) of the Code set out in the Schedule**
Item 47 will make the same changes to subsection 28(2) of the Agvet Code as are made to subsection 11(2) of the Agvet Code by item 45. This will mean the same preliminary assessment process will apply for applications to vary relevant particulars or conditions as applies for applications for approval or registration. Item 47 is consequential to the amendments made by item 48.

**Item 48 Subsection 28(3) of the Code set out in the Schedule**
Item 48 will make the same amendments to subsection 28(3) of the Agvet Code as are made to subsection 11(3) of the Agvet Code by item 46. This will mean the same preliminary assessment process will apply for applications to vary relevant particulars or conditions as applies for applications for approval or registration.

Consistent with the amendments made to subsection 11(3) of the Agvet Code, the amendments to subsection 28(3) of the Agvet Code will provide an applicant with an opportunity to rectify minor defects in their application. This will ensure both the APVMA and the applicant are provided with more flexibility during the assessment of an application, while preserving the integrity of the application process.

As with item 46, item 48 also inserts a note at the end of new subsection 28(3A) of the Agvet Code to direct the reader to section 8G of the Agvet Code, which outlines the process the APVMA must follow when notifying an applicant of an application refusal.

**Item 49 Subsection 110A(2) of the Code set out in the Schedule**
Item 49 omits the reference to “from the preliminary assessment” in subsection 110A(2) of the Agvet Code, and substitutes that reference with a reference to “to the APVMA, after completing a preliminary assessment of the application or after defects in the application have been rectified in response to a notice under subsection (3),”.

Section 110A of the Agvet Code currently provides the APVMA with the ability to notify an applicant that they have an opportunity to rectify minor defects in an application (see subsections 110A(3) and (4) of the Agvet Code). Item 49 clarifies that the notice requirements in subsection 110A(2) of the Agvet Code apply to applications that meet the application requirements and applications that had minor defects that have since been rectified. These amendments will mean that the same preliminary assessment process will apply for permit applications as applies for applications for approval or registration.
**Item 50 Subsection 110A(3) of the Code set out in the Schedule**

Item 50 omits the reference to “from the preliminary assessment” in subsection 110A(3) of the Agvet Code, and substitutes that reference with a reference to “to the APVMA, after completing a preliminary assessment of the application”.

Item 50 ensures that amended subsection 110A(3) of the Agvet Code is worded consistently with new subsections 11(3) and 28(3) of the Agvet Code, to avoid ambiguity and provide that the same preliminary assessment process will apply for permit applications as applies for applications for approval or registration.

**Item 51 Application provision**

Item 51 provides that the proposed amendments in Part 6 of Schedule 1 to the Bill will apply in relation to applications lodged under sections 10, 27 or 110 of the Agvet Code on or after the commencement of Part 6 of Schedule 1 to the Bill. Item 51 ensures that the amendments proposed by Part 6 of Schedule 1 to the Bill will not apply retrospectively.

Part 6 of Schedule 1 to the Bill will commence on the day after the end of the period of 12 months beginning on the day the Bill receives the Royal Assent.
PART 7—VARIATION OF RELEVANT PARTICULARS AND CONDITIONS

Overview

Part 7 of Schedule 1 to the Bill amends 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 product, in a way other than as set out in the original application for variation. This may include granting part of a variation application.

Currently, under section 27 of the Agvet Code, a *holder* (which is defined by section 3 of the Agvet Code) may apply to the APVMA for variation of the relevant particulars or conditions of the approval of an active constituent, registration of a chemical product, or approval of a label for containers for a chemical product. The APVMA must vary the relevant particulars or conditions if it is satisfied that the application meets certain application requirements, and that the variation would meet applicable statutory criteria and established standards (see section 29 of the Agvet Code). However, the APVMA does not currently have the power to vary relevant particulars or conditions in a way other than as set out in the original application for variation, including the ability to grant part of such an application. As a result, the APVMA must grant or refuse an entire application based on its satisfaction of the matters set out in subsection 29(1) of the Agvet Code.

In practice, the APVMA currently assists applicants to ensure that proposed variations are appropriately constructed in an application for variation in such a manner that would satisfy the APVMA of the matters set out in subsection 29(1) of the Agvet Code. For example, the application for variation may relate to chemical products for the purposes of wheat, barley and rice, but the information provided may only support satisfaction by the APVMA of the proposed variations in relation to wheat and barley. In such an example, the APVMA would work with the applicant to amend the application so that it relates only to wheat and barley.

The proposed amendments provide the APVMA with the flexibility to vary relevant particulars or conditions in a way other than as set out in the original application for variation, including providing an applicant with the opportunity to provide written submissions on such a variation.

*Agricultural and Veterinary Chemicals Code Act 1994*

**Item 52** At the end of subsection 8S(1) of the Code set out in the Schedule (before the note)

Item 52 amends subsection 8S(1) of the Agvet Code to insert new paragraph 8S(1)(c).

New paragraph 8S(1)(c) of the Agvet Code provides that the APVMA must give an applicant written notice of what it proposes to do before it varies, under section 29 of the Agvet Code, relevant particulars or conditions in a way other than set out in the original application.

New paragraph 8S(1)(c) of the Agvet Code ensures an applicant has the opportunity to provide written submissions to the APVMA in relation to a proposed variation that is in a way other than as set out in the original application for variation.

**Item 53** After paragraph 8S(2)(a) of the Code set out in the Schedule

Item 53 amends subsection 8S(2) of the Agvet Code to insert new paragraph 8S(2)(b).
Subsection 8S(2) of the Agvet Code currently provides that the written notice issued under subsection 8S(1) of the Agvet Code must contain a number of matters, which are currently set out by paragraphs 8S(2)(a), (c), (d) and (e) of the Agvet Code. New paragraph 8S(2)(b) of the Agvet Code provides that the written notice issued under subsection 8S(1) of the Agvet Code must, for a notice issued under new paragraph 8S(1)(c) of the Agvet Code, set out the proposed variation.

New paragraph 8S(2)(b) of the Agvet Code is necessary to ensure an applicant receives a copy of the proposed variation so that they may provide written submissions to the APVMA about the proposed variation. Item 53 complements the amendments to section 8S of the Agvet Code by item 52.

**Item 54 Paragraphs 29(1)(b), (c) and (d) of the Code set out in the Schedule**

Item 54 omits the references to “in accordance with the application” in paragraphs 29(1)(b), (c) and (d) of the Agvet Code, and substitutes those references with references to “in a particular way (which may not be the same way as set out in the application)”.

Item 54 will provide applicants and the APVMA with greater flexibility in relation to the variation of relevant particulars and 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 product. The proposed amendments will enable that variation to occur in a way that is different than what was originally set out in the application, while still ensuring the statutory criteria and established product standards are complied with.

It is important to note that the amendments to section 8S of the Agvet Code by items 52 and 53 will ensure that an applicant has the opportunity to provide a written submission to the APVMA on a proposed variation that is in a way other than as set out in the original variation application.

**Item 55 After paragraph 167(1)(c) of the Code set out in the Schedule**

Item 55 amends subsection 167(1) of the Agvet Code to insert new paragraph 167(1)(ca) of the Agvet Code.

Subsection 167(1) of the Agvet Code identifies a number of decisions of the APVMA that are reviewable decisions internally and by the AAT. New paragraph 167(1)(ca) of the Agvet Code provides that an application may be made to the APVMA for internal review and the AAT of decisions under subsection 29(1) of the Agvet Code to vary relevant particulars or conditions in a way other than as set out in the original application for variation.

Subsection 29(1) of the Agvet Code currently requires 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 product, if it is satisfied of a number of matters, which are currently set out by paragraphs 29(1)(a) to (d) of the Agvet Code.

New paragraph 167(1)(ca) of the Agvet Code is necessary to enable an affected applicant to apply to the AAT for review of a decision made by the APVMA under subsection 29(1) of the Agvet Code to vary relevant particulars or conditions in a way other than as set out in the original application for variation. It is appropriate that subsection 167(1) of the Agvet Code be amended to provide a pathway for applicants to seek merits review of such a decision by the APVMA, as an applicant could be affected by such a decision.
Subsection 167(3) of the Agvet Code provides that section 167 of the Agvet Code has effect subject to the Administrative Appeals Tribunal Act 1975. Accordingly, the provisions of that Act will apply to new paragraph 167(1)(ca) of the Agvet Code.

**Item 56 Application provision**

Item 56 provides that the amendments made by Part 7 of Schedule 1 to the Bill will apply in relation to applications lodged under section 27 of the Agvet Code on or after the commencement of Part 7 of Schedule 1 to the Bill.

Item 56 ensures that the amendments proposed by Part 7 of Schedule 1 to the Bill will not apply retrospectively.

Part 7 of Schedule 1 to the Bill will commence on the day after the end of the period of three months beginning on the day the Bill receives the Royal Assent.
PART 8—VARIATION OF APPROVAL OR REGISTRATION DURING SUSPENSION

Overview

Part 8 of Schedule 1 to the Bill amends the Agvet Code to enable the APVMA to introduce practical measures to deal with suspended label approvals or registrations and to address the reason for a suspension. It will also allow holders to request a suspension of an approval or registration.

The Bill will allow a holder to apply to vary the relevant particulars and conditions for a label approval or product registration that is suspended, provided the application relates to the reasons for the suspension. This will ensure that the issues with a label or product that led to its suspension can be appropriately rectified prior to revocation of the suspension.

Currently, under Division 5 of Part 2 of the Agvet Code, the APVMA may suspend an approval (including an approval for a label for containers for a chemical product) or registration. Subsection 43(2) of the Agvet Code relevantly provides that an approval or registration is taken, for the purposes of the Agvet Code (other than sections 74 and 75), not to be in force during any period in which it is suspended. Division 3 of Part 2 of the Agvet Code currently sets out matters in relation to varying relevant particulars and conditions of approvals and registrations. However, the APVMA cannot currently amend a label approval or product registration to address the problem that led to the requirement to suspend the label approval or product registration without first revoking the suspension.

The amendments in the Bill will remedy this unintended administrative barrier to the appropriate rectification of issues with suspended label approvals or product registrations, which prevents the holder of a label approval or product registration from dealing with the suspension problem.

In addition, because a holder currently can only request cancellation of their approval or registration, and not suspension, a holder may be placed in a difficult position of having to cancel their approval or registration to deal with administrative matters (for example, an overseas holder arranging a new nominated agent in Australia). The holder then has to re-apply for approval or registration at a later time. This is an unnecessarily restrictive and costly means of dealing with administrative matters.

Agricultural and Veterinary Chemicals Code Act 1994

Items 57 to 59  Section 42 of the Code set out in the Schedule

Items 57 to 59 amend section 42 of the Agvet Code to provide that a holder can request suspension of an approval or registration in addition to the current option of requesting cancellation of an approval or registration. This will enable a holder to have their approval or registration suspended while they deal with any issues with it. It will mean that the holder will not have to cancel their approval or registration to deal with administrative matters and then have to re-apply for approval or registration at a later time.

Item 59 also amends subsection 42(1) to require the APVMA to suspend or cancel an approval or registration where a holder requests either suspension or cancellation and the APVMA is satisfied that there are no valid reasons why it should not agree to the request.
**Item 60**  **Subsection 43(2) of the Code set out in the Schedule**

Item 60 omits the reference to “An” in subsection 43(2) of the Agvet Code, and substitutes that reference with a reference to “Subject to this section, an”.

Subsection 43(2) of the Agvet Code currently provides that an approval or registration is taken, for the purposes of the Agvet Code, other than sections 74 and 75 of the Agvet Code, not to be in force during any period in which it is suspended.

Item 60 is consequential to the amendment to section 43 of the Agvet Code by item 61.

**Item 61**  **At the end of section 43 of the Code set out in the Schedule**

Item 61 amends section 43 of the Agvet Code to insert new subsections 43(4) and (5) of the Agvet Code. Section 43 of the Agvet Code provides for matters in relation to the effect of a suspension of an approval or registration.

New subsection 43(4) of the Agvet Code ensures that, despite the suspension of an approval of an active constituent or label or registration of a chemical product, a person is not prevented from lodging a notice, making an application or seeking a variation of the relevant particulars or conditions provided this is relevant to the reasons for the suspension. This amendment will ensure that the issue or issues with an approval or registration that led to its suspension could be appropriately rectified prior to revocation of the suspension.

While current subsection 47(1) of the Agvet Code already means active constituents can be varied while suspended (since it specifies that an active constituent approval remains in force until cancelled), inclusion of all approvals in amended subsection 43(4) will simplify the legislation.

New subsection 43(5) of the Agvet Code provides that a notice referred to in new paragraph 43(4)(a) of the Agvet Code, an application referred to in new paragraphs 43(4)(b) or (c) of the Agvet Code, or a variation referred to in new paragraph 43(4)(d) of the Agvet Code must be in relation to the reasons for the suspension of the approval.

New subsection 43(5) of the Agvet Code ensures that the notice, application or variation appropriately relates to the issue or issues with an approval or registration that led to its suspension.

**Item 62**  **Subsection 45A(2) of the Code set out in the Schedule**

Item 62 omits the reference to “subsection (1)” in subsection 45A(2) of the Agvet Code, and substitutes that reference with a reference to “paragraph (1)(a)”.

Subsection 45A(2) of the Agvet Code currently provides that a notice of suspension or cancellation under subsection 45A(1) of the Agvet Code must contain a number of matters, which are currently set out by paragraphs 45A(2)(a) and (b) of the Agvet Code.

Item 62 ensures that subsection 45A(2) of the Agvet Code correctly identifies the provision under which the applicable notice of suspension or cancellation is issued. As paragraph 45A(1)(b) of the Agvet Code currently relates to the publication of a notice of suspension or cancellation, it is appropriate that subsection 45A(2) of the Agvet Code be amended to expressly refer to paragraph 45A(1)(a) of the Agvet Code.
Item 63  Paragraph 45A(2)(b) of the Code set out in the Schedule
Item 63 omits the reference to “in respect of a suspension or cancellation of the approval of an active constituent for a proposed or existing chemical product or the registration of a chemical product—” from paragraph 45A(2)(b) of the Agvet Code.

Paragraph 45A(2)(b) of the Agvet Code currently provides that a notice or suspension or cancellation under subsection 45A(1) of the Agvet Code, in respect of a suspension or cancellation of the approval of an active constituent for a proposed or existing chemical product or the registration of a chemical product must contain certain matters, which are currently set out by subparagraphs 45A(2)(b)(i) to (iv) of the Agvet Code.

Accordingly, a notice of cancellation or suspension of the approval of a label is not subject to the same notification requirements as a notice of cancellation or suspension of the approval of an active constituent for a proposed or existing chemical product or the registration of a chemical product, which are currently set out by paragraph 45A(2)(b) of the Agvet Code.

It is necessary to amend paragraph 45A(2)(b) of the Agvet Code to enable the requirements in that paragraph to apply to a notice of suspension or cancellation of a label approval. This will ensure that notices of suspension or cancellation for approvals of active constituents, registrations of chemical products or approvals of labels are treated consistently.

Items 64 and 65  Subsection 45A(4) of the Code set out in the Schedule
Items 64 and 65 are consequential amendments to subsection 45A(4) of the Agvet Code to reflect the amendments made by items 57 to 59. These provide that notices about the suspension of an approval or registration under section 45A do not need to be given to the holder where the holder requests suspension. This aligns with the current approach where notices about cancellation of an approval or registration do not need to be given to the holder where the holder requests cancellation. It is unnecessary for a holder to be notified about these suspensions or cancellations under section 45A because these holders would already have been notified of the suspension or cancellation under subsection 42(2).

Item 66  Application provisions
Item 66 provides that the amendments to section 42 of the Agvet Code only apply to requests for suspension of an approval or registration made on or after the commencement of Part 8 of Schedule 1 to the Bill.

Item 66 also provides that amendments to section 43 of the Agvet Code apply to suspensions made on or after commencement and suspensions made before commencement that were in effect immediately before commencement.

It is appropriate that the amendments to section 43 of the Agvet Code by items 60 and 61 above apply to a suspension made before the commencement of Part 8 of Schedule 1 to the Bill that was in effect immediately before that commencement because it will ensure any existing suspended label approvals are also able to access the ability to address underlying issues in order to have the suspension lifted.

Sub-item 66(3) provides that the amendments to section 45A of the Agvet Code by items 62 to 65 will apply in relation to a suspension or cancellation made on or after the commencement of Part 8 of Schedule 1 to the Bill. Sub-item 66(3) ensures that the proposed amendments to section 45A of the Agvet Code by items 62 to 65 will not apply retrospectively.
Part 8 of Schedule 1 to the Bill will commence on the day after the end of the period of three months beginning on the day the Bill receives the Royal Assent.
PART 9—FALSE AND MISLEADING INFORMATION

Overview

Part 9 of Schedule 1 to the Bill amends the Administration Act and the Agvet Code to establish civil pecuniary penalties for contraventions of provisions relating to false or misleading information.

Currently, under section 69ER of the Administration Act and section 146 of the Agvet Code, a person commits an offence if that person gives false or misleading information or produces false or misleading documents.

Unlike other provisions in the Administration Act and the Agvet Code, section 69ER of the Administration Act and section 146 of the Agvet Code do not also subject that conduct to civil pecuniary penalties.

The absence of civil pecuniary penalties for a contravention of section 69ER of the Administration Act or a contravention of section 146 of the Agvet Code reduces the enforcement tools available to the APVMA. Accordingly, the creation of civil pecuniary penalties for those provisions encourages compliance with the Administration Act and the Agvet Code, and provides greater flexibility for the APVMA to proportionately respond to circumstances of non-compliance.

Agricultural and Veterinary Chemicals (Administration) Act 1992

Item 67  Before subsection 69ER(1)

Item 67 amends section 69ER of the Administration Act to insert a new subheading before current subsection 69ER(1) of that Act. The new subheading, Offences, will assist the reader to identify that subsections 69ER(1) and (2) of the Administration Act are offence provisions, and also ensures that section 69ER of the Administration Act, as amended by item 68, is structured consistently.

Item 68  At the end of section 69ER

Item 68 amends section 69ER of the Administration Act to insert new subsections 69ER(3), (4) and (5). Item 68 also inserts the subheading, Civil penalties, for those new subsections.

Section 69ER of the Administration Act currently provides for offences in relation to the giving or production of false or misleading information or documents. Subsections 69ER(1) and (2) of the Administration Act detail these offences and the relevant penalties (300 and 60 penalty units, depending on the offence).

New subsections 69ER(3) and (4) of the Administration Act respectively complement current subsections 69ER(1) and (2) of that Act, by creating corresponding civil penalty provisions for the same conduct.

New subsection 69ER(5) of the Administration Act provides that new subsections 69ER(3) and (4) of that Act are civil penalty provisions.

Item 68 also inserts a note at the end of new subsection 69ER(5) of the Administration Act to direct the reader to Division 1 of Part 7AB of that Act. This creates a framework to use civil pecuniary penalties to enforce the civil penalty provisions of the Administration Act and the Levy Act (see the definition of civil penalty provision in section 4 of the Administration Act).
The note to new subsection 69ER(5) of the Administration Act is merely included to assist the reader.

Subsection 69EJA(1) of the Administration 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 conduct that is the same as the conduct constituting the contravention.

Subsection 69EJA(2) of the Administration Act provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

It is important to note that subsection 69EJA(1) of the Administration Act refers to the maximum monetary penalty that could be imposed by a court if a body corporate were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

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.

The applicable criminal pecuniary penalty for an individual for a contravention of current subsection 69ER(1) of the Administration Act is 300 penalty units. The applicable criminal pecuniary penalty for an individual for a contravention of current subsection 69ER(2) of the Administration Act is 60 penalty units.

Accordingly, as there is no contrary intention in the Administration Act, the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 69ER(1) of the Administration Act will be 1,500 penalty units, and the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 69ER(2) of the Administration Act will be 300 penalty units.

By virtue of section 69EJA of the Administration Act, and the matters prescribed by current subsection 69ER(1) of the Administration Act (including the application of subsection 4B(3) of the Crimes Act to that subsection), the civil pecuniary penalty for new subsection 69ER(3) of that Act will be 900 penalty units for individuals and 7,500 penalty units for bodies corporate.

New subsection 69ER(3) of the Administration Act is necessary to achieve the legitimate objective of protecting human and animal health, the environment and trade. Subjecting the conduct in new subsection 69ER(3) of the Administration Act to a civil pecuniary penalty of 900 penalty units for individuals and 7,500 penalty units for bodies corporate provides a necessary and proportionate deterrent to non-compliance with the requirement in that new subsection not to give false or misleading information or documents. Further, the proposed penalties are reflective of the seriousness of the conduct and the risk that contravening behaviour may pose to human and animal health, the environment and trade.
By virtue of section 69EJA of the Administration Act, and the matters prescribed by current subsection 69ER(2) of the Administration Act (including the application of subsection 4B(3) of the Crimes Act to that subsection), the civil pecuniary penalty for new subsection 69ER(4) of that Act will be 180 penalty units for individuals and 1,500 penalty units for bodies corporate.

New subsection 69ER(4) of the Administration Act is necessary to achieve the legitimate objective of protecting human and animal health, the environment and trade.

Subjecting the conduct in new subsection 69ER(4) of the Administration Act to a civil pecuniary penalty of 180 penalty units for individuals and 1,500 penalty units for bodies corporate provides a necessary and proportionate deterrent to non-compliance with the requirement in that new subsection not to give false or misleading information or documents. Further, the proposed penalties are reflective of the seriousness of the conduct and the risk that contravening behaviour may pose to human and animal health, the environment and trade.

Further the proposed penalties in new subsections 69ER(3) and (4) are significantly less than the civil pecuniary penalties prescribed by section 31AAA of the Therapeutic Goods Act for similar conduct in relation to the provision of false or misleading information or documents, which are 5,000 penalty units for individuals and 50,000 penalty units for bodies corporate.

New subsections 69ER(3) and (4) of the Administration Act seek to encourage compliance with that Act, and will provide the APVMA with greater flexibility to proportionately respond to circumstances of non-compliance.

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Item 69  Before subsection 146(1) of the Code set out in the Schedule
Similar to item 67, item 69 amends section 146 of the Agvet Code to insert a new subheading before current subsection 146(1) of the Agvet Code. The new subheading, Offences, will assist the reader to identify that subsections 146(1) and (2) of the Agvet Code are offence provisions, and also ensures that section 146 of the Agvet Code, as amended by item 70, is structured consistently.

Item 70  At the end of section 146 of the Code set out in the Schedule
Similar to item 68, item 70 amends section 146 of the Agvet Code to insert new subsections 146(3), (4) and (5) of the Agvet Code. Item 70 also inserts the subheading, Civil penalties, for those new subsections.

Section 146 of the Agvet Code currently provides for offences in relation to the giving or production of false or misleading information or documents. Subsections 146(1) and (2) of the Agvet Code detail these offences and the relevant penalties (300 and 60 penalty units, depending on the offence).

New subsection 146(3) and (4) of the Agvet Code respectively complement current subsections 146(1) and (2) of the Agvet Code, by creating corresponding civil penalty provisions for the same conduct.

New subsection 146(5) of the Agvet Code provides that new subsections 146(3) and (4) of the Agvet Code are civil penalty provisions.
Item 70 also inserts a note at the end of new subsection 146(4) of the Agvet Code to direct the reader to Division 2 of Part 9A of the Agvet Code, which creates a framework for the use of civil pecuniary penalties to enforce the civil penalty provisions of the Agvet Code.

Subsection 145AA(1) of the Agvet Code 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 conduct that is the same as the conduct constituting the contravention.

Subsection 145AA(2) of the Agvet Code provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

It is important to note that subsection 145AA(1) of the Agvet Code refers to the maximum monetary penalty that could be imposed by a court if a body corporate were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

Subsection 170(5) of the Agvet Code states that, where a body corporate is convicted of an offence against the Agvet Code, a court may, if the court thinks fit, impose a monetary penalty not greater than five times the amount of the maximum monetary penalty that could be imposed by the court on an individual convicted of the same offence.

The applicable criminal pecuniary penalty for an individual for a contravention of current subsection 146(1) of the Agvet Code is 300 penalty units. The applicable criminal pecuniary penalty for an individual for a contravention of current subsection 146(2) of the Agvet Code is 60 penalty units.

Due to subsection 170(5) of the Agvet Code, the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 146(1) of the Agvet Code will be 1,500 penalty units, and the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 146(2) of the Agvet Code will be 300 penalty units.

By virtue of section 145AA of the Agvet Code, and the matters prescribed by current subsection 146(1) of the Agvet Code (including the application of subsection 4B(3) of the Crimes Act to that subsection), the civil pecuniary penalty for new subsection 146(3) of the Agvet Code will be 900 penalty units for individuals and 7,500 penalty units for bodies corporate.

New subsection 146(3) of the Agvet Code is necessary to achieve the legitimate objective of protecting human and animal health, the environment and trade. Subjecting the conduct in new subsection 146(3) of the Agvet Code to a civil pecuniary penalty of 900 penalty units for individuals and 7,500 penalty units for bodies corporate provides a necessary and proportionate deterrent to non-compliance with the requirement in that new subsection not to give false or misleading information or documents. Further, the proposed penalties are reflective of the seriousness of the conduct and the risk that contravening behaviour may pose to human health and safety, the environment and trade if agvet chemicals are used inappropriately on the basis of false or misleading information or documents.
By virtue of section 145AA of the Agvet Code, and the matters prescribed by current subsection 146(2) of the Agvet Code, the civil pecuniary penalty for new subsection 146(4) of the Agvet Code will be 180 penalty units for individuals and 1,500 penalty units for bodies corporate.

New subsection 146(4) of the Agvet Code is necessary to achieve the legitimate objective of protecting human and animal health, the environment and trade. Subjecting the conduct in new subsection 146(4) of the Agvet Code to a civil pecuniary penalty of 180 penalty units for individuals and 1,500 penalty units for bodies corporate provides a necessary and proportionate deterrent to non-compliance with the requirement in that new subsection not to give false or misleading information or documents. Further, the proposed penalties are reflective of the seriousness of the conduct and the risk that contravening behaviour may pose to human health and safety, the environment and trade if agvet chemicals are used inappropriately on the basis of false or misleading information or documents.

Further, the proposed penalties for new subsections 146(3) and (4) are significantly less than the civil pecuniary penalties prescribed by section 31AAA of the Therapeutic Goods Act for similar conduct in relation to the provision of false or misleading information or documents, which are 5,000 penalty units for individuals and 50,000 penalty units for bodies corporate.

New subsections 146(3) and (4) of the Agvet Code seek to encourage compliance with the Agvet Code, and will provide the APVMA with greater flexibility to proportionately respond to circumstances of non-compliance.

**Item 71 Application provision**

Item 71 provides that the amendments made by Part 9 of Schedule 1 to the Bill will apply in relation to information given, or a document produced, on or after the commencement of Part 9 of Schedule 1 to the Bill.

Item 71 ensures that the amendments proposed by Part 9 of Schedule 1 to the Bill will not apply retrospectively.

Part 9 of Schedule 1 to the Bill will commence on the day after the end of the period of three months beginning on the day the Bill receives the Royal Assent.
PART 10—SUSPENSION OR CANCELLATION OF APPROVAL OR REGISTRATION FOR PROVISION OF FALSE OR MISLEADING INFORMATION

Overview

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.

Section 38A of the Agvet Code provides for the APVMA to suspend or cancel an active constituent approval or product registration where false or misleading information has been provided. However, section 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.

New section 38A addresses these deficiencies 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 (introduced by Part 9 of Schedule 1 to the Bill) in section 146 of the Agvet Code for providing false or misleading information.

The amendments do not affect the existing requirement (section 34P of the Agvet Code) for the APVMA to provide the holder with a notice of reasons for a proposed decision under section 38A and invite (and consider) submissions from the holder. Decisions under section 38A will also continue to be subject to internal review by the APVMA (section 166 of the Agvet Code) and merits review by the AAT (section 167 of the Agvet Code).

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Item 72 Paragraph 34N(4)(d) of the Code set out in the Schedule
Item 72 amends section 34N of the Agvet Code so that the explanation section for suspensions and cancellations refers to persons instead of holders. This is a consequential amendment arising from item 73.

Item 73 Section 38A of the Code set out in the Schedule
Item 73 replaces section 38A of the Agvet Code so that the APVMA may suspend or cancel an approval or registration if any person has given information that was false or misleading in a material particular in relation to any of the following:

- an application for approval or registration (including for the new approval of a prescribed active constituent or registration of a prescribed chemical product provided for in Part 2 of Schedule 1 to the Bill)
• an application for a variation of an approval or registration (which also applies to a notice of a notifiable variation under Division 2AA of Part 2 of the Agvet Code and an application for a prescribed variation under Division 2A of Part 2 of the Agvet Code)

• in response to notices to provide information (under subsection 32(1) or section 33 or 159 of the Agvet Code)

• new information that comes to light, either before or after, the APVMA has made an approval or registration decision as required by sections 160A or 161 of the Agvet Code, such as information that shows that a product or active constituent may not meet the safety criteria.

The amendments will complement the existing powers the APVMA has to consider suspending or cancelling an approval of an active constituent or registration of a chemical product if a holder provides information that is false or misleading in a material particular. This will improve the post-registration response capability of the APVMA.

The power of the APVMA to suspend or cancel an approval or registration remains subject to a notice issued under section 34P of the Agvet Code. Section 34P provides that before making a decision to suspend or cancel an approval or registration, the APVMA must notify the holder of its proposed decision, setting out its reasons. It must also invite submissions from the holder about the proposed suspension or cancellation, and have regard to these submissions before making a decision.

New section 38A also applies to information given by any person—extending the scope of the current powers which only apply to the holder of an approval or registration. As a result, there is the potential for persons other than holders (for example, persons providing information on behalf of the holder) to provide false or misleading information to the APVMA and for this information to impact on holders of approval or registration i.e. by triggering a suspension or cancellation. The potential for this ‘mischief’ is low and can be managed through any notices to the holder under section 159 and 34P of the Agvet Code. This provides the holder with the opportunity to address any issues with the relevant information and ensures that there are safeguards to mitigate the potential for any ‘mischief’ from other persons providing false or misleading information. The potential for mischief is also minimised by the existing constraints on who can submit information.

Decisions made under section 38A are subject to internal review by the APVMA (section 166 of the Agvet Code) and merits review by the AAT (section 167 of the Agvet Code). This will further ensure that there are safeguards in place to provide that the correct and preferable decision is made.

**Item 74 Application provision**

Item 74 provides that new section 38A only applies in relation to information given on or after the commencement of Part 10 of Schedule 1 to the Bill. This application provision ensures that there is no retrospective application of new section 38A.

Part 10 of Schedule 1 to the Bill will commence on the day after the end of the period of three months beginning on the day the Bill receives the Royal Assent.
PART 11—VOLUNTARY RECALLS

Overview

Part 11 of Schedule 1 to the Bill amends the Agvet Code to require persons to inform the APVMA when they are undertaking certain voluntary recalls and requires the APVMA to publish such recalls. This person need not be the holder of an approval or registration, as there are a number of different points in the supply chain of a chemical product where a voluntary recall may occur.

Part 6 of the Agvet Code provides for the APVMA to issue recall notices for chemical products (compulsory recalls). These provisions provide for industry to recall products but also provide for the APVMA to issue notices to require persons who have, or have had, stocks of chemical products in their possession to stop supplying the products or to take action in relation to the products as directed by the APVMA. Part 6 of the Agvet Code also clarifies that this power is in addition to those powers conferred on the Australian Competition and Consumer Commission under the *Competition and Consumer Act 2010*.

The APVMA receives some notifications from industry about voluntary recalls and may, at its discretion, publish this information on its website. However, the Agvet Code does not currently specify notification and publication requirements if an agvet chemical product is being voluntarily recalled. As a result, it is left to the person recalling the product to determine how the recall is conducted and how stakeholders are notified.

The measures in the Bill will ensure that the APVMA must be informed if certain voluntary recalls are being conducted, where these relate to the matters set out in sections 5A to 5D of the Agvet Code (that is, the safety, efficacy, trade and labelling criteria). The APVMA will then be required to publish such recalls. This will improve transparency and ensure a baseline of information is available to all stakeholders.

*Agricultural and Veterinary Chemicals Code Act 1994*

**Items 75 and 76**  
Section 100 of the Code set out in the Schedule

Items 75 and 76 amend section 100 of the Agvet Code, which is the explanation section for Part 6 of the Agvet Code (Part 6 deals with recall notices the APVMA may issue). These amendments insert a new subsection 100(2) to inform readers of the Agvet Code that section 106 (as amended by the Bill) specifies requirements for voluntary recalls of chemical products. These amendments are editorial only and ensure the explanation of Part 6 of the Agvet Code includes the new voluntary recall requirements inserted by item 77.

**Item 77**  
Section 106 of the Code set out in the Schedule

Item 77 replaces the existing section 106 of the Agvet Code with a new section that will improve the transparency about voluntary recalls of certain chemical products. Notably, the term ‘recall’ has its common meaning and the reasons for recall are not limited to issues relating to human safety.

New subsection 106(1) sets out that section 106 applies if a person (who does not need to be the holder of registration) voluntarily proposes to take action to recall a chemical product because it appears to the person that:

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

Section 106 does not apply if a person is recalling a chemical product for a reason that is not set out in subsection 106(1) (e.g. not commercially viable, passed expiry date).

If a person is recalling a chemical product for a reason set out in subsection 106(1) then new subsection 106(2) requires the person to notify the APVMA within two days of this recall in an approved form. The approved form will be a form that the APVMA has approved or a form prescribed in the regulations. It is anticipated the approved form would require a description of the reasons for the recall. Requiring publication of notices according to prescribed criteria reflects the approach used in Australia for food safety recalls.

New subsection 106(3) provides that the regulations may prescribe circumstances where a person does not need to notify the APVMA of the voluntary recall of a chemical product i.e. subsection 106(2) will not apply. An example might include where a product has not yet been supplied to users.

**Strict liability offence**

New subsection 106(4) makes it an offence of strict liability for a person to fail, or refuse, to notify the APVMA of certain recalls of chemical products (where required to under subsection 106(2)). An applicable pecuniary penalty of 60 penalty units applies as the maximum criminal pecuniary penalty that a relevant court could impose on an individual. The maximum criminal pecuniary penalty that a relevant court could impose on a body corporate for a contravention of new subsection 106(4) of the Agvet Code will be 300 penalty units, due to the application of subsection 170(5) of the Agvet Code.

Subsection 170(5) of the Agvet Code states that, where a body corporate is convicted of an offence against the Agvet Code, a court may, if the court thinks fit, impose a monetary penalty not greater than five times the amount of the maximum monetary penalty that could be imposed by the court on an individual convicted of the same offence.

Prescribing the conduct in new subsection 106(4) of the Agvet Code as an offence of strict liability will place persons on notice to guard against the possibility of any contravention of the Agvet Code by encouraging persons voluntarily recalling certain chemical products for the reasons set out in subsection 106(1) to notify the APVMA of the recall. It is appropriate for these elements to be strict liability because persons engaged in voluntarily recalling chemical products should know their legal obligations before supplying these products and because the offence is necessary to ensure the integrity of the regulatory scheme. This builds on section 9.3 of the Criminal Code to put beyond doubt that ignorance of the law is not a ground on which a person may escape liability. Notifying the APVMA about certain voluntary recalls of chemical products is essential to ensure the regulator is appropriately informed of actions being taken to remove products from the market and to monitor any public health and environment risks and ensure these are managed through the recall.

Further, the proposed penalty in new subsection 106(4) is consistent with the Guide to Framing Commonwealth Offences, which provides that 50 to 60 penalty units is a comparable penalty for the failure to lodge a return or report. A penalty in the upper range of 60 penalty units is considered appropriate given the potential risks to public safety, the
environment, animal and plant health or trade that could be relevant or are being managed by the recall of a chemical product.

**Civil penalty provision**

New subsection 106(5) of the Agvet Code provides that new subsection 106(2) of the Agvet Code is also a civil penalty provision. A note at the end of new subsection 106(5) of the Agvet Code directs the reader to Division 2 of Part 9A of the Agvet Code, which creates a framework for the use of civil pecuniary penalties to enforce the civil penalty provisions of the Agvet Code.

Existing subsection 145AA(1) of the Agvet Code 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 conduct that is the same as the conduct constituting the contravention.

Existing subsection 145AA(2) of the Agvet Code provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

Existing subsection 170(5) of the Agvet Code states that, where a body corporate is convicted of an offence against the Agvet Code, a court may, if the court thinks fit, impose a monetary penalty not greater than five times the amount of the maximum monetary penalty that could be imposed by the court on an individual convicted of the same offence.

The applicable criminal pecuniary penalty for an individual for a contravention of subsection 106(4) of the Agvet Code is 60 penalty units. Due to subsection 170(5) of the Agvet Code, the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 106(4) of the Agvet Code will be 300 penalty units.

By virtue of section 145AA of the Agvet Code, the civil pecuniary penalty for new subsection 106(5) of the Agvet Code will be 180 penalty units for individuals and 1,500 penalty units for bodies corporate.

This provides a necessary and proportionate deterrent to non-compliance with the requirement to provide a notice about certain recalls of chemical products and reflects the seriousness of the conduct and the risk that contravening behaviour may pose to human health and safety, the environment and trade if agvet chemicals are not appropriately recalled and monitored by the regulator.

**APVMA publication of recalls**

New subsection 106(6) provides that where the APVMA is notified of a voluntary recall under new subsection 106(2) then it must publish a copy of the notice about this voluntary recall on its website within three working days and in the Gazette within 14 days, this does not prevent the APVMA from also publishing the recall in any other manner it thinks appropriate. These measures will allow stakeholders to be informed of the recall and will promote the effectiveness of the recall.
New subsection 106(7) provides that the publication requirements in new subsection 106(6) do not apply in circumstances prescribed by the regulations. The effect of this measure is to allow the regulations to prescribe circumstances where the APVMA needs to be informed of a recall but does not need to publish the recall (e.g. product hasn’t been distributed to users through the retail chain). There is no value in publicising these kinds of recalls, as the products have only been distributed to a limited range of persons. It is more efficient to contact these persons directly rather than publicise the recalls of the relevant chemical products.

No limitation on obligations under Australian Consumer Law

New subsection 106(8) clarifies that the voluntary recall requirements under section 106(1) to (8) of the Agvet Code do not limit section 128 of Schedule 2 to the Competition and Consumer Act 2010 (about voluntary recall of consumer goods). This reflects the existing section 106 of the Agvet Code.

Item 78 Application provision

Item 78 provides that the amendments made by Part 11 of Schedule 1 to the Bill will apply in relation to recalls on or after the commencement of Part 11 of Schedule 1 to the Bill and will not apply retrospectively.

Part 11 of Schedule 1 to the Bill will commence on the day after the end of the period of three months beginning on the day the Bill receives the Royal Assent.
PART 12—NOTIFICATION OF NEW INFORMATION

Overview

Part 12 of Schedule 1 to the Bill amends the Agvet Code to ensure that obligations to provide relevant information to the APVMA apply to holders of label approvals, and applicants for both label approvals and variations to approvals or registrations; as they do in relation to holders of active constituent approvals and product registrations under sections 160A and 161 of the Agvet Code.

Currently, information is ‘relevant information’ if it shows the active constituent or chemical product may not meet the statutory criteria, or if it contradicts information in the application or information the APVMA has recorded in the record or the register.

Section 160A of the Agvet Code applies to applications lodged with the APVMA for: approval of an active constituent; registration of a chemical product; issue of a permit in respect of an active constituent or chemical product; or issue of a licence in respect of the manufacture of a chemical product.

Section 161 applies to holders of an approval for an active constituent, registration of a chemical product and existing permits in relation to an active constituent or chemical product.

These provisions are intended to ensure the regulator is aware of the latest information that is available and provide safeguards to protect public, animal and plant health and the environment from potential damage where new information about an agvet chemical comes to light. This addresses a gap in the current requirements in sections 160A and 161 (to provide relevant information) as they do not apply to an applicant for approval of a label for containers for a chemical product nor to applicants seeking to vary an approval or registration.

Agricultural and Veterinary Chemicals Code Act 1994

Items 79 and 80  Paragraph 160A(1)(a) of the Code set out in the Schedule

Items 70 and 80 amend paragraph 160A(1)(a) of the Agvet Code to insert new subparagraphs 160A(1)(a)(vi) and (vii), with a consequential minor change to 160(1)(a)(v). Section 160A of the Agvet Code currently deals with requiring applicants for approval of an active constituent and registration of a chemical product to provide relevant information to the APVMA. The amendments extend the scope of applicants that must inform the APVMA of relevant information about their application. The amendments mean the following applicants must also provide relevant information to the APVMA:

- applicants for approval of a label for containers for a chemical product
- applicants for variations of approvals or registrations.

Relevant information is information that contradicts any information that was given in the application and relates to the relevant particulars (set out in paragraphs 19(c) or 20(1)(c) of the Agvet Code), as well as information that shows the constituent or product may not meet the safety criteria, trade criteria or efficacy criteria.

Item 81  Paragraph 160A(1)(c) of the Code set out in the Schedule

Item 81 amends paragraph 160A(1)(c) of the Agvet Code to insert references to the label of a chemical product. This amendment is necessary to complement the amendments in item 80,
which extends the scope of applicants that must inform the APVMA of new relevant information about their application.

**Items 82 and 83**  
**Paragraphs 160A(4)(a) and (b) of the Code set out in the Schedule**  
Items 82 and 83 amend paragraphs 160A(4)(a) and (b) of the Agvet Code to insert references to instructions and particulars on an approved label and labelling criteria. The amendments will extend the meaning of ‘relevant information’ in section 160A so that it includes information about these label-related matters. These amendments are necessary to give full effect to the amendments in item 80.

Item 82 amends subparagraph 160A(4)(a)(ii) of the Agvet Code to include a reference to the relevant particulars for a label approval. The purpose of this amendment is to require an applicant for a label approval to provide information to the APVMA if they become aware of information in their application that contradicts information relating to the matters prescribed for subparagraphs 21(c)(iv) or (iva) of the Agvet Code (instructions and particulars on an approved label, including any particulars prescribed by regulations). This would include information that contradicts information relating to the name of the active constituent or product, or the signal words that are required in a label by the current Poisons Standard.

Item 83 amends subparagraph 160A(4)(b) of the Agvet Code to refer to where the label may not meet the labelling criteria. The purpose of this amendment is to require an applicant for a label approval to provide information to the APVMA if they become aware of information that shows the label may not meet the labelling criteria.

The amendments made by items 82 and 83 will ensure the APVMA remains informed of the latest available information for an application for a label approval and can take the appropriate action to respond to that information.

**Item 84**  
**After paragraph 161(1)(b) of the Code set out in the Schedule**  
Items 84 inserts new paragraph 161(1)(c). Section 161 currently deals with requiring holders of approval of active constituents and registrations of chemical products to provide relevant information to the APVMA. The amendment extends the scope of holders that must inform the APVMA of relevant information to include the holder of the approval of a label for containers for a chemical product.

Currently, relevant information is information that contradicts any information entered in the record or register or record of permits or information that shows the constituent or product may not meet the safety, trade or efficacy criteria.

The amendment means that holders of the approval of a label for containers for a chemical product will have the same obligations to provide relevant information about their approval as currently applies for other holders. The amendment will ensure the APVMA remains informed of the latest available information and can take the appropriate action to respond to any new relevant information.

**Item 85**  
**Subsection 161(1) of the Code set out in the Schedule**  
Item 85 amends subsection 161(1) of the Agvet Code to insert references to the label of a chemical product. This amendment is necessary to complement the amendment in item 84, which extends the scope of holders that must inform the APVMA of relevant information to include holders of approval of a label for containers of a chemical product.
Item 86  **Subsection 161(2) of the Code set out in the Schedule**  
Item 86 is an editorial amendment to replace the current unbolded text of ‘relevant information’ with bolded italicised text of ‘relevant information’. This aligns with the approach used in section 160A. This amendment has no other effect.

Items 87 and 88  **Subsection 161(2) of the Code set out in the Schedule**  
Items 87 and 88 amend subsection 161(2) of the Agvet Code to insert references to label matters and labelling criteria. These amendments are necessary to give full effect to the amendment in item 84, so that the relevant information that must be given to the APVMA includes information about matters relating to labels.

Item 87 amends paragraph 161(2)(a) of the Agvet Code to include a reference to the relevant APVMA file for the label. The purpose of this amendment is to require a holder of a label approval to provide information to the APVMA if they become aware of information that contradicts information in the relevant APVMA file for the label.

Item 88 amends paragraph 161(2)(b) of the Agvet Code to expand the definition of relevant information to incorporate information that shows the label may not meet the labelling criteria. The purpose of this amendment is to require a holder of a label approval to provide information to the APVMA if they become aware of information that shows the label may not meet the labelling criteria.

**Item 89  Application provisions**  
Item 89 provides that the amendments made by Part 12 of Schedule 1 to the Bill will apply in relation to applications lodged on or after the commencement of the amendments. This ensures that the obligations on applicants do not apply retrospectively to applications that have already been lodged with the APVMA. Item 89 also provides that the amendments made by Part 12 of Schedule 1 to the Bill will apply in relation to information a holder becomes aware of after commencement of the amendments. This ensures that the obligations on holders do not apply retrospectively.

Part 12 of Schedule 1 to the Bill will commence on the day after the end of the period of three months beginning on the day the Bill receives the Royal Assent.
PART 13—ANNUAL OPERATIONAL PLANS

Overview

Part 13 of Schedule 1 to the Bill simplifies the APVMA’s corporate reporting requirements by removing the need for the APVMA to develop and seek approval of an annual operational plan in addition to a corporate plan.

Part 6 of the Administration Act currently includes requirements for the APVMA to prepare an annual operational plan. The annual operational plan sets out the actions the APVMA intends to take to comply with the objectives in the corporate plan in the coming year. It includes any performance indicators that the CEO considers appropriate and any information prescribed by regulations. The plan requires annual ministerial approval.

Section 35 of the Public Governance, Performance and Accountability Act 2013 and Part 6 of the Administration Act currently both require the APVMA to prepare a corporate plan. As with the annual operational plan, the corporate plan is prepared annually (but covers four years), and requires ministerial approval. The corporate plan is also presented to the Minister for Finance. Currently, under this Act, the corporate plan must include the following matters (section 16E of the Public Governance, Performance and Accountability Rule 2014):

- 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.

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.

The Public Governance, Performance and Accountability Act 2013 also requires the APVMA to report annually on its performance against the corporate plan. Section 61 of the Administration Act requires that this is done in the APVMA’s annual report.

Agricultural and Veterinary Chemicals (Administration) Act 1992

Items 90 and 91 Part 6 (heading) and sections 55, 56 and 57

Items 90 and 91 amend the heading for Part 6 of the Administration Act and omit sections 55, 56 and 57 of the Administration Act to remove the requirement for the APVMA to develop an annual operational plan.

Items 92 to 94 Paragraphs 61(a), (b) and (d)

Items 92 to 94 make consequential amendments to section 61 (annual report requirements) of the Administration Act to reflect the removal of the annual operational plan.

Item 95 Application and transitional provisions

Item 95 provides that the amendments in Part 13 will apply from the calendar year beginning after the day these amendments commence. Repealed sections 55 to 57 and section 61.
(unamended) will continue to apply to an annual operational plan relating to the period beginning on 1 July of the financial year in which these amendments commence. Item 95 also provides that any regulations made under paragraph 61(b) prior to commencement of this Part continue in force, so the regulations made for the annual report requirements continue to apply.
PART 14—DEFINITION OF REGISTERED CHEMICAL PRODUCT

Overview

Part 14 of Schedule 1 to the Bill amends the Agvet Code definition of a registered chemical product so it is consistent with variations authorised under section 83 of the Agvet Code.

Section 83 of the Agvet Code already provides for the regulations to prescribe, among other things, concentration ranges for constituents in chemical products (‘constituent’ is defined in section 3 of the Agvet Code and includes both active and non-active constituents). This, for example, allows for the routine variations in constituent concentration arising in manufacturing to be prescribed. However, offences and civil penalty provisions in Part 4 of the Agvet Code operate such that a product cannot be supplied if it is formulated differently to the ‘registered’ formulation (therefore, the concentration of the constituents in a product must match that in the register). Thus, there is an anomaly in the Agvet Code in that, for the offences and civil penalty provisions in Part 4, the chemical product formulation must align exactly with the concentrations of constituents in the register, irrespective of any variation in constituent concentration that is provided for by the regulations made for section 83.

This inconsistency places an unreasonable burden on the APVMA and industry because the only means to address this would be through holders making applications to the APVMA to include more detail about a product’s composition in the register. The regulatory effort associated with this task is inconsistent with the risks, particularly given that some provisions of the Agvet Code already provide for these reasonable variations in a product’s composition.

The amendments in the Bill address these inconsistencies by providing, through the definition of registered chemical product, for prescribed standards for the concentration range of constituents, the kinds of constituents, and the composition and purity of constituents in chemical products to apply for all offences and civil penalty provisions in the Agvet Code.

It is not intended that the amendments would allow for fundamental changes in a product’s composition which would continue to require a variation application to the APVMA.

Agricultural and Veterinary Chemicals Code Act 1994

Item 96 Section 3 of the Code set out in the Schedule (definition of registered chemical product)

Item 96 inserts a new provision in section 3 of the Agvet Code to refer to a new definition of ‘registered chemical product’ in section 5AA (as inserted by item 97).

Item 97 After section 5 of the Code set out in the Schedule

Item 97 inserts a new definition of a ‘registered chemical product’ at new section 5AA of the Agvet Code. This extends the scope of what constitutes a registered chemical product under the Agvet Code to reflect the variations in a product’s composition that are authorised by regulations made for section 83 of the Agvet Code.

Section 83 of the Agvet Code effectively provides for reasonable variations in a product’s composition, such as those that reflect manufacturing processes for chemical products. Specifically, it provides that the following may vary within certain limits that are prescribed in regulations:

- a chemical product’s constituents
• the concentration of each constituent in the product
• the composition and purity of each constituent in the product.

Currently, regulation 41 of the Code Regulations sets out the variations prescribed for the purpose of section 83.

However, the variations prescribed for section 83 do not extend to other provisions in the Agvet Code, including the offences and civil penalty provisions in sections 75 and 78 (which relate to possessing with the intention of supply, or supplying an unregistered chemical product). This results in an inconsistency where, although some provisions allow for reasonable variations in a product’s composition, others do not.

The new definition addresses this inconsistency. This will reduce the burden on the APVMA and industry. Holders will no longer need to apply to the APVMA to amend the relevant particulars of their registration, as the reasonable variations in a product’s composition could be prescribed in the regulations and there would be no need for the register to include these details for each chemical product.

Like the current definition of registered chemical product, the definition in new section 5AA continues to provide that a registered chemical product includes a chemical product that is registered by the APVMA and complies with the relevant particulars for that registration in the register. However, the new definition extends the scope of the current definition so that a registered chemical product includes where a product varies within the extent (i.e. the range) of:

• the constituents prescribed in regulations made for paragraph 83(1)(a) of the Agvet Code (subsection 5AA(2))
• the concentration of each constituent prescribed in regulations made for paragraph 83(1)(b) of the Agvet Code (subsection 5AA(3))
• the composition of each constituent prescribed in regulations made for paragraph 83(1)(c) of the Agvet Code (subsection 5AA(4))
• the purity of each constituent prescribed in regulations made for paragraph 83(1)(c) of the Agvet Code (subsection 5AA(5)).

New subsection 5AA(1) is the general rule that specifies the requirements for the relevant particulars of a chemical product registration. New subsections 5AA(2) to (5) modify that rule so as to extend the scope of these requirements but only if:

• there are regulations made to extend the scope; and
• the particulars are within the scope prescribed in the regulations made for section 83.

For example, where the register specifies a product must contain 100 g/kg of a constituent then that is precisely what the chemical product must contain unless provided for in a regulation made under subsection 83(3) of the Agvet Code. However, if the regulations prescribe that the constituents in a chemical product must not differ by more than six per cent of the concentration in the register, then the chemical product would be allowed to contain between 94 g/kg and 106 g/kg of the constituent and still remain a registered chemical product for the purposes of the Agvet Code.
PART 15—SUPPLY OF REGISTERED CHEMICAL PRODUCTS WITH UNAPPROVED LABEL

Overview

Part 15 of Schedule 1 to the Bill addresses an inconsistency in the Agvet Code by clarifying what information must be included in a label.

The current section 81 of the Agvet Code requires that the label attached to the container for a chemical product must state the ‘relevant particulars’. However, it is not appropriate that all relevant particulars should appear on a label. For example, the name of the nominated agent and the holder of approval—as opposed to the marketer of the product—are unnecessary. This inconsistency needs to be addressed as there is a serious criminal offence and a civil penalty provision for not including all ‘relevant particulars’ on a label.

Agricultural and Veterinary Chemicals Code Act 1994

Items 98 to 101 Subsections 81(1) and (2) of the Code set out in the Schedule

Items 98 to 101 amend subsections 81(1) and (2) of the Agvet Code to replace all references to ‘relevant particulars’ with ‘the minimum information’ (defined in new subsection 81(5)—see item 103) when discussing the correct information that must be in a label. The effect of these amendments would be to specify only those minimum information requirements that must be included on a label to reduce the need for inappropriate and unnecessary information. See the Statement of Compatibility with Human Rights for more information about the existing reverse burden defence in subsection 81(2).

Item 102 Paragraphs 81(3)(a), (b) and (c) of the Code set out in the Schedule

Item 102 replaces paragraphs 81(3)(a), (b) and (c) with new paragraphs 81(3)(a), (b), (c) and (d). Subsection 81(3) provides for a registered chemical product to be supplied for a limited period (2 years, or other period as determined by the APVMA) if the information on the label is different from that required when supply occurs, but is information that was required on the label at a time before supply took place.

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 to subsection 81(3) continue to 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. See the Statement of Compatibility with Human Rights for more information about the existing reverse burden exception in subsection 81(3).

Item 103 At the end of section 81 of the Code set out in the Schedule

Item 103 inserts new subsection 81(5) into the Agvet Code to specify what ‘minimum information’ means for the purposes of section 81. Minimum information is the information covered by subparagraphs 21(c)(iii) and (iv) of the Agvet Code (the distinguishing number, instructions and particulars that are to be contained on a label). These particulars can include matters such as any signal heading required by a constituent’s poisons scheduling and the name of the product.
Item 104  Application provision
Item 104 provides that the amended requirements in Part 15 of Schedule 1 would only apply to supplies occurring on or after the commencement of Part 15, to avoid retrospective application. Part 15 of Schedule 1 to the Bill will commence on the day after the Bill receives the Royal Assent.
PART 16—SAFETY, EFFICACY, TRADE AND LABELLING CRITERIA

Overview

Part 16 of Schedule 1 to the Bill amends the Agvet Code to address anomalies in relation to prescribing matters for the labelling criteria and for overseas trials and experiments (including international assessments and data) in relation to the safety, efficacy, trade and labelling criteria.

Under section 5D of the Agvet Code, there is no power for the regulations to prescribe matters the APVMA must have regard to for the purposes of being satisfied that a label meets the labelling criteria. This is inconsistent with the regulation-making powers for the other statutory criteria in sections 5A (safety criteria), 5B (efficacy criteria) and 5C (trade criteria).

Separately, section 160 of the Agvet Code provides the APVMA with the discretion to consider overseas trials and experiments, including international assessments and information. This discretion creates an anomaly in that it means the regulations made under sections 5A to 5C may not be able to prescribe that the APVMA must have regard to overseas trials and experiments. This is because the discretion in primary legislation means the regulations cannot modify this discretion.

Agricultural and Veterinary Chemicals Code Act 1994

Item 105  At the end of subsection 5D(2) of the Code set out in the Schedule
Item 105 amends section 5D of the Agvet Code to allow the regulations to prescribe matters the APVMA must have regard to for the purposes of being satisfied that a label meets the labelling criteria, similar to the current regulation-making powers in sections 5A to 5C of the Agvet Code.

Item 106  After section 5D of the Code set out in the Schedule
Item 106 inserts a new section 5E into the Agvet Code to allow regulations, if necessary in the future, to prescribe that the APVMA must have regard to the matters in section 160 of the Agvet Code.

Item 107  Application provision
To avoid retrospective application, item 107 provides that any matters prescribed in regulations for the labelling criteria only apply after Part 16 commences. Part 16 will commence the day after the Royal Assent.
PART 17—MAXIMUM RESIDUE LIMITS STANDARD

Overview

Part 17 of Schedule 1 to the Bill amends:

- the Agvet Code to simplify, and provide flexibility on the timing of, the notification that must be provided to FSANZ by the APVMA in relation to an approval, registration, variation or permit under the Agvet Code which would, if given, made or issued be likely to require a corresponding variation to the Maximum Residue Limits Standard
- the Administration Act to clarify that the requirement to publish an APVMA legislative instrument for residues of chemical products in protected commodities under section 7A of the Administration Act also provides the authority for this legislative instrument to be made and amended as required.

The *Australia New Zealand Food Standards Code — Schedule 20 – Maximum residue limits* (under the *Food Standards Australia New Zealand Act 1991*)—defined in section 3 of the Agvet Code as the Maximum Residue Limits Standard, is adopted by various state laws for setting the maximum concentration of a residue in food. It covers food from any source (domestic or overseas), so includes residues of chemicals not authorised for use in Australia.

Section 82 of the Food Standards Australia New Zealand Act allows the APVMA to directly vary the *Foods Standards Code Maximum Residue Limits Standard* (that is, the standard under food law). This process is triggered by the APVMA notifying FSANZ of the proposed variation under section 8E of the Agvet Code.

Separately, current section 7A of the Administration Act requires the APVMA to publish, in each calendar year, approved standards for residues of chemical products in protected commodities (that is, a standard under agvet chemical law). This helps authorities monitor whether agvet chemical products are being used in accordance with the APVMA-approved labels.

*Agricultural and Veterinary Chemicals (Administration) Act 1992*

**Item 108 Section 7A (heading)**

Item 108 amends the heading for section 7A of the Administration Act to replace the words ‘Annual publication’ with ‘Approval’. This change is consequent to the amendments made to subsection 7A(1) of the Administration Act by item 109.

**Item 109 Subsection 7A(1)**

Item 109 repeals and substitutes subsection 7A(1) of the Administration Act. New subsection 7A(1) makes clear that the APVMA is authorised to approve standards for residues of chemical products in protected commodities and not merely *publish* such standards (as per the wording of the repealed subsection 7A).

Subsection 7A(1) also clarifies that the standards are approved by way of legislative instrument. Whereas the previous requirement was to publish the standards every calendar year, the new requirement does not require the standards to be approved every calendar year. This means that the APVMA may approve, and hence publish these residues standards as often as it finds necessary. Subsection 33(1) of the *Acts Interpretation Act 1901* provides that where an Act confers a power or function or imposes a duty, then the power may be exercised and the function or duty must be performed from time to time as occasion requires.
Agricultural and Veterinary Chemicals Code Act 1994

Item 110  Subparagraph 8E(2)(b)(i) of the Code set out in the Schedule
Item 110 amends subparagraph 8E(2)(b)(i) to simplify the requirements for notices provided to FSANZ, while still ensuring these include the information that FSANZ requires (specifically the names, or proposed names, of the active constituents concerned). This reflects the information required to be recorded in the Maximum Residue Limits Standard.

Paragraph 8E(2)(b) of the Agvet Code sets out what information must be included in an APVMA notice to FSANZ under section 8E of the Agvet Code. This includes the relevant particulars, or proposed relevant particulars, of the active constituents and products concerned, other than confidential commercial information. FSANZ is subsequently obliged to publish these particulars (under paragraph 81(1)(b) of the Food Standards Australia New Zealand Act 1991). However, at the time of application (for many applications, but not all) most of the relevant particulars are confidential commercial information and are not needed/serve no purpose for FSANZ. The only particular that is actually of relevance to the proposed MRL change is the name of the active constituent. The proposed amendment in this Bill will require only the name of the active constituent concerned to be included in the notice to FSANZ.

Item 111  Paragraph 8E(2)(c) of the Code set out in the Schedule
Item 111 repeals paragraph 8E(2)(c) of the Agvet Code and inserts a new paragraph 8E(2)(c).

Subsections 8E(1) and (2) of the Agvet Code currently provide that the APVMA must notify FSANZ within 28 days if an approval, registration, variation or permit proposed under the Agvet Code (whether by application or on the initiative of the APVMA) would, if it were given, made or issued, be likely to require a variation to the Maximum Residue Limits Standard. New paragraph 8E(2)(c) of the Agvet Code provides that the notice of an approval, registration, variation or permit proposed under the Agvet Code would, if it were given, made or issued, be likely to require a variation to the Maximum Residue Limit Standard, must be given to FSANZ before it is given, made or issued. Accordingly, item 111 removes the current 28 day notification timeframe in subparagraph 8E(2)(c)(i) of the Agvet Code.

New paragraph 8E(2)(c) of the Agvet Code ensures that the notification requirements for proposed approvals, registrations, variations or permit applications are treated consistently. New paragraph 8E(2)(c) of the Agvet Code will provide the APVMA and FSANZ with the flexibility to liaise and agree on appropriate timeframes. This will enable the APVMA to assess whether a variation to the Maximum Residue Limit Standard is likely to be required due to the giving, making or issuing of an approval, registration, variation or permit under the Agvet Code, while still providing FSANZ with appropriate time to consider the notification and undertake any necessary preparatory work.

Item 112  Application provision
Item 112 provides that the amendments to section 8E of the Agvet Code by items 110 and 111 will apply in relation to notices given on or after the commencement of Part 17 of Schedule 1 to the Bill. Item 112 ensures that the proposed amendments will not apply retrospectively.

Part 17 of Schedule 1 to the Bill will commence on the day after the Bill receives the Royal Assent.
PART 18—EXPIRY DATE

Overview

Part 18 of Schedule 1 to the Bill amends the definition of expiry date in section 3 of the Agvet Code to clarify that the expiry date is the date after which a chemical product must not be used. The proposed amendment ensures that the expiry date reflects the timeframe in which the use of a chemical product is safe, effective and does not cause unmanageable risks.

Agricultural and Veterinary Chemicals Code Act 1994

Item 113  Section 3 of the Code set out in the Schedule (definition of expiry date)
Item 113 omits the reference to “should” in the definition of expiry date in section 3 of the Agvet Code, and substitutes that reference with a reference to “must”.

Section 3 of the Agvet Code defines expiry date, in relation to the contents of a container, to mean the month and year after which the contents should not be used. Item 113 clarifies that the expiry date for a date-controlled chemical product is the date after which a chemical product must not be used.

Section 3 of the Agvet Code defines date-controlled chemical product to mean a chemical product declared by the regulations made under section 6 of the Code Act to be a date-controlled chemical product. Schedule 1 to the Agvet Code Regulations declares certain chemical products to be date-controlled chemical products.

The proposed amendment ensures that the definition of expiry date reflects the timeframe in which the use of a chemical product is safe, effective and does not cause unmanageable risks.

Item 114  Application provision
Item 114 provides that the amendment to the definition of expiry date in section 3 of the Agvet Code by item 113 will apply in relation to a supply referred to in subsections 85(1), 91(1) or (2) of the Agvet Code that occurs on or after the commencement of Part 18 of Schedule 1 to the Bill. Item 114 is consequential to the amendment to the definition of expiry date in section 3 of the Agvet Code by item 113, and ensures that the proposed amendment will not apply retrospectively.

Part 18 of Schedule 1 to the Bill will commence on the day after the Bill receives the Royal Assent.
PART 19—OTHER AMENDMENTS

Overview

Part 19 of Schedule 1 to the Bill will improve the operation of the Administration Act and the Agvet Code by:

- removing redundant and unnecessary provisions (including unnecessary transitional provisions)
- clarifying how ‘classes’ of matter are dealt with to ensure consistency with both subsection 33(3A) of the Acts Interpretation Act 1901 and subsection 13(3) of the Legislation Act 2003
- authorising the APVMA to reconsider (internally review) decisions on its own initiative to improve the ability of the APVMA to respond where errors are made and reduce the onus on other persons to request the APVMA to internally review a decision
- make a number of minor amendments to the Administration Act and the Agvet Code to improve the operation of these laws and remove redundant and unnecessary provisions.

Agricultural and Veterinary Chemicals (Administration) Act 1992

Items 115 and 116  Paragraphs 7(1A)(a) and 8A(2)(a) and (b)

Items 115 and 116 are minor amendments to the Administration Act to align section 7 with the role of the APVMA and to align section 8A with the approach used for applications in the Agvet Code.

Item 117  Subsection 58(7)

Items 117 removes an unnecessary definition of Finance Minister as this is already defined in section 4 of the Administration Act.

Item 118  Subsection 69D(1)

Item 118 amends section 69D of the Administration Act, which deals with export certificates the APVMA may issue. The amendment clarifies that the fee for export certificates is to be paid to the Commonwealth, like all other fees the APVMA receives.

Item 119 and sub-item 123(1)  After subsection 69D(1A) and application provision

Item 119 adds to the amendment in item 118 to section 69D of the Administration Act to provide that the APVMA may, on its own initiative, reconsider a decision to refuse to give an export certificate and must give notice of the outcome of the reconsideration to the person who applied for the certificate.

Sub-item 123(1) provides that the amendments made by item 119 only apply to decisions made after commencement, to avoid retrospective application of the amendments. Part 19 of Schedule 1 to the Bill will commence on the day after the Bill receives the Royal Assent.

These measures allow the APVMA to deal with errors without a person having to apply to have a decision reconsidered.

Item 120 and sub-item 123(2)  Part 7B and savings provision

Item 120 repeals Part 7B of the Administration Act. Part 7B of the Administration Act currently provides for the modification of the Agvet Code for the purpose of giving effect to paragraph 3 of Article 39 of the Trade-Related Aspects of Intellectual Property Rights.
Part 7B of the Administration Act became redundant in November 2016 because there are no longer any applications remaining to which Part 7B of that Act could apply. As there are no longer any applications before the APVMA to which Part 7B of the Administration Act could apply, it is no longer necessary to retain Part 7B of the Administration Act.

Sub-item 123(2) provides that, despite the repeal of Part 7B of the Administration Act by item 120, an approval referred to in section 69EZ of the Administration Act, as in force immediately before the commencement of Part 19 of Schedule 1 to the Bill, continues to apply on and after that commencement in relation to an approval that was given before that commencement. Part 19 of Schedule 1 to the Bill will commence on the day after the Bill receives the Royal Assent.

Sub-item 123(2) preserves the effect of section 69EZ of the Administration Act for the purposes of applications that have been granted but would have otherwise been prohibited by section 69EY of that Act. Sub-item 123(2) is consequential to the repeal of Part 7B of the Administration Act by item 120.

Item 121   Subsection 72(5)
Item 121 amends subsection 72(5) of the Administration Act to provide that the review of agvet legislation in section 72 of the Administration Act may be tabled before the 10 year anniversary of the commencement of that section. This addresses an anomaly in section 72 whereby, although subsection 72(1) requires that the minister ensures a review of the agvet legislation is required at least every 10 years, subsection 72(5) prevents this review report from being tabled until after 10 years have passed. The amendment provides flexibility around when the review can be tabled, consistent with the timing for the conduct of the review under existing subsection 72(1).

Item 122   Sections 78, 79 and 80
Item 122 repeals sections 78, 79 and 80 of the Administration Act as these transitional provisions (from commencement of the Administration Act in 1993) are no longer necessary.

Item 123   Application and saving provisions
Item 123 consists of two sub-items. Sub-item 123(1) is an application provision discussed at item 119. Sub-item 123(2) is a savings provision discussed at item 120.

Agricultural and Veterinary Chemicals Code Act 1994

Item 124   After section 6E of the Code set out in the Schedule
Item 124 inserts a new section 6F into the Agvet Code to make it clear that references to a kind of matter or thing includes classes of matter or things (particularly relevant to matters such as substances, chemical products, constituents or labels) consistent with the approach provided for in the Acts Interpretation Act 1901 and the Legislation Act 2003.

Item 125   Subparagraph 8A(a)(v) of the Code set out in the Schedule
Item 125 omits the reference to “subparagraph.” in subparagraph 8A(a)(v) of the Agvet Code, and substitutes that reference with a reference to “subparagraph; and”. Section 8A of the Agvet Code currently provides for the definition of meets the application requirements.

Subparagraph 8A(a)(v) of the Agvet Code currently forms part of a list in section 8A of the Agvet Code and the full stop currently at the end of subparagraph 8A(a)(v) of the Agvet Code appears to conclude the list. As there are other paragraphs after subparagraph 8A(a)(v) of the
Agvet Code that form part of the definition of *meets the application requirements*, it is appropriate that subparagraph 8A(a)(v) of the Agvet Code be amended to include a semi-colon at the end of that subparagraph.

**Item 126** Subparagraph 14A(1)(a)(ii) of the Code set out in the Schedule
Item 126 corrects the spelling of the ‘United States Pharmacopeia’ in subparagraph 14A(1)(a)(ii).

**Item 127** Subsection 46(1) of the Code set out in the Schedule
Item 127 omits the reference to “relevant file” in subsection 46(1) of the Agvet Code, and substitutes that reference with a reference to “relevant APVMA file”. This clarifies that the file referred to in subsection 46(1) of the Agvet Code is the same file defined by section 3 of the Agvet Code.

Item 127 ensures that consistent terminology is used throughout the Agvet Code and seeks to overcome any ambiguity in interpreting subsection 46(1) of the Agvet Code.

**Item 128** Paragraph 51(c) of the Code set out in the Schedule
Item 128 omits the reference to “relevant file” in paragraph 51(c) of the Agvet Code, and substitutes that reference with a reference to “relevant APVMA file”. This clarifies that the file referred to in paragraph 51(c) of the Agvet Code is the same file defined by section 3 of the Agvet Code.

Item 128 ensures that consistent terminology is used throughout the Agvet Code and seeks to overcome any ambiguity in interpreting paragraph 51(c) of the Agvet Code.

**Items 129 to 152 and 156** Sections 74, 75, 76, 78 and 167 of the Code set out in the Schedule
Items 129 to 152 and 156 will remove unnecessary provisions for exceptions and determinations that the APVMA could make about approvals and registrations that had ceased under sections 74, 75, 76 and 78. These provisions have never been used by the APVMA and provide for the APVMA to authorise the supply, possession and custody of active constituents and products after the approval or registration has ceased. The APVMA has not needed these provisions as its existing powers to issue permits or exemptions have been sufficient to deal with any supply, possession or custody authorisations needed after an approval or registration has ceased.

**Item 153** Paragraph 117A (1)(a) of the Code set out in the Schedule
Item 153 corrects an error in paragraph 117A(1)(a) of the Agvet Code so that it refers to where the APVMA proposes ‘to suspend or cancel a permit’ rather than an ‘approval or registration’ (‘approval or registration’ is an error).

**Items 154, 155 and 158** Section 166 of the Code set out in the Schedule and application provision
Items 154 and 155 provide for the APVMA to, on its own initiative, reconsider a decision under the Agvet Code or regulations. This includes a requirement to give a notice of the outcome of the reconsideration to the relevant persons (new subsection 166(4B)). To avoid retrospective application, item 158 provides that these amendments only apply to original decisions made after commencement.
Under section 166 of the Agvet Code a person can request the APVMA to reconsider a decision the APVMA has made under the Agvet Code. These are known as ‘internal reviews’. However, the APVMA cannot currently internally review a decision on its own initiative. This reduces the ability of the APVMA to respond where errors are made and places the onus on other persons to request the APVMA to internally review a decision. These amendments make it easier for the APVMA to deal with any errors in decisions and not have to rely on other persons requesting reconsiderations of decisions.

**Item 157 Sections 180, 183 and 184 of the Code set out in the Schedule**

Item 157 will repeal three transitional provisions in the Agvet Code that are no longer necessary. The transitional provisions that dealt with reconsiderations (chemical reviews), pending AAT proceedings and notices for information from before the commencement of the Agvet Code in 1995 are no longer necessary.
PART 20—REPEALS

Overview

Part 20 of Schedule 1 to the Bill repeals the Removing Re-approval and Re-registration Act.

Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014

Item 159 The whole of the Act
Item 159 repeals the Removing Re-approval and Re-registration Act, as all the transitional provisions for this Act are no longer required.
Schedule 2—Australian Pesticides and Veterinary Medicines Authority Board

Agricultural and Veterinary Chemicals (Administration) Act 1992

Item 1 Section 4 (definition of Advisory Board)
Item 1 repeals the definition of the Advisory Board in section 4 of the Administration Act. The definition of Advisory Board is obsolete consequential to item 11 below which repeals the provisions establishing the Advisory Board.

Item 2 Section 4
Item 2 inserts new definitions of ‘appointed Board member’ and ‘Board’ in the Administration Act.

Items 3 and 4 Section 4 (definitions of Board Member and Chair)
Items 3 and 4 repeal the definitions of ‘Board member’ and ‘Chair’ in the Administration Act relating to the Advisory Board and substitute new definitions for these terms that are appropriate for the establishment of the APVMA Board.

Item 5 Section 4
Item 5 inserts the definition of ‘paid work’ in section 4 of the Administration Act to clarify what may be considered to be conflicting outside employment undertaken by Board members. The definition is consistent with enabling legislation for other Australian Government bodies and with the Office of Parliamentary Counsel’s Drafting Direction No. 3.6 Commonwealth bodies.

Item 6 Subsection 8(3)
Item 6 repeals subsection 8(3) of the Administration Act that provides that the APVMA does not consult the APVMA Advisory Board for the purpose of this section when the CEO requests advice from the Board. This provision is obsolete consequential to item 11 below which repeals the provisions establishing the Advisory Board.

Item 7 Paragraph 10(2)(c)
Item 7 repeals ‘Chief Executive Officer’ from paragraph 10(2)(c) of the Administration Act and substitutes ‘Board’. The Board, rather than the CEO, will report directly to the Minister.

Item 8 Section 10A
Item 8 repeals section 10A that relates to the CEO not being subject to direction on certain matters. The Board will be the accountable authority under the PGPA Act and corresponding provisions are now captured at new subsection 27G(3). The CEO will remain the Agency Head under the Public Service Act 1999 and corresponding provisions are now captured in new subsection 32(7).

Item 9 Part 3 (heading)
Item 9 repeals the heading to Part 3 of the Administration Act ‘Constitution of APVMA and Advisory Board’ and substitutes a new heading, ‘Constitution of APVMA, the Board and committees’.
**Item 10** **Section 13**
Item 10 repeals section 13 of the Administration Act, which sets out that the APVMA consists of the CEO. This provision is inconsistent with the APVMA’s status as a body corporate with a governing Board.

**Item 11** **Divisions 2, 3 and 4 of Part 3**
Item 11 repeals Divisions 2, 3 and 4 of Part 3 to the Administration Act as these contain provisions relating to the APVMA Advisory Board, including its establishment, membership, appointment of members and procedures. Repealing these provisions ceases the Advisory Board.

This item also inserts into Part 3 to the Administration Act a new Division 2—Board of the APVMA, which sets out the provisions of the Board. These provisions are grouped into new subdivisions A to K of Division 2 as follows:

**Subdivision A—Establishment and functions of the Board**

This subdivision sets out the establishment and functions of the Board as follows.

**Section 14 Establishment of the Board**

This section establishes the Board of the APVMA.

**Section 15 Functions and powers of the Board**

This section sets out the functions and powers of the Board of the APVMA which include:

- ensuring the proper, efficient and effective performance of the APVMA’s functions
- determining the objectives, strategies and policies to be followed by the APVMA
- doing anything incidental to or conducive to the performance of these functions.

This new section also empowers the Board to do all things necessary or convenient to be done for, or in connection with the performance of its functions.

The Board must have regard to section 1A of the Agvet Code when determining objectives, strategies and policies to be followed by the APVMA. Section 1A of the Agvet Code sets out how the Agvet Code is to be implemented by the APVMA and provides the framework for the evaluation, approval, registration and control of the supply of agvet chemicals. The purpose of this measure is to prevent the potential for any inconsistency or conflict in the objectives, strategies and policies determined by the Board of the APVMA and the implementation of the Agvet Code by the APVMA.

The functions of the Board will complement, but not duplicate the duties of the CEO (as set out in section 32 of the Administration Act and amended by item 13 and 14 below). This split in responsibilities will ensure the Board provides the appropriate level of oversight, but will prevent it from getting involved in the day-to-day decision making of the APVMA (such as individual agvet chemical product registrations or compliance activities), which could affect the APVMA’s ability to deliver independent and evidence-based decisions.
Section 16 Limitation on functions and powers of the Board

The Board of the APVMA is a separate entity from the legal body corporate that is the APVMA. Amended section 32 of the Administration Act (see items 13 and 14) provides that only the APVMA CEO may exercise any of the powers and perform any of the functions of the APVMA, and existing section 44 provides for the APVMA CEO to delegate these functions and powers.

The Board of the APVMA cannot make decisions that the APVMA may make. The Board of the APVMA provides the appropriate level of oversight of the APVMA, but is prevented from getting involved in the day-to-day decision making of the APVMA. New section 16 makes this clear by specifying that the functions and powers of the Board of the APVMA do not include making decisions under agvet chemical legislation, other than certain parts of the Administration Act.

Subdivision B—Board members

This subdivision sets out the Board membership requirements as follows.

Section 17 Membership of the Board

The Board consists of a Chair, the APVMA CEO and three other members. 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. The CEO is included as an ex officio Board member to support informed and collective decision making and ensure the Board’s policies are effectively integrated into day-to-day operations, for example, policies to support quality decision-making.

Section 18 Appointment of appointed Board members

New subsection 18(1) allows for the Minister to appoint Board members by written instrument. Under this provision, the Minister will also appoint one of the appointed members as Chair. Board members will be appointed on a part-time basis. An instrument of appointment under subsection 18(1) would not be a legislative instrument by virtue of the existing exemption under item 8 in the table at subsection 6(1) of the Legislation (Exemptions and Other Matters) Regulation 2015. This provides that an instrument of appointment is not a legislative instrument.

It is important that, as a group, the Board has the skills, knowledge and experience needed to oversee the APVMA. New subsection 18(2) sets out the range of skills that the government considers necessary to have within the Board for it to effectively exercise its responsibilities. It provides that a person cannot be appointed as a Board member unless the responsible Minister is satisfied they have appropriate qualifications, skills or experience in one or more of the following:

- financial management
- law
- risk management
- public sector governance
- science (including agricultural science and veterinary science)
public health or occupational health and safety.

The risk management skills requirement relates to risk management generally and is not limited to chemical risk management skills.

A note in new section 18 makes it clear that an appointed Board member may be reappointed, in accordance with section 33AA of the Acts Interpretation Act 1901.

New subsection 18(3) also provides that the Minister ensures, to the extent practicable, an appropriate mix of persons from the above fields of expertise so there is sufficient diversity in the skills, qualifications and experience on the Board.

Section 19 Term of appointment

This new section specifies that an appointed Board member holds office for the period specified in their instrument of appointment. This period cannot exceed four years. New subsection 19(2) also sets out that appointed Board members may be eligible for reappointment for a second term (that is, appointed Board members may be appointed for no longer than eight consecutive years).

While the 2003 Review of Corporate Governance of Statutory Authorities and Office Holders (the Uhrig Review) supported finite Board terms and suggested appointments generally be limited to three years, there is no standard or prescribed term for Board appointments. Board terms generally range between three and five years across government bodies, with re-appointment an option in some circumstances.

It is considered that appointments of up to four years are appropriate for this Board given its size. This approach balances the benefits of Board continuity with rejuvenation, and provides a mechanism to retain high performing appointed Board members for a second term.

Section 20 Acting Board members

New subsections 20(1) and 20(2) empower the Minister to appoint, by written instrument, a Board member to act as the Chair, or a person to act as a member of the Board. The circumstances where these acting appointments are permitted are:

- during a vacancy in the office of Chair or appointed Board member
- during a period when the Chair or appointed Board member is absent from duty or from Australia or
- during a period where the Chair or the appointed Board member is, for any reason, unable to perform the duties of the office.

New subsection 20(3) provides that the Minister may only appoint a person to act as an appointed Board member if the Minister is satisfied that the person is qualified under new subsection 18(2). This requires the Minister to maintain the skills balance while any acting arrangements are in place.

These provisions have been included to assist in the continuing and effective functioning of the Board in the absence of the Chair or other Board member.
An instrument of appointment as an acting appointed Board member would not be a legislative instrument, by virtue of the exception in item 8 of the table in subsection 6(1) of the *Legislation (Exemptions and Other Matters) Regulation 2015*.

A note in new section 20 identifies that sections 33AB and 33A of the *Acts Interpretation Act 1901* provides further information about acting appointments, including validity of things done during an acting appointment.

**Section 21 Remuneration**

This new section requires appointed Board members to be paid the remuneration that is determined by the Remuneration Tribunal or, if no determination is in operation, the member is to be paid the remuneration that is prescribed by the regulations.

While the Remuneration Tribunal’s determination would include remuneration, the Tribunal is not required to make additional determinations. As such, this section also allows for appointed Board members to be paid the allowances that are prescribed by the regulations (which may include travelling allowances).

New subsection 21(3) specifies that this section has effect subject to the *Remuneration Tribunal Act 1973*, which establishes the Remuneration Tribunal and sets out the rules for the making of determinations by the Tribunal.

**Section 22 Paid work**

This new section restricts Board members from engaging in any paid work (consistent with the definition inserted by item 5) that, in the opinion of the responsible Minister, conflicts or could conflict with the proper performance of their duties. This is intended to ensure the expected duties and performance of Board members will not be impacted by any outside employment.

**Section 23 Leave of absence**

This new section provides that the Minister may grant the Chair a leave of absence, subject to terms and conditions determined by the Minister. It also provides that the Chair may grant a leave of absence to an appointed Board member, subject to terms and conditions determined by the Chair.

**Section 24 Resignation of appointment**

New subsection 24(1) allows for an appointed Board member to resign by giving the Minister a written resignation. New subsection 24(2) provides that the resignation takes effect on the day it is received by the Minister, unless another day is specified in the resignation.

**Section 25 Termination of appointment**

This new section sets out the grounds upon which the Minister may terminate the appointment of an appointed Board member:

- for misbehaviour
- if the appointed Board member is unable to perform their duties due to physical or mental incapacity
• if the member becomes bankrupt, applies for relief from bankruptcy, compounds with their creditors, or assigns part of their remuneration for the benefit of creditors

• if the member does not attend three consecutive meetings of the Board and is not on a leave of absence during that time

• if the member engages in paid work that, in the opinion of the Minister, conflicts or could conflict with the proper performance of their duties (refer new section 22 of the Administration Act) or

• if the Minister is satisfied that the member’s performance has been unsatisfactory.

The note also provides for an appointed Board member to be terminated for contravening the general duties of officials under section 30 of the PGPA Act.

These provisions are intended to ensure appointed Board members are financially responsible and are competently carrying out their duties.

Section 26 Other terms and conditions

This new section allows for the Minister to determine the terms and conditions on which an appointed Board member holds office for matters not provided for in this Bill.

Subdivision C—Meetings of the Board

This subdivision sets out requirements for meetings of the Board as follows.

Section 27 Convening meetings

This new section requires the Board to hold meetings as necessary for the efficient performance of its functions. It allows the Chair to convene a meeting at any time. It also requires the Chair to convene at least four meetings per year and within 30 days of receiving a written request for a meeting from another Board member. These provisions have been included to support the appropriate functioning of the Board.

Because of the transitional provision at item 40, the Chair is not required to convene four meetings in the calendar year of the Board’s establishment.

Section 33B of the Acts Interpretation Act 1901 contains provisions about participation in meetings other than in person. Under that section, the Board may permit any or all members to participate in a meeting by telephone, closed-circuit television or any other means of communication and these members are taken to be present at the meeting and to form part of any quorum for the meeting. Where permission has been granted to participate in meetings by telephone, closed-circuit television or any other means of communication, a meeting may be held at two or more places at the same time.

Section 27A Presiding at meetings

This new section requires the Chair to preside at all meetings they attend. In the absence of the Chair or Acting Chair, the other Board members present must appoint one of themselves to preside. There is no restriction on which Board members are eligible to preside at meetings in this instance. This provision ensures there is always a Chair presiding over a Board meeting.
Section 27B Quorum
This new section provides that a quorum is constituted by a majority of Board members.

Section 27B also provides that should a Board member not be present during the deliberations, due to the requirements of section 29 of the PGPA Act and a quorum is no longer present, then the remaining Board members at the meeting constitute a quorum.

Section 27C Voting at meetings
This new section deals with voting at Board meetings. It specifies that questions at Board meetings are to be decided by a majority of the votes of the members present and voting. It also specifies that the person presiding at a meeting, as outlined under section 27A has a deliberative and, if votes are equal, a casting vote (i.e. an extra vote to allow a question to be decided). This provision is included to ensure the effective functioning of the Board.

Section 27D Conduct of meetings
This new section gives discretion to the Board to regulate the conduct of its meetings on terms it considers appropriate. The note provides that section 33B of the Acts Interpretation Act 1901 contains further information about participation in meetings.

Section 27E Minutes
This new section requires the Board to keep minutes of its meetings. Subsection 27E(2) requires the Board to provide its meeting minutes and papers to the Secretary of the Department within 20 business days of the relevant meeting. While this is not a standard provision, it is included to ensure ongoing transparent communication between the Board, the Department and the Minister. This is necessary given the Minister’s overarching responsibility for agvet chemical policy, in which the APVMA plays a key role.

Section 27F Decisions without meetings
This new section allows for the Board to determine that decisions can be made without a meeting and also the method by which Board members are to indicate agreement with proposed decisions.

Subsection 27F(1) provides that a decision is taken to have been made at a Board meeting if:

- without meeting, a majority of Board members entitled to vote on the proposed decision indicate their agreement
- that agreement is in accordance with the method determined by the Board (under subsection 27F(2))
- all members were informed of the proposed decision, or reasonable efforts had been made to inform them of it.

Subsection 27F(1) only applies if the Board has agreed it may make decisions of that kind without a meeting and has also agreed the method by which Board members can indicate agreement to a proposed decision. A Board member cannot vote on a proposed decision that they would not have been entitled to vote on if the decision was being considered at a
meeting of the Board. These provisions are included to provide flexibility for the Board and are intended to assist in its effective functioning.

Subsections 27F(4) and 27F(5) require the Board to keep a record of its decisions made in accordance with this section, and to provide the Secretary of the Department with details of these decisions within 20 business days. These provisions have been included to ensure ongoing transparent communication between the Board, the Department and the Minister.

**Subdivision D—Minister may give directions to the Board**

This subdivision sets out requirements for when the Minister may give directions to the Board as follows.

**Section 27G Minister may give directions to the Board**

This new section allows for the Minister to give a direction, in writing, to the Board about the performance of its functions or the exercise of its powers. The Board must comply with a direction made by the Minister, unless the direction relates to its obligations as the accountable authority under the PGPA Act.

Subsection 27G(4) requires that the Minister must not give a direction to the Board unless the Minister has given written notice stating the intention to give a direction, and has given the Board an adequate opportunity to discuss the need for the proposed direction. These provisions are included to clarify and ensure the need for a direction prior to it being issued.

Subsection 27G(5) provides that a direction under subsection 27G(1) is a notifiable instrument.

Subsection 27G(6) provides that a direction under subsection 27G(1) is laid before each House of Parliament within 15 sitting days of giving the direction. This is consistent with directions made under paragraph 10(3)(b) of the Administration Act and provides for public scrutiny of a direction.

This provision is in addition to section 10, which provides for the Minister to give written directions to the APVMA about the performance of its functions or exercise of its powers. The APVMA Annual Report must include any direction given to the Board and the APVMA by the Minister and the impact of any direction on the APVMA (see item 38).

**Subdivision E—Board to give documents to Secretary**

This subdivision sets out requirements for the Board to give certain documents to the Secretary of the Department as follows.

**Section 27H Board to give documents to Secretary**

New section 27H requires the Board to provide the Secretary of the Department with a copy of any document they request within 20 business days of the Secretary of the Department making the request. While this is not a standard provision for governance Boards, it is included to ensure ongoing transparent communication between the Board, the Department and the Minister. This is necessary given the Minister’s overarching responsibility for agvet chemical policy, in which the APVMA Board plays a key role.
Subdivision F—Board committees

This subdivision sets out requirements for Board committees as follows.

Section 27J Board committees

New section 27J provides that the Board may establish and abolish committees to assist it in the performance of its functions and exercise of its powers. The Board may determine the members of any committee and members may include Board members (subsection 27J(2)). The Board will also determine the terms of reference for any committee, the terms and conditions of appointment of committee members and any procedures the committee is to follow (subsection 27J(3)).

The Board does not have the power to delegate any of its functions or powers. In addition, the Board may determine the procedures for these Board committees (paragraph 27J(3)(c)). As a result there is no need for these Board committee members to meet the obligations for ‘officials’ in Division 3 of Part 2-2 of Chapter 2 of the PGPA Act. Subsection 27J(4) therefore specifies that people who sit on a Board committee, with the exception of Board members, are not officials for the purposes of the PGPA Act.

This section is necessary as it provides an express power for the Board to establish committees. Committees may provide the Board with valuable opportunities to engage with stakeholders and seek advice, as well as access specific expertise when required.

Subdivision G—Review of the Board

This subdivision sets out requirements for a review of the Board as follows.

Section 27K Review of the Board

This new section requires the Minister to undertake a review of the functions and operations of the Board. The review is to be finalised within four years of the commencement of this section. Subsection 27K(3) also allows for the Minister to undertake subsequent reviews.

A written report of any review under this section is to be provided to the Minister under new subsection 27K(4), and the Minister must table the report in each House of Parliament within 15 sitting days of receipt under new subsection 27K(5).

This provision is included to enable an independent review of the operations of the Board to be undertaken to ensure it is effective and efficient. This provision is not a standard provision and is not included in the enabling legislation for other Australian Government bodies. However, it is considered necessary to ensure an independent mechanism to review the APVMA’s governance arrangements.

Item 12 Division 5 of Part 3 (heading)

Item 12 omits the existing ‘Committees’ heading for Division 5 of Part 3 and replaces it with ‘APVMA Committees’. This amendment clarifies that sections 28, 29, 29A and 30 in Division 5 only apply to committees established by the APVMA and do not apply for committees established by the Board.
**Item 13**  **Subsection 32(1)**
Item 13 amends subsection 32(1) of the Administration Act to clarify that the CEO will be responsible for the day-to-day management and decision making of the APVMA and, in doing this, may exercise any of the powers and perform any of the functions of the APVMA. The CEO is also to remain the APVMA’s Agency Head under the *Public Service Act 1999*.

This subsection provides that the CEO will continue to have responsibility for the day-to-day management and decision-making for the APVMA, which include, for example, decisions on the registration of agvet chemical products and enforcement and compliance activities. As set out at item 11 and new section 15 of the Administration Act, the Board will complement and not duplicate the duties of the CEO.

**Item 14**  **At the end of section 32**
Item 14 amends section 32 of the Administration Act to require the CEO to:

- act in accordance with objectives, strategies and policies determined by the Board
- comply with written directions given by the Board about the performance of their duties.

New subsection 32(5) allows for the Board to give a direction, in writing, to the CEO about the performance of the CEO’s duties. The CEO must comply with a direction made by the Board under new subsection 32(5), unless the direction relates to the CEO’s obligations as the Agency Head under the *Public Service Act 1999*.

New subsection 32(8) requires that the Board must not give a direction to the CEO unless it has given written notice stating the intention to give a direction, and has given the CEO an adequate opportunity to discuss the need for the proposed direction. These provisions are included to provide the CEO an opportunity to discuss the direction with the Board prior to a direction being issued.

New subsection 32(9) provides that a direction under subsection 32(5) is not a legislative instrument.

**Item 15**  **Section 32A**
Item 15 repeals section 32A of the Administration Act, which provides for how the CEO is to work with the APVMA Advisory Board. This provision is obsolete consequential to item 11 above which repeals the provisions establishing the Advisory Board.

It is not considered necessary to insert an equivalent provision setting out how the CEO is to work with the Board, as subsection 32(4) will require the CEO to act in accordance with the objectives, strategies and policies of the Board and subsection 32(5) will allow for the Board to direct the CEO in relation to their duties (refer item 14).

**Items 16, 17 and 18  Section 33**
Items 16, 17 and 18 amend section 33 of the Administration Act regarding the appointment arrangements for the CEO. To ensure clear accountability arrangements between the Minister, the Board and the CEO, future CEOs will be appointed by the Board by written instrument, following consultation with the Minister. The CEO will remain a full-time position and the Board may appoint any person the Board considers suitable to the role.

Item 18 clarifies under subsection 33(2) that an appointed Board member is not eligible to be appointed as the CEO, this is to retain a separation between the Board and the CEO.
An instrument of appointment under subsection 33(1) would not be a legislative instrument by virtue of the existing exemption under item 8 in the table at subsection 6(1) of the 
Legislation (Exemptions and Other Matters) Regulation 2015. This provides that an instrument of appointment is not a legislative instrument.

Because of the application provision at item 41 below, these amendments only apply to subsequent CEO appointments to ensure these requirements do not apply retrospectively to the current CEO.

**Items 19, 20 and 21  Sections 34, 35 and 37**
Items 19, 20 and 21 replace all references to the ‘Minister’ with the ‘Board’ in section 34, subsections 35(1) and 35(2) and section 37 of the Administration Act to ensure consistency with the appointment and accountability arrangements for the Chief Executive Officer under subsection 33(1) (outlined in item 16). Because of the application provision at item 41 below, this amendment only applies to subsequent CEO appointments.

**Items 22 and 23  Section 38**
Items 22 and 23 replace ‘paid employment’ with ‘paid work’ in section 38 of the Administration Act to align with the definition under section 4 as outlined in item 5.

**Items 24 and 25  Sections 38, 40 and 41**
Items 24 and 25 replace all references to the ‘Minister’ with the ‘Board’ in sections 38, 40 and 41 of the Administration Act to ensure consistency with the appointment and accountability arrangements for the CEO under subsection 33(1) (outlined in item 16). Because of the application provision at item 41 below, this amendment only applies to subsequent CEO appointments.

**Items 26, 27, 28, 29, 30 and 31  Section 41A**
Items 26, 27, 28, 29, 30 and 31 amend section 41A of the Administration Act regarding the termination of appointment arrangements for the CEO.

Items 26, 28 and 30 replace all references to the ‘Minister’ to the ‘Board’.

Item 27 is a minor technical amendment to update the reasons for terminating the CEO so that they are consistent with provisions to terminate appointed Board members as outlined in item 11 above and new section 25 of the Administration Act.

Item 29 of the Bill replaces ‘paid employment’ with ‘paid work’ in paragraph 41A(d) of the Administration Act to align with the definition under section 4 of the Administration Act as outlined in item 5 above.

Item 31 sets out that the Board, under new subsection 41A(2), may only terminate the CEO following consultation with the Minister.

These amendments are included to ensure consistency with the appointment and accountability arrangements for the CEO under section 33(1) (outlined in item 16). Because of the application provision at item 41, this amendment only applies to subsequent CEO appointments.

**Item 32  Subsection 42(1)**
Item 32 replaces reference to the ‘Minister’ with the ‘Board’ in subsection 42(1) of the Administration Act to ensure consistency with the appointment and accountability
arrangements for the CEO under subsection 33(1) (outlined in item 16). Because of the application provision at item 41, this amendment only applies to subsequent CEO appointments.

**Items 33 and 34 Subsection 43**
Items 33 and 34 amend section 43 of the Administration Act regarding the appointment of an Acting CEO. Item 33 replaces reference to the ‘Minister’ to the ‘Board’. Item 34 sets out that the Board, under new subsection 43(2), may only appoint an acting CEO following consultation with the Minister.

These amendments are included to ensure consistency with the appointment and accountability arrangements for the CEO under subsection 33(1) (outlined in item 16). Because of the application provision at item 41, this amendment only applies to subsequent CEO appointments.

**Items 35, 36 and 37 Sections 51, 52 and 61**
Items 35, 36 and 37 replace reference to the ‘Chief Executive Officer’ with ‘Board’ in subsections 51(1), 51(3), 52(1), 52(2), and 52(3) and section 61 of the Administration Act. These amendments are included to ensure consistency with the functions of the Board outlined in item 11 above and new section 15 of the Administration Act, and the role of the Board as the accountable authority under the PGPA Act.

**Item 38 At the end of section 61**
Item 38 amends section 61 to include reference to any written directions given to the Board of the APVMA by the Minister (new subsection 61(g)). This will mean that the APVMA Annual Report must include any written direction given to the Board by the Minister and the impact of those written directions on the APVMA. This is the same approach that already applies for any direction given to the APVMA by the Minister (subsection 61(f)). The amendment provides necessary transparency regarding the performance of the Board.

**Item 39 Paragraph 69EP(7)(a)**
Item 39 omits reference to the CEO in paragraph 69EP(7)(a) of the Administration Act, which sets out that Board members may attend a private hearing. This reference is no longer necessary, as the CEO is encompassed by the new definition of ‘Board member’, set out at item 3.

**Item 40 Transitional provision—meetings of the Board**
Item 40 is a transitional provision that provides that paragraph 27(2)(b) of the Administration Act does not apply in relation to the calendar year in which this item commences. This means that the Board will not be required to hold four meetings in the calendar year it is established.

**Item 41 Application provision—Chief Executive Officer**
Item 41 is an application provision that provides the amendments to sections 33 to 43 of the Administration Act (as set out in items 16 to 34) apply to CEOs appointed on or after the commencement of this item. This application provision means many (but not all) of the provisions relating to the current appointed CEO will remain unchanged until the end of their current appointment term, including:

- the CEO will hold office as agreed in writing between the Minister and the CEO, on such terms and conditions are agreed with the Minister (sections 34 and 37)
- the CEO is to be paid the remuneration (if there is no Remuneration Tribunal determination operational) and allowances determined by the Minister in writing (section 35)
- the CEO must not engage in paid work, except with the approval of the Minister (section 38)
- the Minister may grant the CEO leave of absence, other than recreation leave, on terms and conditions determined by the Minister (section 40)
- the CEO may resign in writing to the Minister (section 41)
- the Minister may terminate the CEO (section 41A)
- the CEO must disclose all indirect and financial interests to the Minister (section 42).

The Minister will also remain responsible for acting CEO appointments during this period, as set out in section 43.

The current CEO may be reappointed by the Board, following consultation with the Minister, at the end of their current term (refer items 16 to 18).

As set out in items 13 and 14, the duties of the current CEO will be amended once the Board is established.

**Item 42 Application and saving provisions—corporate plans and annual report**

Item 42 is an application and saving provision that provides that section 51 of the Administration Act (in relation to approval of a corporate plan) applies in each calendar year that begins after the commencement of this item; and that amendments made to Part 6 of the Administration Act by items 35 and 36 do not affect the validity of the corporate plan or a variation of a corporate plan approved by the Minister before the commencement of this item.

New subitem 42(3) is an application provision that provides that section 61 (as amended) of the Administration Act in relation to the reporting periods for annual reports is applicable in relation to each reporting period from commencement of this item.

**Item 43 Transitional provision—transfer of records and documents of Advisory Board to the APVMA**

Item 43 is a transitional provision that provides for any records or documents that are held by the Advisory Board immediately before the commencement of this amendment to be transferred to and retained by the APVMA.
STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS


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

This Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act.

Overview of the Bill

The Bill makes amendments to the Agricultural and Veterinary Chemicals (Administration) Act 1992 (the Administration Act), the Agricultural and Veterinary Chemicals Code Act 1994 (the Code Act) and the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994 (the Levy Act). The Bill also repeals the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014 (the Removing Re-approval and Re-registration Act).

The Bill will improve the effectiveness and efficiency of the national system for regulating agricultural and veterinary (agvet) chemical products. The Bill will:

- provide the Australian Pesticides and Veterinary Medicines Authority (APVMA) and industry with more flexibility to deal with certain types of new information provided when the APVMA is considering an application
- enable the use of new, simpler regulatory processes for chemicals of low regulatory concern, to simplify the approval of active constituents and labels, and the registration of certain products
- provide for extensions to limitation periods and protection periods as an incentive for chemical companies to register certain new uses of chemical products—particularly those uses (minor uses) with insufficient commercial return for chemical companies to normally add to the product label
- reduce the regulatory burden on industry by simplifying reporting requirements for annual returns
- support computerised decision-making by the APVMA
- reduce the administrative burden on the APVMA and industry by increasing the flexibility of the APVMA to manage errors in an application at the preliminary assessment stage
- reduce the regulatory burden by enabling the APVMA to grant part of a variation application under section 27 of the Schedule to the Code Act
- enable a person to apply to vary an approval or registration that is suspended, to the extent that the variation relates to the grounds for suspension
- establish civil pecuniary penalties for contraventions of provisions in the Agvet Code and the Administration Act relating to providing false or misleading information to the APVMA
- provide the APVMA with more comprehensive grounds for suspending or cancelling approvals or registrations where information is provided in a variation application that is false or misleading
• optimise risk communication about chemical products by improving the transparency of voluntary recalls
• harmonise the need to inform the APVMA of new information (where it relates to the safety criteria) so that the same obligations apply to all holders and applicants
• simplify the APVMA’s corporate reporting requirements
• provide a more practical mechanism for dealing with minor variations in the constituents in a product, that normally occur in the manufacturing process
• clarify what information must be included on a label
• fix anomalies in the regulation-making powers for the labelling criteria
• amend the notification requirements in section 8E of the Agvet Code so that the APVMA and Food Standards Australia New Zealand (FSANZ) will have the flexibility to agree on appropriate timeframes for notifications and amend section 7A of the Administration Act to clarify the authority to make an APVMA legislative instrument for residues of chemical products in protected commodities
• amend the definition of expiry date in the Agvet Code to mean the date after which a chemical product ‘must not’ be used
• make minor and machinery changes including removal of unnecessary and redundant provisions and other changes to realise operational efficiencies, reduce unnecessary regulation and clarify ambiguities.

The Bill will also establish a governance Board for the APVMA and cease the existing APVMA Advisory Board. Establishing an APVMA Board will strengthen the APVMA’s governance arrangements and provide the necessary oversight to help the regulator manage operational, financial and performance matters. The Board will replace the Chief Executive Officer (CEO) as the accountable authority under the Public Governance, Performance and Accountability Act 2013 (PGPA Act), and will set the APVMA’s strategic direction, drive its operational performance, set an appropriate risk management framework and ensure greater accountability.

Human rights implications
Some parts of the Bill engage, or have the potential to engage, Articles 2, 6, 9, 14, 15, 17 and 19 of the International Covenant on Civil and Political Rights (ICCPR). These are identified and assessed below for each part of the Bill.

Schedule 1—Main Improvements

Part 1 of Schedule 1—Information to be taken into account in determining applications
Part 1 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 2 of Schedule 1—Approval and registration for prescribed active constituents, chemical products or labels
Part 2 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.
Part 3 of Schedule 1—Limits on use of information

Part 3 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 4 of Schedule 1—Annual returns and record-keeping

Right to the presumption of innocence (strict liability offences)

Article 14(2) of the ICCPR states that everyone charged with a criminal offence shall have the right to be presumed innocent until proven guilty according to law. The right to the presumption of innocence is also a fundamental common law principle in Australia.

When strict liability applies to an offence, the prosecution is only required to prove the physical elements of an offence. That is, they are not required to prove fault elements in order for the defendant to be found guilty. Strict liability is used in circumstances where there is a public interest in ensuring that regulatory schemes are observed and it can be reasonably expected that the person was aware of their duties and obligations. Strict liability offences can be considered a limitation of the presumption of innocence because the defendant can be found guilty without the prosecution being required to prove fault. It is important to note that the defence of honest and reasonable mistake of fact is available to the defendant (see section 9.2 of the Criminal Code).

Strict liability offences will not necessarily be inconsistent with the presumption of innocence, provided that the removal of the presumption of innocence pursues a legitimate objective and is reasonable, necessary and proportionate to achieving that objective. Whether a strict liability provision impermissibly limits the right to the presumption of innocence will depend on the circumstances of the case and the particular justification for an offence being a strict liability offence.

Part 4 of Schedule 1 to the Bill proposes to establish strict liability offences in relation to new sections 35 and 37 of the Levy Act. The application of strict liability in Part 4 of Schedule 1 to the Bill, and the offences to which it relates, has been developed in line with the Guide to Framing Commonwealth Offences.

New subsection 35(3) of the Levy Act provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty of 50 penalty units, if that person contravenes new subsection 35(1) of the Levy Act.

New subsection 35(1) of the Levy Act provides that an interested person in relation to a chemical product who is liable to pay levy in respect of leviable disposals of that product that took place anywhere in Australia at any time during a financial year, must give to the APVMA, before 30 November in the next financial year, a return setting out the total quantity of the chemical product covered by those leviable disposals. The term interested person is currently defined by subsection 3(1) of the Levy Act.

It is important to note that the applicable pecuniary penalty of 50 penalty units in new subsection 35(3) of the Levy Act is the maximum criminal pecuniary penalty that a relevant court could impose on an individual for a contravention of new subsection 35(3) of the Levy Act.
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. Accordingly, as there is no contrary intention in the Levy Act, the corresponding maximum criminal pecuniary penalty that a relevant court could impose on a body corporate for a contravention of new subsection 35(1) of the Levy Act will be 250 penalty units.

New subsection 37(2) of the Levy Act provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty of 50 penalty units, if that person contravenes new subsection 37(1) of the Levy Act.

New subsection 37(1) of the Levy Act provides that the interested person in relation to a chemical product who is liable to pay levy in respect of leviable disposals of the chemical product that took place anywhere in Australia at any time during a financial year must:

- keep any records relating to those disposals that are reasonably necessary to enable the APVMA to find out whether new section 35 of the Levy Act has been complied with; and
- retain those records for six years.

It is important to note that the applicable pecuniary penalty of 50 penalty units in new subsection 37(2) of the Levy Act is the maximum criminal pecuniary penalty that a relevant court could impose on an individual for a contravention of new subsection 37(1) of the Levy Act. Due to the application of subsection 4B(3) of the Crimes Act to the Levy Act, the corresponding maximum criminal pecuniary penalty that a relevant court could impose on a body corporate for a contravention of new subsection 37(1) of the Levy Act will be 250 penalty units.

The Levy Act, the Administration Act and the Code Act form part of the cooperative Commonwealth legislative framework that provides for the evaluation, registration and control of agvet chemical products. The Levy Act pursues the legitimate objective of supporting the broader regulatory framework of that legislative scheme by providing for the assessment and collection of levies in relation to agricultural and veterinary chemical products.

It is necessary to prescribe a contravention of new subsection 35(1) of the Levy Act as an offence of strict liability, with a corresponding criminal pecuniary penalty of 50 penalty units for individuals and 250 penalty units for bodies corporate, to achieve the legitimate objective of the Levy Act, as it ensures that interested persons liable to pay levy provide appropriate information to the APVMA about the leviable disposal of chemical products.

It is necessary to prescribe a contravention of new subsection 37(1) of the Levy Act as an offence of strict liability, with a corresponding criminal pecuniary penalty of 50 penalty units for individuals and 250 penalty units for bodies corporate, to achieve the legitimate objective of the Levy Act. This ensures that interested persons liable to pay levy keep appropriate records relating to leviable disposals that can substantiate information provided to the APVMA about those disposals.
New subsections 35(1) and 37(1) of the Levy Act ensure that the APVMA has access to information that is necessary for the ongoing regulation of agvet chemicals. The strict liability offences proposed by new subsections 35(3) and 37(2) of the Levy Act are reasonable and proportionate to the legitimate objective of that Act because the offences are not punishable by imprisonment and the proposed penalties are low (50 penalty units for individuals and 250 penalty units for bodies corporate).

Further, punishment of the proposed strict liability offences is likely to significantly enhance the effectiveness of the enforcement regime of the Levy Act by deterring interested persons from not providing annual returns to the APVMA or not keeping appropriate records to substantiate those annual returns. This will, in turn, ensure that the legitimate objective of the Levy Act is not frustrated due to the absence of necessary information about leviable disposals of chemical products.

Summary

New subsections 35(3) and 37(2) of the Levy Act, as inserted by Part 4 of Schedule 1 to the Bill, are compatible with human rights because, to the extent that they may limit the right to be presumed innocent in Article 14(2) of the ICCPR, that limitation is reasonable, necessary and proportionate to the achievement of a legitimate objective.

Civil penalties and Articles 14 and 15

New subsection 35(4) of the Levy Act provides that new subsection 35(1) of the Levy Act is a civil penalty provision. New subsection 35(1) of the Levy Act provides that an interested person in relation to a chemical product who is liable to pay levy in respect of leviable disposals of that product that took place anywhere in Australia at any time during a financial year, must give to the APVMA, before 30 November in the next financial year, a return setting out the total quantity of the chemical product covered by those leviable disposals. The term interested person is currently defined by subsection 3(1) of the Levy Act.

New subsection 37(3) of the Levy Act also provides that new subsection 37(1) of the Levy Act is a civil penalty provision. New subsection 37(1) of the Levy Act provides that the interested person in relation to a chemical product who is liable to pay levy in respect of leviable disposals of the chemical product that took place anywhere in Australia at any time during a financial year must:

- keep any records relating to those disposals that are reasonably necessary to enable the APVMA to find out whether new section 35 of the Levy Act has been complied with; and
- retain those records for six years.

Prescribing conduct that is subject to a civil penalty could engage criminal process rights if the imposition of a civil penalty is classified as ‘criminal’ under international human rights law. Guidance Note 2: Offence provisions, civil penalties and human rights (December 2014), which is published by the Parliamentary Joint Committee on Human Rights, states that civil penalty provisions may engage criminal process rights under Articles 14 and 15 of the ICCPR, regardless of the distinction between criminal and civil penalties in domestic law. When a provision imposes a civil penalty, an assessment is required as to whether it amounts to a ‘criminal’ penalty for the purposes of the ICCPR.
Determining whether penalties could be considered to be criminal under international human rights law requires consideration of the classification of the penalty provisions under Australian domestic law, the nature and purpose of the penalties, and the severity of the penalties.

Items 29 and 30 in Part 4 of Schedule 1 to the Bill, which insert new subsections 35(4) and 37(3) of the Levy Act, also inserts notes at the end of those new subsections. In particular, note 2 to new subsections 35(4) and 37(3) of the Levy Act directs the reader to Division 1 of Part 7AB of the Administration Act, which creates a framework for the use of civil penalties to enforce the civil penalty provisions of the Administration Act and the Levy Act (see the definition of civil penalty provision in section 4 of the Administration Act). Division 1 of Part 7AB of the Administration Act will apply to new subsections 35(4) and 37(3) of the Levy Act.

Importantly, subsection 69EJA(1) of the Administration 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 conduct that is the same as the conduct constituting the contravention. Subsection 69EJA(2) of the Administration Act provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

New subsection 35(3) of the Levy Act provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty of 50 penalty units, if that person contravenes new subsection 35(1) of the Levy Act. New subsection 37(2) of the Levy Act provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty of 50 penalty units, if that person contravenes new subsection 37(1) of the Levy Act.

It is important to note that subsection 69EJA(1) of the Administration Act refers to the maximum monetary penalty that could be imposed by a court if a body corporate were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

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.

Accordingly, as there is no contrary intention in the Levy Act, the maximum criminal pecuniary penalty that a relevant court could impose on a body corporate for a contravention of new subsection 35(1) of the Levy Act will be 250 penalty units, due to the application of subsection 4B(3) of the Crimes Act to new subsection 35(3) of the Levy Act. Further, the maximum criminal pecuniary penalty that a relevant court could impose on a body corporate for a contravention of new subsection 37(1) of the Levy Act will be 250 penalty units, due to the application of subsection 4B(3) of the Crimes Act to new subsection 37(2) of the Levy Act.
By virtue of section 69EJA of the Administration Act, and the matters prescribed by new subsections 35(3) and 37(2) of the Levy Act (including the application of subsection 4B(3) of the Crimes Act to those new subsections), the civil pecuniary penalty for new subsections 35(4) and 37(3) of the Levy Act will be 150 penalty units for individuals and 1250 penalty units for bodies corporate.

The penalty provisions proposed by new subsections 35(4) and 37(3) of the Levy Act are expressly classified as civil penalty provisions. That is, new subsections 35(4) and 37(3) of the Levy Act create pecuniary penalties in the form of a debt payable to the Commonwealth (see section 69EJB of the Administration Act).

The purpose of new subsection 35(4) of the Levy Act is to encourage compliance with the requirement to submit annual returns to the APVMA, which is set out in new subsection 35(1) of the Levy Act. The purpose of new subsection 37(3) of the Levy Act is to encourage compliance with the requirement to keep records relating to leviable disposals, which is set out in new subsection 37(1) of the Levy Act.

The proposed civil penalty provisions do not impose criminal liability, and do not lead to the creation of a criminal record. The penalties will only apply to those interested persons (as defined by subsection 3(1) of the Levy Act) who do not comply with the requirement to give annual returns to the APVMA (new subsection 35(1) of the Levy Act) or who do not keep records in relation to leviable disposals (new subsection 37(1) of the Levy Act). That is, the penalties will not apply to the public in general.

Further, the imposition of the civil pecuniary penalties in new subsections 35(4) and 37(3) of the Levy Act are not dependent on a finding of guilt, and section 69EJG of the Administration Act expressly states that the contravention of a civil penalty provision is not an offence.

The applicable penalty for new subsections 35(4) and 37(3) of the Levy Act—being 150 penalty units for individuals and 1250 penalty units for bodies corporate—is reflective of the seriousness of the conduct and the risk contravening behaviour may pose to the Australian Government’s ability to meet its international obligations. The proposed penalties are also consistent with other penalties for similar conduct provisions across the Commonwealth statute book, for example section 36 of the Levy Act.

Section 69EJD of the Administration Act provides that a court may make a single civil penalty order against a person for multiple contraventions of a civil penalty provision if proceedings for the contraventions are founded on the same facts, or if the contraventions form, or are part of, a series of contraventions of the same or a similar character; however, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions. There are no criminal consequences associated with civil penalty orders for multiple contraventions (for example, they do not carry the possibility of imprisonment). As such, the civil penalties proposed by new subsections 35(4) and 37(3) of the Levy Act are not sufficiently severe, such that they could be considered to be criminal penalties for the purposes of Australia’s human rights obligations.

These factors all suggest that the civil penalties proposed by new subsections 35(4) and 37(3) of the Levy Act are civil penalties rather than criminal penalties for the purposes of Australia’s human rights obligations. Accordingly, the criminal process rights provided for
by Articles 14 and 15 of the ICCPR are not engaged. However, for completeness, and to
demonstrate that new subsections 35(4) and 37(3) of the Levy Act are nonetheless compliant
with the rights provided for by Articles 14 and 15 of the ICCPR, key provisions of Division 1
of Part 7AB of the Administration Act, which apply to new subsections 35(4) and 37(3) of
the Levy Act by virtue of the definition of civil penalty provision in section 4 of the
Administration Act, are set out below.

Article 14 of the ICCPR requires that, in the determination of criminal charges, everyone
shall be entitled to a fair and public hearing by a competent, independent and impartial
tribunal established by law. Various other rights are provided for persons charged with
criminal offences.

Due to the operation of subsection 69EJ(2) of the Administration Act, the time period for the
making of an application for a civil penalty order will be within 6 years of the alleged
contravention. As the criminal process rights in Article 14 of the ICCPR are not engaged by
new subsections 35(4) and 37(3) of the Levy Act, the right to be tried without undue delay
provided by paragraph 14(3)(c) of the ICCPR is not engaged.

Under section 69EJ of the Administration Act, civil penalty orders can only be granted by a
court, which must consider all relevant matters before determining the amount of the penalty.
Accordingly, the right to a fair hearing is not limited.

Section 69EJJ of the Administration Act clarifies that criminal proceedings may be
commenced against a person for conduct that is the same, or substantially the same, as
conduct that would constitute a contravention of a civil penalty provision, regardless of
whether a civil penalty order has been made against the person in relation to the
contravention. This section recognises the importance of criminal proceedings and criminal
penalties in dissuading and sanctioning contraventions of the Levy Act, and ensures that
criminal remedies are not precluded by earlier civil action.

Section 69EJJ of the Administration Act engages the criminal process rights in Article 14 of
the ICCPR, but does not limit those rights. Article 14(7) of the ICCPR provides that “no one
shall be liable to be tried or punished again for an offence for which he has already been
finally convicted or acquitted in accordance with the law and penal procedure of each
country”. This prohibition on double jeopardy is a fundamental safeguard in the common law
of Australia. It means that a person who has been convicted or acquitted of a criminal charge
is not to be re-tried for the same or substantially the same offence.

As section 69EJJ of the Administration Act permits both civil and criminal proceedings, but
not multiple criminal proceedings for the same conduct, Article 14(7) of the ICCPR is not
infringed. Further, section 69EJH of the Administration Act provides that a court cannot
make a civil penalty order against a person for a contravention of a civil penalty provision if
the person has been convicted of an offence constituted by conduct that is the same, or
substantially the same, as the conduct constituting the contravention.

Section 69EJK of the Administration Act provides that evidence of information given, or
evidence of the production of documents, by an individual is not admissible in criminal
proceedings against the individual if:
the individual previously gave the information or produced the documents in proceedings for a civil penalty order against the individual for an alleged contravention of a civil penalty provision (whether or not the order was made); and

the conduct alleged to constitute the offence is the same, or substantially the same, as the conduct alleged to constitute the contravention.

Section 69EJK of the Administration Act ensures that information or documents produced during civil proceedings are not relied upon to support subsequent criminal proceedings, unless those proceedings are criminal proceedings relating to falsifying evidence in civil proceedings. Accordingly, that section engages, but does not limit, the criminal process rights in Article 14 of the ICCPR.

Section 69EJL of the Administration Act provides that if an act or thing is required under a civil penalty provision to be done within a particular period or before a particular time, the obligation to do that act or thing continues until that act or thing is done, even if the period has expired or the time has passed. This section further provides that a person commits a separate contravention of the civil penalty provision in respect of each day during which the contravention occurs, including the day the civil penalty order is made (or any later day). This section is necessary to ensure that failure to comply with an obligation does not excuse a person from meeting that obligation.

As discussed above, section 69EJD of the Administration Act provides that a relevant court may make a single civil penalty order against a person for multiple contraventions of a civil penalty provision if proceedings for the contraventions are founded on the same facts, or if the contraventions form, or are part of, a series of contraventions of the same or a similar character; however, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions. There are no criminal consequences associated with civil penalty orders for multiple contraventions (for example, they do not carry the possibility of imprisonment). Accordingly, the application of section 69EJL of the Administration Act does not engage any human rights.

Section 69EJP of the Administration Act provides that, in proceedings for a civil penalty order against a person for a contravention of a civil penalty provision, a person bears an evidential burden where that person wishes to rely on any exception, exemption, excuse, qualification or justification provided by the law creating the civil penalty provision. As section 69EJP of the Administration Act only relates to proceedings for civil penalty orders, not offences, the right to be presumed innocent in Article 14(2) of the ICCPR is not engaged.

Sections 69EJC, 69EJE, 69EJF, 69EJI, 69EJM, 69EJN, 69EJO, 69EJQ, 69EJR and 69EJS of the Administration Act relate to:

- conduct contravening more than one civil penalty provision;
- the ability to hear two or more civil penalty order proceedings together;
- the application of the rules and evidence and procedure for civil matters;
- the stay of civil proceedings during criminal proceedings;
- ancillary contraventions of civil penalty provisions;
- mistake of fact;
- the relevance of a person’s state of mind;
• liability of employees, agents or officers of a body corporate, respectively;
• liability of executive officers of a body corporate; and
• establishing whether an executive officer took reasonable steps to prevent the contravention of a civil penalty provision.

Those provisions do not impact upon criminal proceedings and do not engage the criminal process rights in Article 14 of the ICCPR.

Article 15 of the ICCPR prohibits the retrospective application of criminal laws. As the amendments to the Levy Act by Part 4 of Schedule 1 to the Bill will only apply in relation to leviable disposals that take place in the financial year in which this Part commences, or in a later financial year, Article 15 of the ICCPR is not engaged. There are no additional human rights implications beyond those discussed above.

**Summary**

Part 4 of Schedule 1 to the Bill is compatible with the criminal process rights provided for by Articles 14 and 15 of the ICCPR because new subsections 35(4) and 37(3) of the Levy Act do not engage those rights.

**Right to privacy**

Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual’s privacy, family, home or correspondence, and protects a person’s honour and reputation from unlawful attacks. The right to privacy can be limited to achieve a legitimate objective where the limitations are lawful and not arbitrary. In order for an interference with the right to privacy to be permissible, the interference must be authorised by law, be for a reason consistent with the ICCPR and be reasonable in the circumstances. The United Nations Human Rights Committee has interpreted the requirement of ‘reasonableness’ as implying that any interference with privacy must be proportionate to a legitimate end and be necessary in the circumstances.

New subsections 35(1), 35(5) and 37(1) of the Levy Act engage the protection against arbitrary or unlawful interference with privacy, as those proposed provisions enable information to be collected, used and disclosed by the APVMA. To the extent that new subsections 35(1), 35(5) and 37(1) of the Levy Act may limit the right to privacy, any limitation is reasonable, necessary and proportionate to the achievement of a legitimate objective.

New subsection 35(1) of the Levy Act provides that an interested person in relation to a chemical product who is liable to pay levy in respect of leviable disposals of that product that took place anywhere in Australia at any time during a financial year, must give to the APVMA, before 30 November in the next financial year, a return setting out the total quantity of the chemical product covered by those leviable disposals. The term *interested person* is currently defined by subsection 3(1) of the Levy Act.

New subsection 35(5) of the Levy Act provides that, from the returns given to the APVMA under new subsection 35(1) of the Levy Act in relation to a financial year, the APVMA must give the Secretary, before the end of the next financial year, a statement or statements setting out the total quantities of each active constituent for each chemical product covered by those returns.
New subsection 37(1) of the Levy Act provides that the interested person in relation to a chemical product who is liable to pay levy in respect of leviable disposals of the chemical product that took place anywhere in Australia at any time during a financial year must:

- keep any records relating to those disposals that are reasonably necessary to enable the APVMA to find out whether new section 35 of the Levy Act has been complied with; and

- retain those records for six years.

The Levy Act, the Administration Act and the Code Act form part of the cooperative Commonwealth legislative framework that provides for the evaluation, registration and control of agvet chemical products. The Levy Act pursues the legitimate objective of supporting the broader regulatory framework of that legislative scheme by providing for the assessment and collection of levies in relation to agricultural and veterinary chemical products.

New subsections 35(1), 35(5) and 37(1) of the Levy Act will ensure that the APVMA can collect, use and disclose information about agvet chemicals in the marketplace. This information will be used by the Australian Government for policy development and to meet international reporting requirements under international conventions and arrangements. The information will also be important to ensure that the assessment and collection of levies in relation to agricultural and veterinary chemical products is based on accurate data.

It is important to note that disclosure will be limited to the Department and will not include personal information. In addition, information will be limited to that information received by the APVMA through the submission of annual returns relating to leviable disposals of chemical products (new subsection 35(5) of the Levy Act). This information will be similar to the information on the financial value of leviable disposals of products that is already provided to the APVMA, and which may already include some personal information e.g. the name and address of the interested person. Therefore, the new annual return reporting requirement will not result in the collection of any new personal information and the APVMA will manage this information in the same manner as it manages personal information now.

New subsections 35(1), 35(5) and 37(1) of the Levy Act are necessary to ensure that the Australian Government has sufficient information available to meet its international obligations and can consider the implications for trade in Australian goods if other countries impose restrictions or conditions on agvet chemicals.

New subsections 35(1) and 37(1) of the Levy Act will enable the APVMA to collect information about leviable disposals of chemical products, and new subsection 35(5) of the Levy Act will enable the APVMA to disclose that information to the Department. The type of information collected will primarily be commercial information, but compliance with new subsections 35(1) and 37(1) of the Levy Act may incidentally require the provision of personal information.

The APVMA may incidentally collect personal information about disposals of agvet chemicals. This is necessary to ensure the APVMA can prepare a statement for the Department (without personal information) in a form that specifies the agvet chemical active constituents disposed of in Australia during a financial year.
The APVMA only collects personal information that is reasonably necessary for, or directly related to, one or more of its functions or activities. The APVMA stores all personal information securely and restricts access to a limited number of staff who need access to the information to perform their duties or assist individuals concerned. The APVMA stores information electronically or on hard copy files.

The APVMA takes all reasonable steps to ensure that personal information is protected from misuse, loss and interference. When information is no longer required, the APVMA securely destroys it in accordance with the *Archives Act 1983* and relevant disposal authorities. The types of information that the APVMA generally collects and holds include personal contact details, financial payments records and mailing and subscription lists.

Further, to ensure there is no arbitrary interference with an individual’s privacy, the powers and functions in new subsections 35(1), 35(5) and 37(1) of the Levy Act must be exercised in compliance with the Privacy Act. The Privacy Act provides for protections on the collection, storage, use, disclosure or publication of personal information.

Items 29 and 30 in Part 4 of Schedule 1 to the Bill, which insert new sections 35 and 37 of the Levy Act, also insert notes at the end of new subsections 35(4) and 37(3) of the Levy Act. Note 1 to new subsections 35(4) and 37(3) of the Levy Act directs the reader to Part 7AA of the Administration Act, which provides for the monitoring and investigation powers of inspectors (as defined by section 4 of the Administration Act). Part 7AA of the Administration Act will apply to new sections 35 and 37 of the Levy Act due to subsection 69EAB(1), sections 69EAH and 69EB and the definition of *evidential material* in section 4 of the Administration Act.

The application of Part 7AA of the Administration Act to new sections 35 and 37 of the Levy Act engages the protection against arbitrary or unlawful interference with privacy.

The Levy Act, the Administration Act and the Code Act form part of the cooperative Commonwealth legislative framework that provides for the evaluation, registration and control of agvet chemical products. The Levy Act pursues the legitimate objective of supporting the broader regulatory framework of that legislative scheme by providing for the assessment and collection of levies in relation to agvet chemical products. The Administration Act pursues the legitimate objective of establishing the APVMA as an independent statutory authority of the Commonwealth that is responsible for the regulation and control of agvet chemicals in Australia up to and including the point of retail sale. The Administration Act also provides for the control of the import and export of chemical products, and establishes the coercive and enforcement powers of the APVMA that are applicable to the provisions of the Levy Act and the Administration Act.

The entry, monitoring, search, seizure and information-gathering powers of the APVMA in Part 7AA of the Administration Act are provided by law. The monitoring and investigation powers are necessary to enable the APVMA to monitor compliance with the Administration Act and the Levy Act, and to collect evidential material relating to contraventions of those Acts. The monitoring and investigation powers are constrained in various ways, as set out below, ensuring that their use is not arbitrary.

Part 7AA of the Administration Act protects against arbitrary interference with privacy, as the monitoring and investigation powers cannot be exercised in relation to premises without the consent of the occupier, or another person who apparently represents the occupier, or
through prior judicial authorisation in the form of a warrant (see sections 69EAB and 69EB of the Administration Act). Where entry is based on the consent of the occupier, consent must be informed and voluntary, and the occupier of premises can restrict entry by inspectors to a particular period (see section 69ED of the Administration Act). Additional safeguards are provided through provisions requiring inspectors, and any persons assisting, to leave the premises if the occupier withdraws their consent (see subsection 69ED(5) of the Administration Act).

The Administration Act also provides constraints on the issuing of a monitoring or investigation warrant. For example, in the case of an investigation warrant, an issuing officer may issue an investigation warrant only when satisfied, by oath or affirmation, that there are reasonable grounds for suspecting that there is, or may be within 72 hours, evidential material on the premises (see section 69EHA of the Administration Act). An issuing officer must not issue a warrant unless the issuing officer has been provided, either orally or by affidavit, with such further information as they require concerning the grounds on which the issue of the warrant is being sought (see subsection 69EHA(3) of the Administration Act). Such constraints on this power ensure adequate safeguards against arbitrary limitations on the right to privacy in the issuing of warrants.

In addition, an inspector cannot enter premises under a warrant unless their identity card is shown to the occupier of the premises (see paragraph 69EDA(1)(b) of the Administration Act). If entry is authorised by warrant, the inspector must also provide a copy of the warrant to the occupier of the premises (section 69EDC of the Administration Act). This provides for the transparent utilisation of the powers and mitigates arbitrariness and risk of abuse.

Further, the power to seize evidence of a kind not specified in a warrant may only be exercised in the limited circumstances set out in sections 69EAE and 69EBC of the Administration Act. These constraints on the exercise of monitoring and investigations powers also limit their susceptibility to arbitrary use or abuse and ensure that their use is reasonable and proportionate in the circumstances.

Accordingly, the monitoring and investigating powers in Part 7AA of the Administration Act are necessary, proportionate and reasonable in the pursuance of the legitimate objectives of the Administration Act and the Levy Act.

Summary

Part 4 of Schedule 1 to the Bill is compatible with human rights because, to the extent that the application of Part 7AA of the Administration Act to new sections 35 and 37 of the Levy Act may limit the right to privacy in Article 17 of the ICCPR, that limitation is reasonable, necessary and proportionate to the achievement of a legitimate outcome.

Right to security of person and right to life

Items 29 and 30 in Part 4 of Schedule 1 to the Bill, which insert new sections 35 and 37 of the Levy Act, also insert notes at the end of new subsections 35(4) and 37(3) of the Levy Act. Note 1 to new subsections 35(4) and 37(3) of the Levy Act directs the reader to Part 7AA of the Administration Act, which provides for the monitoring and investigation powers of inspectors (as defined by section 4 of the Administration Act). Part 7AA of the Administration Act apply to new sections 35 and 37 of the Levy Act due to
subsection 69EAB(1), sections 69EAH and 69EB and the definition of *evidential material* in section 4 of the Administration Act.

Under sections 69EAG and 69EBE of the Administration Act, an inspector, or a person assisting an inspector, executing a monitoring or investigation warrant may use such force against things as is necessary and reasonable in the circumstances. Sections 69EAG and 69EBE of the Administration Act ensure that the effect of a monitoring and investigation warrant is not frustrated by an inability to open locked doors, cabinets, drawers, containers and other similar objects that the inspector reasonably suspects contains things or information that would provide evidence of non-compliance with the provisions of the Administration Act or the Levy Act.

As this power does not extend to the use of force against persons, it does not engage the right to security of person in Article 9 of the ICCPR or the right to life in Article 6 of the ICCPR. Further, the power can only be exercised under a monitoring or investigation warrant, which must be issued by a judicial officer, and the power may only be used as is necessary and reasonable in the circumstances.

**Summary**

Part 4 of Schedule 1 to the Bill is compatible with the right to security of person in Article 9 of the ICCPR and the right to life in Article 6 of the ICCPR because the application of Part 7AA of the Administration Act to new sections 35 and 37 of the Levy Act does not engage those rights.

**Criminal process rights (monitoring and investigation powers)**

Items 29 and 30, which insert new sections 35 and 37 of the Levy Act, also insert notes at the end of new subsections 35(4) and 37(3) of the Levy Act. Note 1 to new subsections 35(4) and 37(3) of the Levy Act directs the reader to Part 7AA of the Administration Act, which provides for the monitoring and investigation powers of inspectors (as defined by section 4 of the Administration Act). Part 7AA of the Administration Act will apply to new sections 35 and 37 of the Levy Act due to subsection 69EAB(1), sections 69EAH and 69EB and the definition of *evidential material* in section 4 of the Administration Act.

The application of Part 7AA of the Administration Act to new sections 35 and 37 of the Levy Act engages the criminal process rights contained in Article 14 of the ICCPR, as a number of offences in Part 7AA of the Administration Act apply to the exercise of monitoring or investigation powers in relation to new sections 35 and 37 of the Levy Act. These provisions have been set out below.

Sections 69EAH and 69EC of the Administration Act provide questioning powers to inspectors. Under subsection 69EAH(3) of the Administration Act, where entry is authorised by a monitoring warrant, the inspector may require any person on the premises to answer questions or produce documents relating to the operation of the Administration Act or the Levy Act or information provided under those Acts. Under subsection 69EAH(4) of the Administration Act, if the person fails to do so, they commit an offence subject to a criminal pecuniary penalty of 50 penalty units. Similarly, under subsection 69EC(3) of the Administration Act an inspector who enters premises under an investigation warrant may require persons on the premises to answer questions or produce documents relating to evidential material of the kind specified in the warrant. Under subsection 69EC(4) of the
Administration Act, if the person fails to do so, they commit an offence subject to a criminal pecuniary penalty of 50 penalty units.

Sections 69EAC and 69EBA of the Administration Act provide for monitoring and investigation powers. Subsection 69EAC(2) of the Administration Act provides that a person must comply with a direction that has been given to that person under paragraphs 69EAC(1)(i) or (1)(j) of that Act. Under subsection 69EAC(3) of the Administration Act, if the person fails to do so, they commit an offence of strict liability subject to a criminal pecuniary penalty of 30 penalty units. Subsection 69EBA(2) of the Administration Act provides that a person must comply with a direction that has been given to that person under paragraphs 69EBA(1)(i) or (1)(j) of that Act. Under subsection 69EBA(3) of the Administration Act, if the person fails to do so, they commit an offence of strict liability subject to a criminal pecuniary penalty of 30 penalty units.

Section 69EBC of the Administration Act enables an inspector to seize evidence of related offences and related civil penalty provisions where an inspector has entered premises under an investigation warrant. Subsection 69EBC(4) of the Administration Act provides that a person must comply with a direction that has been given to that person under subsection 69EBC(3) of that Act. Under subsection 69EBC(3) of the Administration Act, if the person fails to do so, they commit an offence of strict liability subject to a criminal pecuniary penalty of 30 penalty units.

Subsection 69EFA(1) of the Administration Act provides that an occupier of premises to which a monitoring or investigation warrant relates, or another person who apparently represents the occupier, must provide the inspector executing the warrant, or any person assisting, with all reasonable facilities and assistance for the effective exercise of their powers. Under subsection 69EFA(2) of the Administration Act, if the person fails to do so, they commit an offence subject to a criminal pecuniary penalty of 30 penalty units.

Section 69EHD of the Administration Act creates an offence, subject to imprisonment for two years, where an inspector inappropriately deals with a warrant that was issued by a telephone, fax machine or other electronic means.

These offence provisions do not limit a person’s access to a fair trial or limit the other criminal process rights in any way. Section 69EQ of the Administration Act makes it clear that the privilege against self-incrimination has not been abrogated by the monitoring and investigation powers provisions, including the offence provisions. These protections guarantee the criminal process rights protected in Articles 14(3)(d) and (3)(g) of the ICCPR. The usual guarantees and criminal process rights apply to these offences and are not abrogated by the application of Part 7AA of the Administration Act to new sections 35 and 37 of the Levy Act.

Summary
Part 4 of Schedule 1 to the Bill is compatible with the criminal process rights provided for by Article 14 of the ICCPR because, to the extent that the application of Part 7AA of the Administration Act to new sections 35 and 37 of the Levy Act engages those rights, it does not limit those rights.
Infringement notices and Article 14

Items 29 and 30 in Part 4 of Schedule 1 to the Bill, which insert new sections 35 and 37 of the Levy Act, also insert notes at the end of new subsections 35(4) and 37(3) of the Levy Act. Note 3 to new subsections 35(4) and 37(3) of the Levy Act direct the reader to Divisions 2, 3 and 6 of Part 7AB of the Administration Act, which provide for matters in relation to infringement notices, enforceable undertakings and formal warnings that may be used in relation to a contravention of new subsection 35(1) or 37(1) of the Levy Act.

Division 2 of Part 7AB of the Administration Act enables an inspector (as defined in section 4 of the Administration Act) to issue infringement notices where they believe, on reasonable grounds, that a person has contravened a prescribed civil penalty provision. Section 4 of the Administration Act defines prescribed civil penalty provision to mean a civil penalty provision that is prescribed by the Administration Regulations. Section 3A.01 of the Administration Regulations states that, for the definition of prescribed civil penalty provision in section 4 of the Administration Act, each civil penalty provision mentioned in Schedule 5 to the Administration Regulations is prescribed.

New sections 35 and 37 of the Levy Act are not mentioned in Schedule 5 to the Administration Regulations. Accordingly, Division 2 of Part 7AB of the Administration Act will not apply to new sections 35 and 37 of the Levy Act unless Schedule 5 to the Administration Regulations is amended to list new sections 35 and 37 of the Levy Act. It is intended that Schedule 5 to the Administration Regulations will be amended at a later date to list new sections 35 and 37 of the Levy Act.

An infringement notice issued under Division 2 of Part 7AB of the Administration Act is a notice of a pecuniary penalty imposed on a person. It sets out the particulars of an alleged contravention of a law. An infringement notice gives the person to whom the notice is issued the option of paying the penalty set out in the notice, or electing to have the matter dealt with by a court. As Division 2 of Part 7AB of the Administration Act only applies to civil penalty provisions, the criminal process rights in Article 14 of the ICCPR are not engaged. There are no criminal consequences associated with infringement notices for civil penalty provisions. For example, they do not carry the possibility of imprisonment if the person does not pay the penalty or attend court.

Paragraph 69EKA(1)(k) of the Administration Act provides that an infringement notice is required to state that the person may choose not to pay the penalty and notify them that, if they do so, proceedings seeking a civil penalty order may be brought against them in a court. Accordingly, the person must always be advised of the consequences of not paying the penalty, and of their right to have the matter dealt with by a court. As the person may elect to have the matter heard by a court, rather than pay the penalty, the right to a fair and public hearing for by Article 14(2) of the ICCPR is not limited. Accordingly, the application of Division 2 of Part 7AB of the Administration Act to new sections 35 and 37 of the Levy Act is consistent with human rights.

Summary

Part 4 of Schedule 1 to the Bill is compatible with the criminal process rights provided for by Article 14 of the ICCPR because the application of Division 2 of Part 7AB of the Administration Act to new sections 35 and 37 of the Levy Act does not engage those rights.
**Enforceable undertakings and Article 14**

Items 29 and 30 in Part 4 of Schedule 1 to the Bill, which insert new sections 35 and 37 of the Levy Act, also insert notes at the end of new subsections 35(4) and 37(3) of the Levy Act. Note 3 to new subsections 35(4) and 37(3) of the Levy Act directs the reader to Divisions 2, 3 and 6 of Part 7AB of the Administration Act, which provide for matters in relation to infringement notices, enforceable undertakings and formal warnings that may be used in relation to a contravention of new subsection 35(1) or 37(1) of the Levy Act.

Division 3 of Part 7AB of the Administration Act enables the APVMA to accept and enforce undertakings relating to the provisions of the Administration Act or the Levy Act (see sections 69EL and 69ELA of the Administration Act). Under section 69ELA of the Administration Act, if the APVMA is satisfied that a person has breached an undertaking, the APVMA may apply to a court of competent jurisdiction for an order relating to the undertaking.

Applying the enforceable undertakings provisions of the Administration Act to new subsections 35(3) and (4) and 37(2) and (3) of the Levy Act engages the right to a fair and public hearing, and other criminal process rights and minimum guarantees, in Article 14 of the ICCPR. Article 14(1) of the ICCPR provides that everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law. Under Division 3 of Part 7AB of the Administration Act, an order enforcing an undertaking can only be made by a court. Accordingly, the right to a fair and public hearing is not limited.

Further, the application of Division 3 of Part 7AB of the Administration Act to new sections 35 and 37 of the Levy Act does not limit the minimum guarantees and other criminal process rights in Article 14 of the ICCPR. The minimum guarantees and process rights will apply to criminal proceedings.

**Summary**

Part 4 of Schedule 1 to the Bill is compatible with the criminal process rights provided for by Article 14 of the ICCPR because, to the extent that the application of Division 3 of Part 7AB of the Administration Act to new sections 35 and 37 of the Levy Act engages those rights, it does not limit those rights.

**Part 5 of Schedule 1—Computerised decision-making**

Part 5 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

While Part 5 includes measures to allow the APVMA to substitute decisions made by a computer, these measures do not affect a person’s right to an effective remedy, as there is no change to the circumstances in which a person may request an internal review or apply for AAT review.

**Part 6 of Schedule 1—Preliminary assessments**

Part 6 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.
Right to an effective remedy

Article 2(3) of the ICCPR ensures that any person whose rights or freedoms are adversely affected by a person acting in an official capacity shall have an effective remedy, and that such a person shall have his or her rights determined by a competent judicial, administrative or legislative authority.

Part 7 of Schedule 1 to the Bill positively engages the right to an effective remedy in Article 2(3) of the ICCPR, as it provides a mechanism by which affected persons are able to seek a review of certain decisions.

Items 52 and 53 in Part 7 of Schedule 1 to the Bill amend section 8S of the Agvet Code to provide the APVMA with the flexibility to vary 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 product, in a way other than as set out in the original application for variation. The amendments also provide an applicant with the opportunity to provide written submissions on such a variation.

Subsection 8S(1) of the Agvet Code currently provides that the APVMA must give an applicant written notice of what it proposes to do before it:

- refuses an application, other than on preliminary assessment; or
- approves or registers an active constituent, chemical product or label with instructions or relevant particulars other than those set out in the application.

New paragraph 8S(1)(c) of the Agvet Code provides that the APVMA must give an applicant written notice of what it proposes to do before it varies, under section 29 of the Agvet Code, relevant particulars or conditions in a way other than set out in the original application.

Subsection 29(1) of the Agvet Code currently provides that the APVMA must 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 product if it is satisfied:

(a) that the application meets the application requirements; and
(b) for an active constituent—that, if those particulars or conditions were varied in accordance with the application, the constituent would meet the safety criteria; and
(c) for a chemical product—that, if those particulars or conditions were varied in accordance with the application, the product would:
   (i) meet the safety criteria, the trade criteria and the efficacy criteria; or
   (ii) comply with the established standard for the product; and
(d) for a label for a chemical product—that, if those particulars or conditions were varied in accordance with the application, the label would:
   (i) meet the labelling criteria; or
   (ii) comply with the established standard for the product.
New paragraph 8S(2)(b) of the Agvet Code provides that the written notice issued under subsection 8S(1) of the Agvet Code must, for a notice issued under new paragraph 8S(1)(c) of the Agvet Code, set out the proposed variation.

Subsection 8S(2) of the Agvet Code currently provides that the written notice issued under subsection 8S(1) of the Agvet Code must contain a number of matters, which are currently set out by paragraphs 8S(2)(a), (c), (d) and (e) of the Agvet Code to be:

(a) for a notice issued under subsection 8S(1)(b)—the proposed instructions and relevant particulars; and

(c) a draft statement of reasons for the proposed course of action; and

(d) information on which the reasons are based (including information not given to the APVMA by the applicant); and

(e) an invitation for written submissions from the applicant within 28 days, or within such further period as is specified in the notice.

The proposed amendments to section 8S of the Agvet Code will ensure that the APVMA is able to grant part of an original application for variation, where that partial variation meets the criteria set out in subsection 29(1) of the Agvet Code.

For completeness, section 8D of the Agvet Code currently provides that, at any time after an application is made and before it is determined, an applicant may withdraw that application by giving the APVMA written notice of the withdrawal signed by the applicant. Accordingly, an applicant will also be able to withdraw their original variation application after making written submissions to the APVMA in relation to the proposed variation that is in a way other than set out in the original application.

In addition to the proposed amendments to section 8S of the Agvet Code, an applicant will also have access to review rights.

Section 166 of the Agvet Code currently provides for the internal review of decisions by the APVMA under various provisions of the Agvet Code, including a decision under subsection 29(2) of the Agvet Code to refuse 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 product.

Further, due to new paragraph 167(1)(ca) of the Agvet Code and the amendments proposed to subsection 29(1) of the Agvet Code by item 54 in Part 7 of Schedule 1 to the Bill, an affected applicant will have the ability to apply to the APVMA and the AAT for review of a decision made by the APVMA under subsection 29(1) of the Agvet Code to vary relevant particulars or conditions in a way other than as set out in the original application for variation.

New paragraph 167(1)(ca) of the Agvet Code provides that an application may be made to the APVMA and the AAT for review of a decision by the APVMA under subsection 29(1) of the Agvet Code to vary relevant particulars or conditions in a way other than as set out in the original application for variation. Item 54 in Part 7 of Schedule 1 to the Bill omits the references to “in accordance with the application” in paragraphs 29(1)(b), (c) and (d) of the Agvet Code, and substitutes those references with references to “in a particular way (which may not be the same way as set out in the application)”.

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It is appropriate that new paragraph 167(1)(ca) of the Agvet Code will provide a pathway for
applicants to seek merits review of a decision by the APVMA to vary relevant particulars or
conditions in a way other than as set out in the original application for variation, as an
applicant could be affected by such a decision.

Summary

Part 7 of Schedule 1 to the Bill is compatible with the right to an effective remedy provided
for by Article 2(3) of the ICCPR because the amendments proposed by that Part promote and
protect that right by providing a mechanism by which affected persons are able to seek
review of administrative decisions.

Part 8 of Schedule 1—Variation of approval or registration during suspension

Part 8 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised
or declared in the international instruments listed in section 3 of the Human Rights
(Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 9 of Schedule 1—False and misleading information

Civil penalties and Articles 14 and 15

Prescribing conduct that is subject to a civil penalty could engage criminal process rights if
the imposition of a civil penalty is classified as ‘criminal’ under international human rights
law. Guidance Note 2: Offence provisions, civil penalties and human rights
(December 2014), which is published by the Parliamentary Joint Committee on
Human Rights, states that civil penalty provisions may engage criminal process rights under
Articles 14 and 15 of the ICCPR, regardless of the distinction between criminal and civil
penalties in domestic law. When a provision imposes a civil penalty, an assessment is
required as to whether it amounts to a ‘criminal’ penalty for the purposes of the ICCPR.

Agricultural and Veterinary Chemicals (Administration) Act 1992

New subsection 69ER(5) of the Administration Act provides that new subsections 69ER(3)
and (4) of that Act are civil penalty provisions.

New subsection 69ER(3) of the Administration Act complements existing
subsection 69ER(1) of that Act by creating a civil penalty provision that provides that a
person must not, for the purposes of, or in connection with, the making of a decision by
the APVMA as to whether it should give a consent under section 69B of the
Administration Act:

(a) give information (whether orally or in writing) that the person knows to be false or
misleading in a material particular; or

(b) produce a document that the person knows to be false or misleading in a material
particular without:

(i) indicating to the person to whom the document is produced that it is false or
misleading and the respect in which it is false or misleading; and

(ii) providing correct information to that person if the person producing the document
is in possession of, or can reasonably acquire, the correct information.

Subsection 69ER(1) of the Administration Act provides that a person commits an offence
(subject to a criminal pecuniary penalty of 300 penalty units) if, for the purposes of, or in
connection with, the making of a decision by the APVMA as to whether it should give consent under section 69B of the Administration Act, that person:

(a) gives information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or

(b) produces a document that the person knows to be false or misleading in a material particular without:

(i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and

(ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

New subsection 69ER(4) of the Administration Act complements existing subsection 69ER(2) of that Act by creating a civil penalty provision that provides that a person must not, in compliance or purported compliance with a requirement made by an inspector (as defined by section 4 of the Administration Act) under Part 7A, Part 7AA or Part 7AB of the Administration Act, or for the purposes of, or in connection with, any provision of Part 7A (excluding section 69B), Part 7AA or Part 7AB of that Act:

(a) give information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or

(b) produce a document that the person knows to be false or misleading in a material particular without:

(i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and

(ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

Subsection 69ER(2) of the Administration Act provides that a person commits an offence (subject to a criminal pecuniary penalty of 60 penalty units) if, in compliance or purported compliance with a requirement made by an inspector (as defined by section 4 of the Administration Act) under Part 7A, Part 7AA or Part 7AB of the Administration Act, or for the purposes of, or in connection with, any provision of Part 7A (excluding section 69B), Part 7AA or Part 7AB of that Act, that person:

(a) gives information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or

(b) produces a document that the person knows to be false or misleading in a material particular without:

(i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and

(ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

Determining whether penalties could be considered to be criminal under international human rights law requires consideration of the classification of the penalty provisions under Australian domestic law, the nature and purpose of the penalties, and the severity of the penalties.
Item 68 in Part 9 of Schedule 1 to the Bill, which inserts new subsections 69ER(3) to (5) of the Administration Act, also inserts a note at the end of new subsection 69ER(5) of that Act to direct the reader to Division 1 of Part 7AB of the Administration Act. Division 1 of Part 7AB of the Administration Act creates a framework for the use of civil pecuniary penalties to enforce the civil penalty provisions of the Administration Act and the Levy Act (see the definition of *civil penalty provision* in section 4 of the Administration Act).

Subsection 69EJA(1) of the Administration 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 conduct that is the same as the conduct constituting the contravention. Subsection 69EJA(2) of the Administration Act provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

It is important to note that subsection 69EJA(1) of the Administration Act refers to the maximum monetary penalty that could be imposed by a court if a body corporate were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

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.

The applicable criminal pecuniary penalty for an individual for a contravention of current subsection 69ER(1) of the Administration Act is 300 penalty units. The applicable criminal pecuniary penalty for an individual for a contravention of current subsection 69ER(2) of the Administration Act is 60 penalty units.

Accordingly, as there is no contrary intention in the Administration Act, the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 69ER(1) of the Administration Act will be 1,500 penalty units, and the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 69ER(2) of the Administration Act will be 300 penalty units.

By virtue of section 69EJA of the Administration Act, and the matters prescribed by current subsection 69ER(1) of that Act (including the application of subsection 4B(3) of the Crimes Act to that subsection), the civil pecuniary penalty for new subsection 69ER(3) of the Administration Act will be 900 penalty units for individuals and 7,500 penalty units for bodies corporate. By virtue of section 69EJA of the Administration Act, and the matters prescribed by current subsection 69ER(2) of that Act (including the application of subsection 4B(3) to that subsection), the civil pecuniary penalty for new subsection 69ER(4) of the Administration Act will be 180 penalty units for individuals and 1,500 penalty units for bodies corporate.

The penalty provisions proposed to be created by new subsections 69ER(3) and (4) of the Administration Act are expressly classified as civil penalty provisions by new
subsection 69ER(5) of that Act. That is, new subsections 69ER(3) and (4) of the Administration Act create a pecuniary penalty in the form of a debt payable to the Commonwealth (see section 69EJB of the Administration Act).

The purpose of new subsections 69ER(3) and (4) of the Administration Act is to encourage compliance with the prohibition on providing false and misleading information or documents to the APVMA. New subsections 69ER(3) and (4) of the Administration Act do not impose criminal liability and do not lead to the creation of a criminal record. The proposed penalties will only apply to those persons who are seeking a decision by the APVMA under section 69B of the Administration Act, or who are subject to a requirement made by an inspector under Part 7A, Part 7AA or Part 7AB of the Administration Act, or for the purposes of, or in connection with, any provision of Part 7A (other than section 69B), Part 7AA or Part 7AB of that Act. That is, the penalty does not apply to the public in general.

Further, the imposition of the civil pecuniary penalties in new subsections 69ER(3) and (4) of the Administration Act are not dependent on a finding of guilt, and section 69EJG of the Administration Act expressly states that the contravention of a civil penalty provision is not an offence.

The applicable penalty for new subsection 69ER(3) of the Administration Act—being 900 penalty units for individuals and 7,500 penalty units for bodies corporate—is reflective of the seriousness of the conduct and the risk contravening behaviour may pose to human health and safety, the environment and trade if agvet chemicals are used inappropriately on the basis of false or misleading information or documents.

The applicable penalty for new subsection 69ER(4) of the Administration Act—being 180 penalty units for individuals and 1,500 penalty units for bodies corporate—is reflective of the seriousness of the conduct and the risk contravening behaviour may pose to human health and safety, the environment and trade if agvet chemicals are used inappropriately on the basis of false or misleading information or documents.

Further, the penalties proposed by new subsections 69ER(3) and (4) of the Administration Act are significantly less than the civil pecuniary penalties prescribed by section 31AAA of the Therapeutic Goods Act for similar conduct in relation to the provision of false or misleading information or documents, which are 5,000 penalty units for individuals and 50,000 penalty units for bodies corporate. This reflects the lower amounts for the current offences in relation to the provision of false or misleading information or documents in the Administration Act.

Section 69EJD of the Administration Act provides that a court may make a single civil penalty order against a person for multiple contraventions of a civil penalty provision if proceedings for the contraventions are founded on the same facts, or if the contraventions form, or are part of, a series of contraventions of the same or a similar character; however, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions. There are no criminal consequences associated with civil penalty orders for multiple contraventions (for example, they do not carry the possibility of imprisonment). As such, the civil penalties proposed by new subsections 69ER(3) and (4) of the Administration Act are not sufficiently severe such that they could be considered to be criminal penalties for the purposes of Australia’s human rights obligations.
These factors all suggest that the civil penalties proposed by new subsections 69ER(3) and (4) of the Administration Act are civil penalties rather than criminal penalties for the purposes of Australia’s human rights obligations. Accordingly, the criminal process rights provided for by Articles 14 and 15 of the ICCPR are not engaged. However, for completeness, and to demonstrate that new subsections 69ER(3) and (4) of the Administration Act are nonetheless compliant with the rights provided for by Articles 14 and 15 of the ICCPR, key provisions of Division 1 of Part 7AB of the Administration Act are set out below.

Article 14 of the ICCPR requires that, in the determination of criminal charges, everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law. Various other rights are provided for persons charged with criminal offences.

Due to the operation of subsection 69EJ(2) of the Administration Act, the time period for the making of an application for a civil penalty order will be within 6 years of the alleged contravention. As the criminal process rights in Article 14 of the ICCPR are not engaged by new subsections 69ER(3) and (4) of the Administration Act, the right to be tried without undue delay provided by paragraph 14(3)(c) of the ICCPR is not engaged.

Under section 69EJ of the Administration Act, civil penalty orders can only be granted by a court, which must consider all relevant matters before determining the amount of the penalty. Accordingly, the right to a fair hearing is not limited.

Section 69EJJ of the Administration Act clarifies that criminal proceedings may be commenced against a person for conduct that is the same, or substantially the same, as conduct that would constitute a contravention of a civil penalty provision, regardless of whether a civil penalty order has been made against the person in relation to the contravention. This section recognises the importance of criminal proceedings and criminal penalties in dissuading and sanctioning contraventions of the Administration Act, and ensures that criminal remedies are not precluded by earlier civil action.

Section 69EJ of the Administration Act engages the criminal process rights in Article 14 of the ICCPR, but does not limit those rights. Article 14(7) of the ICCPR provides that “no one shall be liable to be tried or punished again for an offence for which he has already been finally convicted or acquitted in accordance with the law and penal procedure of each country”. This prohibition on double jeopardy is a fundamental safeguard in the common law of Australia. It means that a person who has been convicted or acquitted of a criminal charge is not to be re-tried for the same or substantially the same offence.

As section 69EJ of the Administration Act permits both civil and criminal proceedings, but not multiple criminal proceedings for the same conduct, Article 14(7) of the ICCPR is not infringed. Further, section 69EJH of the Administration Act provides that a court cannot make a civil penalty order against a person for a contravention of a civil penalty provision if the person has been convicted of an offence constituted by conduct that is the same, or substantially the same, as the conduct constituting the contravention.

Section 69EJK of the Administration Act provides that evidence of information given, or evidence of the production of documents, by an individual is not admissible in criminal proceedings against the individual if:
• the individual previously gave the information or produced the documents in proceedings for a civil penalty order against the individual for an alleged contravention of a civil penalty provision (whether or not the order was made)

• the conduct alleged to constitute the offence is the same, or substantially the same, as the conduct alleged to constitute the contravention.

Section 69EJK of the Administration Act ensures that information or documents produced during civil proceedings are not relied upon to support subsequent criminal proceedings, unless those proceedings are criminal proceedings relating to falsifying evidence in civil proceedings. Accordingly, that section engages, but does not limit, the criminal process rights in Article 14 of the ICCPR.

Section 69EJL of the Administration Act provides that if an act or thing is required under a civil penalty provision to be done within a particular period or before a particular time, the obligation to do that act or thing continues until that act or thing is done, even if the period has expired or the time has passed. This section further provides that a person commits a separate contravention of the civil penalty provision in respect of each day during which the contravention occurs, including the day the civil penalty order is made (or any later day). This section is necessary to ensure that failure to comply with an obligation does not excuse a person from meeting that obligation.

As discussed above, section 69EJD of the Administration Act provides that a relevant court may make a single civil penalty order against a person for multiple contraventions of a civil penalty provision if proceedings for the contraventions are founded on the same facts, or if the contraventions form, or are part of, a series of contraventions of the same or a similar character; however, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions. There are no criminal consequences associated with civil penalty orders for multiple contraventions (for example, they do not carry the possibility of imprisonment). Accordingly, the application of section 69EJL of the Administration Act does not engage any human rights.

Section 69EJP of the Administration Act provides that, in proceedings for a civil penalty order against a person for a contravention of a civil penalty provision, a person bears an evidential burden where that person wishes to rely on any exception, exemption, excuse, qualification or justification provided by the law creating the civil penalty provision. As section 69EJP of the Administration Act only relates to proceedings for civil penalty orders, not offences, the right to be presumed innocent in Article 14(2) of the ICCPR is not engaged.

Sections 69EJC, 69EJE, 69EJF, 69EJI, 69EJM, 69EJN, 69EJO, 69EJQ, 69EJR and 69EJS of the Administration Act relate to:

• conduct contravening more than one civil penalty provision

• the ability to hear two or more civil penalty order proceedings together

• the application of the rules and evidence and procedure for civil matters

• the stay of civil proceedings during criminal proceedings;

• ancillary contraventions of civil penalty provisions

• mistake of fact

• the relevance of a person’s state of mind
liability of employees, agents or officers of a body corporate, respectively
liability of executive officers of a body corporate
establishing whether an executive officer took reasonable steps to prevent the contravention of a civil penalty provision.

Those provisions do not impact upon criminal proceedings and do not engage the criminal process rights in Article 14 of the ICCPR.

Article 15 of the ICCPR prohibits the retrospective application of criminal laws. As the amendments to the Administration Act in Part 9 of Schedule 1 to the Bill will only apply in relation to information given, or a document produced, on or after the commencement of Part 9—being the end of the period of three months beginning on the day after the Bill receives the Royal Assent—Article 15 of the ICCPR is not engaged. There are no additional human rights implications beyond those discussed above.

Agricultural and Veterinary Chemicals Code Act 1994

New subsection 146(5) of the Agvet Code provides that new subsections 146(3) and (4) of the Agvet Code are civil penalty provisions.

New subsection 146(3) of the Agvet Code complements existing subsection 146(1) of the Agvet Code by creating a civil penalty provision that provides that a person must not, for the purposes of, or in connection with, the consideration by the APVMA, in the course of the performance of any of its functions or the exercise of any of its powers under the Agvet Code, of any matters referred to in sections 5A, 5B, 5C or 5D or subsection 123(1) of the Agvet Code:

(a) give information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or

(b) produce a document that the person knows to be false or misleading in a material particular without:
    (i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and
    (ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

Subsection 146(1) of the Agvet Code provides that a person commits an offence (subject to a criminal pecuniary penalty of 300 penalty units) if, for the purposes of, or in connection with, the consideration by the APVMA, in the course of the performance of any of its functions or the exercise of any of its powers under the Agvet Code, of any matters referred to in section 5A (safety criteria), 5B (trade criteria), 5C (efficacy criteria) or 5D (labelling criteria) or subsection 123(1) (manufacturing licence applications) of the Agvet Code, that person:

(a) gives information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or

(b) produces a document that the person knows to be false or misleading in a material particular without:
    (i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and
(ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

New subsection 146(4) of the Agvet Code complements existing subsection 146(2) of the Agvet Code by creating a civil penalty provision that provides that a person must not, for the purposes of, or in connection with, the consideration by the APVMA, in the course of the performance of any of its functions or the exercise of any of its powers under the Agvet Code, of any matters other than matters referred to in new subsection 146(3) of the Agvet Code:

(a) give information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or

(b) produce a document that the person knows to be false or misleading in a material particular without:

(i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and

(ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

Subsection 146(2) of the Agvet Code provides that a person commits an offence (subject to a criminal pecuniary penalty of 60 penalty units) if, for the purposes of, or in connection with, the consideration by the APVMA, in the course of the performance of any of its functions or the exercise of any of its powers under the Agvet Code, of any matters other than matters referred to in subsection 146(1) of that Code, that person:

(a) gives information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or

(b) produces a document that the person knows to be false or misleading in a material particular without:

(i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and

(ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.

Determining whether penalties could be considered to be criminal under international human rights law requires consideration of the classification of the penalty provisions under Australian domestic law, the nature and purpose of the penalties, and the severity of the penalties.

Item 70 in Part 9 of Schedule 1 to the Bill, which inserts new subsections 146(3) to (5) of the Agvet Code, also inserts a note at the end of new subsection 146(5) of the Agvet Code to direct the reader to Division 2 of Part 9A of the Agvet Code. Division 2 of Part 9A of the Agvet Code creates a framework for the use of civil penalties to enforce civil penalty provisions of the Agvet Code.

Subsection 145AA(1) of the Agvet Code 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 conduct that is the same as the conduct constituting the contravention. Subsection 145AA(2) of the Agvet Code provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

It is important to note that subsection 145AA(1) of the Agvet Code refers to the maximum monetary penalty that could be imposed by a court if a body corporate were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention.

Subsection 170(5) of the Agvet Code states that, where a body corporate is convicted of an offence against the Agvet Code, a court may, if the court thinks fit, impose a monetary penalty not greater than five times the amount of the maximum monetary penalty that could be imposed by the court on an individual convicted of the same offence.

The applicable criminal pecuniary penalty for an individual for a contravention of current subsection 146(1) of the Agvet Code is 300 penalty units. The applicable criminal pecuniary penalty for an individual for a contravention of current subsection 146(2) of the Agvet Code is 60 penalty units.

Accordingly, the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 146(1) of the Agvet Code will be 1,500 penalty units, and the corresponding criminal pecuniary penalty for a body corporate for a contravention of current subsection 146(2) of the Agvet Code will be 300 penalty units.

By virtue of section 145AA of the Agvet Code, and the matters prescribed by current subsection 146(1) of the Agvet Code (including the application of subsection 170(5) of the Agvet Code to that subsection), the civil pecuniary penalty for new subsection 146(3) of the Agvet Code will be 900 penalty units for individuals and 7,500 penalty units for bodies corporate. By virtue of section 145AA of the Agvet Code, and the matters prescribed by current subsection 146(2) of the Agvet Code (including the application of subsection 170(5) of the Agvet Code to that subsection), the civil pecuniary penalty for new subsection 146(4) of the Agvet Code will be 180 penalty units for individuals and 1,500 penalty units for bodies corporate.

The penalty provisions proposed to be created by new subsections 146(3) and (4) of the Agvet Code are expressly classified as civil penalty provisions by new subsection 146(5) of the Agvet Code. That is, new subsections 146(3) and (4) of the Agvet Code create a pecuniary penalty in the form of a debt payable to the Commonwealth (see section 145AB of the Agvet Code).

The purpose of new subsections 146(3) and (4) of the Agvet Code is to encourage compliance with the prohibition on providing false and misleading information or documents to the APVMA. New subsections 146(3) and (4) of the Agvet Code do not impose criminal liability. The proposed penalties will only apply to those persons who manufacture or supply agvet chemical products and are thus subject to the provisions of the Agvet Code due to those activities. That is, the penalty does not apply to the public in general.

Further, the imposition of the civil pecuniary penalties in new subsections 146(3) and (4) of the Agvet Code are not dependent on a finding of guilt, and section 145AG of the
Agvet Code expressly states that the contravention of a civil penalty provision is not an offence.

The applicable penalty for new subsection 146(3) of the Agvet Code—being 900 penalty units for individuals and 7,500 penalty units for bodies corporate—is reflective of the seriousness of the conduct and the risk contravening behaviour may pose to human health and safety, the environment and trade if agvet chemicals are used inappropriately on the basis of false or misleading information or documents.

The applicable penalty for new subsection 146(4) of the Agvet Code—being 180 penalty units for individuals and 1,500 penalty units for bodies corporate—is reflective of the seriousness of the conduct and the risk contravening behaviour may pose to human health and safety, the environment and trade if agvet chemicals are used inappropriately on the basis of false or misleading information or documents.

Further, the penalties proposed by new subsections 146(3) and (4) of the Agvet Code are significantly less than the civil pecuniary penalties prescribed by section 31AAA of the Therapeutic Goods Act for similar conduct in relation to the provision of false or misleading information or documents, which are 5,000 penalty units for individuals and 50,000 penalty units for bodies corporate. This reflects the lower amounts for the current offences in relation to the provision of false or misleading information or documents in the Agvet Code.

Section 145AD of the Agvet Code provides that a court may make a single civil penalty order against a person for multiple contraventions of a civil penalty provision if proceedings for the contraventions are founded on the same facts, or if the contraventions form, or are part of, a series of contraventions of the same or a similar character; however, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions. There are no criminal consequences associated with civil penalty orders for multiple contraventions (for example, they do not carry the possibility of imprisonment). As such, the civil penalty proposed by new subsections 146(3) and (4) of the Agvet Code are not sufficiently severe such that they could be considered to be criminal penalties for the purposes of Australia’s human rights obligations.

These factors all suggest that the civil penalty proposed by new subsections 146(3) and (4) of the Agvet Code are civil penalties rather than criminal penalties for the purposes of Australia’s human rights obligations. Accordingly, the criminal process rights provided for by Articles 14 and 15 of the ICCPR are not engaged. However, for completeness, and to demonstrate that subsections 146(3) and (4) of the Agvet Code are nonetheless compliant with the rights provided for by Articles 14 and 15 of the ICCPR, key provisions of Division 2 of Part 9A of the Agvet Code are set out below.

Article 14 of the ICCPR requires that, in the determination of criminal charges, everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law. Various other rights are provided for persons charged with criminal offences.

Due to the operation of subsection 145A(2) of the Agvet Code, the time period for the making of an application for a civil penalty order will be within 6 years of the alleged contravention. As the criminal process rights in Article 14 of the ICCPR are not engaged by subsections 146(3) and (4) of the Agvet Code, the right to be tried without undue delay provided by paragraph 14(3)(c) of the ICCPR is not engaged.
Under section 145A of the Agvet Code, civil penalty orders can only be granted by a court, which must consider all relevant matters before determining the amount of the penalty. Accordingly, the right to a fair hearing is not limited.

Section 145BB of the Agvet Code clarifies that criminal proceedings may be commenced against a person for conduct that is the same, or substantially the same, as conduct that would constitute a contravention of a civil penalty provision, regardless of whether a civil penalty order has been made against the person in relation to the contravention. This section recognises the importance of criminal proceedings and criminal penalties in dissuading and sanctioning contraventions of the Agvet Code, and ensures that criminal remedies are not precluded by earlier civil action.

Section 145BB of the Agvet Code engages the criminal process rights in Article 14 of the ICCPR, but does not limit those rights. Article 14(7) of the ICCPR provides that “no one shall be liable to be tried or punished again for an offence for which he has already been finally convicted or acquitted in accordance with the law and penal procedure of each country”. This prohibition on double jeopardy is a fundamental safeguard in the common law of Australia. It means that a person who has been convicted or acquitted of a criminal charge is not to be re-tried for the same or substantially the same offence.

As section 145BB of the Agvet Code permits both civil and criminal proceedings, but not multiple criminal proceedings for the same conduct, Article 14(7) of the ICCPR is not infringed. Further, section 145B of the Agvet Code provides that a court cannot make a civil penalty order against a person for a contravention of a civil penalty provision if the person has been convicted of an offence constituted by conduct that is the same, or substantially the same, as the conduct constituting the contravention.

Section 145BC of the Agvet Code provides that evidence of information given, or evidence of the production of documents, by an individual is not admissible in criminal proceedings against the individual if:

- the individual previously gave the information or produced the documents in proceedings for a civil penalty order against the individual for an alleged contravention of a civil penalty provision (whether or not the order was made); and
- the conduct alleged to constitute the offence is the same, or substantially the same, as the conduct alleged to constitute the contravention.

Section 145BC of the Agvet Code ensures that information or documents produced during civil proceedings are not relied upon to support subsequent criminal proceedings, unless those proceedings are criminal proceedings relating to falsifying evidence in civil proceedings. Accordingly, that section engages, but does not limit, the criminal process rights in Article 14 of the ICCPR.

Section 145C of the Agvet Code provides that if an act or thing is required under a civil penalty provision to be done within a particular period or before a particular time, the obligation to do that act or thing continues until that act or thing is done, even if the period has expired or the time has passed. This section further provides that a person commits a separate contravention of the civil penalty provision in respect of each day during which the contravention occurs, including the day the civil penalty order is made (or any later day). This section is necessary to ensure that failure to comply with an obligation does not excuse a person from meeting that obligation.
As discussed above, section 145AD of the Agvet Code provides that a relevant court may make a single civil penalty order against a person for multiple contraventions of a civil penalty provision if proceedings for the contraventions are founded on the same facts, or if the contraventions form, or are part of, a series of contraventions of the same or a similar character; however, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions. There are no criminal consequences associated with civil penalty orders for multiple contraventions (for example, they do not carry the possibility of imprisonment). Accordingly, the application of section 145C of the Agvet Code does not engage any human rights.

Section 145CD of the Agvet Code provides that, in proceedings for a civil penalty order against a person for a contravention of a civil penalty provision, a person bears an evidential burden where that person wishes to rely on any exception, exemption, excuse, qualification or justification provided by the law creating the civil penalty provision. As section 145CD of the Agvet Code only relates to proceedings for civil penalty orders, not offences, the right to be presumed innocent in Article 14(2) of the ICCPR is not engaged.

Sections 145AC, 145AE, 145AF, 145BA, 145CB, 145CC, 145CE, 145CF and 145CG of the Agvet Code relate to:
- conduct contravening more than one civil penalty provision
- the ability to hear two or more civil penalty order proceedings together
- the application of the rules and evidence and procedure for civil matters
- the stay of civil proceedings during criminal proceedings
- ancillary contraventions of civil penalty provisions
- mistake of fact
- the relevance of a person’s state of mind
- liability of employees, agents or officers of a body corporate, respectively
- liability of executive officers of a body corporate
- establishing whether an executive officer took reasonable steps to prevent the contravention of a civil penalty provision.

Those provisions do not impact upon criminal proceedings and do not engage the criminal process rights in Article 14 of the ICCPR.

Article 15 of the ICCPR prohibits the retrospective application of criminal laws. As the amendments proposed to the Agvet Code by Part 9 of Schedule 1 to the Bill will only apply in relation to information given, or a document produced, on or after the commencement of Part 9—being the end of the period of three months beginning on the day after the Bill receives the Royal Assent—Article 15 of the ICCPR is not engaged. There are no additional human rights implications beyond those discussed above.

Summary
Part 9 of Schedule 1 to the Bill is compatible with the criminal process rights provided for by Articles 14 and 15 of the ICCPR because new subsections 69ER(3), (4) and (5) of the
Administration Act and new subsections 146(3), (4) and (5) of the Agvet Code do not engage those rights.

Part 10 of Schedule 1—Suspension or cancellation of approval or registration for provision of false or misleading information

Part 10 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 11 of Schedule 1—Voluntary recalls

Part 11 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Right to privacy

Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual’s privacy, family, home or correspondence, and protects a person’s honour and reputation from unlawful attacks. The right to privacy can be limited to achieve a legitimate objective where the limitations are lawful and not arbitrary. In order for an interference with the right to privacy to be permissible, the interference must be authorised by law, be for a reason consistent with the ICCPR and be reasonable in the circumstances. The United Nations Human Rights Committee has interpreted the requirement of ‘reasonableness’ as implying that any interference with privacy must be proportionate to a legitimate end and be necessary in the circumstances.

Amended section 106 of the Agvet Code engages the protection against arbitrary or unlawful interference with privacy, as the proposed provision enables information to be collected, used and disclosed by the APVMA. To the extent that section 106 may limit the right to privacy, any limitation is reasonable, necessary and proportionate to the achievement of a legitimate objective of an effective recall.

If a person is recalling a chemical product for a reason set out in subsection 106(1) then new subsection 106(2) requires the person to notify the APVMA of this recall in an approved form within 2 days of undertaking the recall action. The approved form will be a form that the APVMA has approved or that is prescribed in the regulations. New subsection 106(6) provides that where the APVMA is notified of a recall then it must publish a copy of the notice about this recall on its website within 3 working days and in the Gazette within 14 days. These measures will ensure that stakeholders are informed of the recall and will promote the effectiveness of the recall.

The Agvet Code pursues the legitimate objective of regulating the supply of safe and effective agvet chemicals that do not unduly prejudice trade. Amended section 106 of the Agvet Code will ensure that the APVMA can collect, use and disclose information about recalls of agvet chemicals in the marketplace. This information will be used by users of chemical products and ensure that voluntary recalls of agvet chemicals are effective. It is anticipated that disclosure of information will be limited to the details necessary to conduct an effective recall.
Summary

Part 11 of Schedule 1 to the Bill is compatible with human rights because, to the extent that amended section 106 of the Agvet Code may limit the right to privacy in Article 17 of the ICCPR, that limitation is reasonable, necessary and proportionate to the achievement of a legitimate outcome of promoting an effective recall.

Right to the presumption of innocence (strict liability offence)

Article 14(2) of the ICCPR states that everyone charged with a criminal offence shall have the right to be presumed innocent until proven guilty according to law. The right to the presumption of innocence is also a fundamental common law principle in Australia.

When strict liability applies to an offence, the prosecution is only required to prove the physical elements of an offence. That is, they are not required to prove fault elements in order for the defendant to be found guilty. Strict liability is used in circumstances where there is a public interest in ensuring that regulatory requirements are observed and it can be reasonably expected that the person was aware of their duties and obligations in regulatory requirements. Strict liability offences can be considered a limitation of the presumption of innocence because the defendant can be found guilty without the prosecution being required to prove fault. It is important to note that the defence of honest and reasonable mistake of fact is available to the defendant (see section 9.2 of the Criminal Code).

Strict liability offences will not necessarily be inconsistent with the presumption of innocence, provided that the limitation of the presumption of innocence pursues a legitimate objective and is reasonable, necessary and proportionate to achieving that objective. Whether a strict liability provision impermissibly limits the right to the presumption of innocence will depend on the circumstances of the case and the particular justification for an offence being a strict liability offence.

Part 11 of Schedule 1 to the Bill establishes a strict liability offence in new subsection 106(4) of the Agvet Code. The application of strict liability in Part 11 of Schedule 1 to the Bill, and the offences to which it relates, has been developed in line with the Guide to Framing Commonwealth Offences.

New subsection 106(4) of the Agvet Code provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty of 60 penalty units, if that person contravenes new subsection 106(4) of the Agvet Code. New subsection 106(4) makes it an offence of strict liability to fail or refuse to notify the APVMA of a recall of a chemical product that is being conducted for one of the reasons set out in new subsection 106(1).

The applicable pecuniary penalty of 60 penalty units in new subsection 106(4) of the Agvet Code is the maximum criminal pecuniary penalty that a relevant court could impose on an individual. The maximum criminal pecuniary penalty that a relevant court could impose on a body corporate for a contravention of new subsection 106(4) of the Agvet Code will be 300 penalty units, due to the application of subsection 170(5) of the Agvet Code.

Subsection 170(5) of the Agvet Code states that, where a body corporate is convicted of an offence against the Agvet Code, a court may, if the court thinks fit, impose a monetary penalty not greater than five times the amount of the maximum monetary penalty that could be imposed by the court on an individual convicted of the same offence.
It is necessary to prescribe the conduct in new subsection 106(4) of the Agvet Code as an offence of strict liability. This is because it will place persons on notice to guard against the possibility of any contravention of the Agvet Code by encouraging persons voluntarily recalling chemical products that do not comply with the statutory criteria set out in sections 5A to 5D of the Agvet Code, or which are not registered chemical products, to notify the APVMA of the recall. In addition, it is appropriate for these elements to be strict liability because persons supplying chemical products should know their legal obligations before supplying these products and because the offence is necessary to ensure the integrity of the regulatory scheme.

Notifying the APVMA about recalls of chemical products is essential to ensure the regulator is fully informed of actions being taken to remove products from the market. This is also necessary to ensure the regulator can monitor any public health and environment risks and ensure these are managed through the recall.

Further, the proposed penalty in new subsection 106(4) is consistent with the Guide to Framing Commonwealth Offences, which provides that 50 to 60 penalty units is a comparable penalty for the failure to lodge a return or report. A penalty in the upper range of 60 penalty units is considered appropriate given the potential risks to public safety, the environment, animal and plant health or trade that could be relevant or are being managed by the recall of a chemical product.

In summary, the application of strict liability in new subsection 106(4) is appropriate because:

- a contravention of new subsection 106(4) of the Agvet Code is not punishable by imprisonment
- the applicable penalty for the strict liability offence is 60 penalty units for an individual and 300 penalty units for a body corporate (consistent with subsection 170(5) of the Agvet Code)
- the punishment of the strict liability offence prescribed by new subsection 106(4) of the Agvet Code is likely to significantly enhance the effectiveness of the enforcement regime of the Agvet Code by encouraging persons to notify the APVMA of voluntary recalls of chemical products (where there are potential risks to public safety, the environment, animal and plant health or trade).

Summary

New subsection 106(4) of the Agvet Code, as inserted by Part 11 of Schedule 1 to the Bill, is compatible with human rights because, to the extent that they may limit the right to be presumed innocent in Article 14(2) of the ICCPR, that limitation is reasonable, necessary and proportionate to the achievement of a legitimate objective of notifying the APVMA about recalls to ensure the APVMA can monitor any public health and environment risks.

Civil penalty and Articles 14 and 15

Prescribing conduct that is subject to a civil penalty could engage criminal process rights if the imposition of a civil penalty is classified as ‘criminal’ under international human rights law. Guidance Note 2: Offence provisions, civil penalties and human rights (December 2014), which is published by the Parliamentary Joint Committee on Human Rights, states that civil penalty provisions may engage criminal process rights under...
Articles 14 and 15 of the ICCPR, regardless of the distinction between criminal and civil penalties in domestic law. When a provision imposes a civil penalty, an assessment is required as to whether it amounts to a ‘criminal’ penalty for the purposes of the ICCPR.

**Agricultural and Veterinary Chemicals Code Act 1994**

New subsection 106(5) of the Agvet Code provides that new subsection 106(4) of the Agvet Code is a civil penalty provision. New subsection 106(4) makes it an offence of strict liability to fail or refuse to notify the APVMA of a recall of a chemical product that is being conducted for one of the reasons set out in subsection 106(1).

Determining whether penalties could be considered to be criminal under international human rights law requires consideration of the classification of the penalty provisions under Australian domestic law, the nature and purpose of the penalties, and the severity of the penalties.

Item 77 in Part 11 of Schedule 1 to the Bill, which inserts new subsection 106(5) of the Agvet Code, also inserts a note at the end of new subsection 106(5) of the Agvet Code to direct the reader to Division 2 of Part 9A of the Agvet Code. Division 2 of Part 9A of the Agvet Code creates a framework for the use of civil penalties to enforce civil penalty provisions of the Agvet Code.

Existing subsection 145AA(1) of the Agvet Code 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 conduct that is the same as the conduct constituting the contravention.

Existing subsection 145AA(2) of the Agvet Code provides that the pecuniary penalty for a contravention of a civil penalty provision by an individual must not exceed three times the amount of the maximum monetary penalty that could be imposed by a court if the person were convicted of an offence constituted by conduct that is the same as the conduct constituting the contravention. Subsection 170(5) of the Agvet Code states that, where a body corporate is convicted of an offence against the Agvet Code, a court may, if the court thinks fit, impose a monetary penalty not greater than five times the amount of the maximum monetary penalty that could be imposed by the court on an individual convicted of the same offence.

The applicable criminal pecuniary penalty for an individual for a contravention of subsection 106(4) of the Agvet Code is 60 penalty units. Accordingly, the corresponding criminal pecuniary penalty for a body corporate for a contravention of subsection 106(4) of the Agvet Code will be 300 penalty units.

By virtue of section 145AA of the Agvet Code, and the matters prescribed by subsection 106(4) of the Agvet Code (including the application of subsection 170(5) of the Agvet Code to that subsection), the civil pecuniary penalty for new subsection 106(5) of the Agvet Code will be 180 penalty units for individuals and 1,500 penalty units for bodies corporate.

The penalty provision proposed to be created by new subsection 106(4) of the Agvet Code is expressly classified as a civil penalty provision by new subsection 106(5) of the Agvet Code.
That is, new subsection 106(5) of the Agvet Code creates a pecuniary penalty in the form of a debt payable to the Commonwealth (see section 145AB of the Agvet Code).

The purpose of new subsection 106(5) of the Agvet Code is to encourage compliance with the requirement to notify the APVMA of a recall of a chemical product. New subsection 106(5) of the Agvet Code does not impose criminal liability. The proposed penalties will only apply to those persons who manufacture or supply agvet chemical products and are thus subject to the provisions of the Agvet Code due to those activities. That is, the penalty does not apply to the public in general, it only applies to persons who would reasonably be expected to be aware of their obligations to inform the APVMA if they are recalling chemical products.

Further, the imposition of the civil pecuniary penalty in new subsection 106(5) of the Agvet Code is not dependent on a finding of guilt, and section 145AG of the Agvet Code expressly states that the contravention of a civil penalty provision is not an offence.

The applicable penalty for new subsection 106(5) of the Agvet Code—being 180 penalty units for individuals and 1,500 penalty units for bodies corporate—is reflective of the seriousness of the conduct and the risk contravening behaviour may pose to human health and safety, the environment, animal and plant health and trade if recalls of agvet chemicals are not notified to the APVMA.

Section 145AD of the Agvet Code provides that a court may make a single civil penalty order against a person for multiple contraventions of a civil penalty provision if proceedings for the contraventions are founded on the same facts, or if the contraventions form, or are part of, a series of contraventions of the same or a similar character; however, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions. There are no criminal consequences associated with civil penalty orders for multiple contraventions (for example, they do not carry the possibility of imprisonment). As such, the civil penalty proposed by new subsection 106(5) of the Agvet Code are not sufficiently severe such that they could be considered to be criminal penalties for the purposes of Australia’s human rights obligations.

These factors all support that the civil penalty created by new subsection 106(5) of the Agvet Code is a civil penalty rather than a criminal penalty for the purposes of Australia’s human rights obligations. Accordingly, the criminal process rights provided for by Articles 14 and 15 of the ICCPR are not engaged. However, for completeness, and to demonstrate that subsection 106(5) of the Agvet Code is nonetheless compliant with the rights provided for by Articles 14 and 15 of the ICCPR, key provisions of Division 2 of Part 9A of the Agvet Code are set out below.

Article 14 of the ICCPR requires that, in the determination of criminal charges, everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law. Various other rights are provided for persons charged with criminal offences.

Due to the operation of subsection 145A(2) of the Agvet Code, the time period for the making of an application for a civil penalty order will be within 6 years of the alleged contravention. As the criminal process rights in Article 14 of the ICCPR are not engaged by subsection 106(5) of the Agvet Code, the right to be tried without undue delay provided by paragraph 14(3)(c) of the ICCPR is not engaged.
Under section 145A of the Agvet Code, civil penalty orders can only be granted by a court, which must consider all relevant matters before determining the amount of the penalty. Accordingly, the right to a fair hearing is not limited.

Section 145BB of the Agvet Code clarifies that criminal proceedings may be commenced against a person for conduct that is the same, or substantially the same, as conduct that would constitute a contravention of a civil penalty provision, regardless of whether a civil penalty order has been made against the person in relation to the contravention. This section recognises the importance of criminal proceedings and criminal penalties in dissuading and sanctioning contraventions of the Agvet Code, and ensures that criminal remedies are not precluded by earlier civil action.

Section 145BB of the Agvet Code engages the criminal process rights in Article 14 of the ICCPR, but does not limit those rights. Article 14(7) of the ICCPR provides that “no one shall be liable to be tried or punished again for an offence for which he has already been finally convicted or acquitted in accordance with the law and penal procedure of each country”. This prohibition on double jeopardy is a fundamental safeguard in the common law of Australia. It means that a person who has been convicted or acquitted of a criminal charge is not to be re-tried for the same or substantially the same offence.

As section 145BB of the Agvet Code permits both civil and criminal proceedings, but not multiple criminal proceedings for the same conduct, Article 14(7) of the ICCPR is not infringed. Further, section 145B of the Agvet Code provides that a court cannot make a civil penalty order against a person for a contravention of a civil penalty provision if the person has been convicted of an offence constituted by conduct that is the same, or substantially the same, as the conduct constituting the contravention.

Section 145BC of the Agvet Code provides that evidence of information given, or evidence of the production of documents, by an individual is not admissible in criminal proceedings against the individual if:

- the individual previously gave the information or produced the documents in proceedings for a civil penalty order against the individual for an alleged contravention of a civil penalty provision (whether or not the order was made); and
- the conduct alleged to constitute the offence is the same, or substantially the same, as the conduct alleged to constitute the contravention.

Section 145BC of the Agvet Code ensures that information or documents produced during civil proceedings are not relied upon to support subsequent criminal proceedings, unless those proceedings are criminal proceedings relating to falsifying evidence in civil proceedings. Accordingly, that section engages, but does not limit, the criminal process rights in Article 14 of the ICCPR.

Section 145C of the Agvet Code provides that if an act or thing is required under a civil penalty provision to be done within a particular period or before a particular time, the obligation to do that act or thing continues until that act or thing is done, even if the period has expired or the time has passed. This section further provides that a person commits a separate contravention of the civil penalty provision in respect of each day during which the contravention occurs, including the day the civil penalty order is made (or any later day). This section is necessary to ensure that failure to comply with an obligation does not excuse a person from meeting that obligation.
As discussed above, section 145AD of the Agvet Code provides that a relevant court may make a single civil penalty order against a person for multiple contraventions of a civil penalty provision if proceedings for the contraventions are founded on the same facts, or if the contraventions form, or are part of, a series of contraventions of the same or a similar character; however, the penalty must not exceed the sum of the maximum penalties that could be ordered if a separate penalty were ordered for each of the contraventions. There are no criminal consequences associated with civil penalty orders for multiple contraventions (for example, they do not carry the possibility of imprisonment). Accordingly, the application of section 145C of the Agvet Code does not engage any human rights.

Section 145CD of the Agvet Code provides that, in proceedings for a civil penalty order against a person for a contravention of a civil penalty provision, a person bears an evidential burden where that person wishes to rely on any exception, exemption, excuse, qualification or justification provided by the law creating the civil penalty provision. As section 145CD of the Agvet Code only relates to proceedings for civil penalty orders, not offences, the right to be presumed innocent in Article 14(2) of the ICCPR is not engaged.

Sections 145AC, 145AE, 145AF, 145BA, 145CA, 145CB, 145CC, 145CE, 145CF and 145CG of the Agvet Code relate to:

- conduct contravening more than one civil penalty provision
- the ability to hear two or more civil penalty order proceedings together
- the application of the rules and evidence and procedure for civil matters
- the stay of civil proceedings during criminal proceedings
- ancillary contraventions of civil penalty provisions
- mistake of fact
- the relevance of a person’s state of mind
- liability of employees, agents or officers of a body corporate, respectively
- liability of executive officers of a body corporate
- establishing whether an executive officer took reasonable steps to prevent the contravention of a civil penalty provision.

Those provisions do not impact upon criminal proceedings and do not engage the criminal process rights in Article 14 of the ICCPR.

Article 15 of the ICCPR prohibits the retrospective application of criminal laws. As the amendments proposed to the Agvet Code by Part 11 of Schedule 1 to the Bill will only apply in relation to actions taken on or after the commencement of Part 11—being the end of the period of three months beginning on the day after the Bill receives the Royal Assent—Article 15 of the ICCPR is not engaged. There are no additional human rights implications beyond those discussed above.

Summary

Part 11 of Schedule 1 to the Bill is compatible with the criminal process rights provided for by Articles 14 and 15 of the ICCPR because new subsection 106(5) of the Agvet Code does not engage those rights.
Part 12 of Schedule 1—Notification of new information

Part 12 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 13 of Schedule 1—Annual operational plans

Part 13 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 14 of Schedule 1—Definition of registered chemical product

Part 14 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Part 15 of Schedule 1—Supply of registered chemical product with unapproved label

Part 15 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Right to the presumption of innocence (existing reverse burden provisions)

The Bill amends section 81 of the Agvet Code to address an inconsistency in the Agvet Code by clarifying what information must be included on a label. The amendments clarify that the only ‘relevant particulars’ that are required on a label are the ‘instructions’ for use and the ‘particulars to be contained on the label’ as prescribed in regulation 18D of the Code Regulations. The amendments mean that not all relevant particulars are required to be included on a label, whereas the existing offence requires all relevant particulars to be included on a label.

The amendments do not alter the penalty for the offence.

The current section 81 of the Agvet Code also includes an exception and a defence, in which the defendant bears a legal burden for the defence (subsection 81(2)) and an exception in which the defendant bears an evidential burden (subsection 81(3)). The amendments replace the current references to ‘relevant particulars’ with references to ‘minimum information’. For this reason an assessment of the compatibility with human rights has been undertaken.

Laws that shift the burden of proof to a defendant, commonly known as ‘reverse burden provisions’, can be considered a limitation of the presumption of innocence. This is because a defendant’s failure to discharge a burden of proof or prove an absence of fault may permit their conviction despite reasonable doubt as to their guilt. This includes where an evidential or legal burden of proof is placed on a defendant.

When a defendant bears an evidential burden in relation to an exception it means that the defendant bears the burden of adducing or pointing to evidence that suggests a reasonable possibility that the exception has been met. It is then up to the prosecution to establish that this exception does not apply. When a defendant bears a legal burden of proof it means that the defendant must discharge the burden on the balance of probabilities.
Reverse burden offences will not necessarily be inconsistent with the presumption of innocence, provided that the reverse burden pursues a legitimate objective and is reasonable, necessary, and proportionate to achieving that objective. Whether a reverse burden provision impermissibly limits the right to the presumption of innocence will depend on the circumstances of the case and the particular justification for the reverse burden.

The Guide to Framing Commonwealth Offences notes that placing the burden of proof on the defendant should be limited to where the matter is peculiarly within the knowledge of the defendant and where it is significantly more difficult and costly for the prosecution to disprove than for the defendant to establish the matter.

The Guide to Framing Commonwealth Offences also notes that a reverse burden provision is more readily justified if:

- the matter in question is not central to the question of culpability for the offence;
- the penalties are at the lower end of the scale; and
- the conduct proscribed by the offence poses a grave danger to public health or safety.

An additional factor to consider is whether the offences only impose an evidential burden—that is, the prosecution must still disprove the matters beyond reasonable doubt if the defendant discharges the evidential burden.

Subsections 81(2) and (3) remain necessary to achieve the legitimate objective of protecting public health and the health of animals, plants, and the environment. Chemical products can be extremely hazardous to people, plants, animals, and the environment if they are not used in accordance with the instructions for use on the label. These instructions may include important information about the handling of the chemical products, including personal protective equipment for people using the product and how the product may be used safely to protect people and the environment. The label, and the instructions for use in the label, are therefore vital to ensuring the safe and effective use of the chemical product.

Exception in subsection 81(3)

Current subsection 81(3) as amended by the Bill place an evidential burden on the defendant in relation to the labels that are attached to chemical products. The current and amended provision are consistent with the Guide to Framing Commonwealth Offences.

Subsection 81(3) deals with a situation where a label has been amended for a chemical product and products with the previously approved label may still be in the supply chain. Subsection 81(3) provides for persons to continue to supply these products for a specified period of time if the APVMA determines that is appropriate. Subsection 81(3) ensures that persons can supply chemical products with previously approved labels only if that supply is authorised. This ensures that chemical products can be used safely for the specified period of time that the APVMA determines is appropriate (under current paragraph 81(3)(c) and amended paragraph 81(3)(d)).

Chemical products can have convoluted supply chains with many persons involved in the supply of a chemical product from manufacture through to delivery in rural or regional areas of the country. As products move through this supply chain the relevant persons keep records (invoices) of the supplies they have handled. These records are peculiarly within the knowledge of the person supplying the products and the records allow the person supplying
the chemical products to easily provide evidence that chemical products with previously approved labels were supplied within the specified period of time allowed by the APVMA. Reversing the burden in these circumstances is reasonable because the defendant will have the relevant information or knowledge available to them, which would form evidence to support the application of the defence. This task would be considerably more difficult and costly for the prosecution to establish, particularly given the wide distribution of chemical products in Australia. For this reason and to protect the safety of people, plants, animals and the environment, the defendant would continue to bear the evidential burden in relation to the exception in subsection 81(3).

Defence in subsection 81(2)

Current subsection 81(2) as amended by the Bill places a legal burden on the defendant in relation to the labels that are attached to chemical products. The current and amended provisions are consistent with the Guide to Framing Commonwealth Offences.

Subsection 81(2) deals with a situation where a product has been supplied and the label does not include the required information or contains information contrary to the required information. This can represent an extremely hazardous situation in that the supply of a chemical product without the required information or with incorrect information could have serious consequences for the public health and safety of people, animals, plants or the environment. These consequences may include death or serious injury to persons, contaminated land or waterways or complete loss of a financially important export market. These consequences may linger for many years.

As previously stated, chemical products can have convoluted supply chains with many persons involved in the supply of a chemical product, including retailers or other persons who would have no technical knowledge about a chemical product. Some persons supplying a chemical product may not have the technical knowledge to know if all the required information is in the label of the product or if the information is contrary to the correct label information, particularly given the technical information that might be included in instructions on a chemical product. Subsection 81(2) provides a defence for these persons, provided they are able to establish that they did not know or could not reasonably be expected to have known the information in a label was missing or contrary to the correct label information.

What a person knows or could reasonably be expected to know is peculiarly within the knowledge of the person and will vary from person to person and may also vary depending on what chemical product is being supplied. For example, a person handling pool chlorine from a store supplying pool chemicals may have more knowledge about the products they supply than a person selling household insecticides in a supermarket. Reversing the burden in these circumstances is both reasonable and proportionate because the defendant will have the relevant information or knowledge available to them, which would form evidence to support the application of the defence in the particular circumstance. This task would be considerably more difficult and costly for the prosecution to establish what a person knows or could reasonably be expected to know in the particular circumstance. For this reason and given both the serious consequences of mislabelled chemical products being supplied and the need to protect the safety of people, plants, animals and the environment, the defendant would continue to bear the legal burden in relation to the defence in subsection 81(2).
Subsections 81(2) and (3) as amended by Part 15 of Schedule 1 to the Bill are compatible with human rights. This is because, to the extent that they may limit the right to be presumed innocent in Article 14(2) of the ICCPR, that limitation is reasonable, necessary and proportionate to the achievement of a legitimate objective of protecting public health and the health of animals, plants and the environment from what may be serious consequences if chemical products are not used in accordance with the approved instructions for use.

**Part 16 of Schedule 1—Safety, efficacy, trade and labelling criteria**

Part 16 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

**Part 17 of Schedule 1—Maximum Residue Limits Standard**

Part 17 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

**Part 18 of Schedule 1—Expiry date**

Part 18 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

**Part 19 of Schedule 1—Other amendments**

Part 19 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

While Part 19 includes measures to allow the APVMA to reconsider certain matters on its own initiative, these measures do not affect a person’s right to an effective remedy, as there is no change to the circumstances in which a person may request an internal review or apply for AAT review.

Part 19 includes amendments to sections 74, 75, 76 and 78 to omit certain exceptions in these offences. These exceptions have never applied since the National Registration Scheme commenced in 1995. This is because the exceptions only apply if the APVMA makes a specific kind of determination and the APVMA has never had to make these kinds of determinations. The amendments to the notes about evidential burden for these exceptions are editorial amendments to reflect the removal of the exceptions that have never applied. As the exceptions have never applied and the editorial amendments to the notes have no effect, the amendments to sections 74, 75, 76 and 78 in Part 19 do not engage any human rights.

**Part 20 of Schedule 1—Repeals**

Part 20 of Schedule 1 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.
Schedule 2—Australian Pesticides and Veterinary Medicines Authority Board

Schedule 2 to the Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights (Parliamentary Scrutiny) Act as it does not engage any human rights.

Conclusion

The Bill is compatible with human rights because, to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

Circulated by authority of the Minister for Agriculture, Senator the Hon. Bridget McKenzie