EXPLANATORY STATEMENT

Issued by Authority of the Minister for Agriculture and Northern Australia

Agricultural and Veterinary Chemicals (Administration) Act 1992
Agricultural and Veterinary Chemicals Code Act 1994

Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021

Legislative Authority

Section 73 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act) provides that the Governor-General may make regulations prescribing all matters:

- required or permitted by the Administration Act to be prescribed; or
- necessary or convenient to be prescribed, for carrying out or giving effect to the Administration Act.

Subsection 6(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act) provides that the Governor-General may make regulations prescribing matters:

- required or permitted by the Agvet Code (as defined in section 3 of the Code Act and as set out in the Schedule to the Code Act) to be prescribed by regulations within the meaning of the Agvet Code; or
- necessary or convenient to be prescribed by such regulations for carrying out or giving effect to the Agvet Code.

The Administration Act and the Code Act also include other provisions for certain matters to be prescribed in regulations. These provisions are described for each of the relevant amending items in Attachment A.

The Administration Act, Code Act and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (the Levy Act), and any regulations or legislative instruments made under these laws, are collectively referred to as agricultural and veterinary (agvet) chemical legislation in this explanatory statement.

Neither the Code Act nor the Administration Act specify any conditions that need to be satisfied before the power to make the Regulations may be exercised.

Purpose

The purpose of the *Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021* (the Regulations) is to improve the efficiency and effectiveness of the national system for regulating agvet chemicals. They amend the *Agricultural and Veterinary Chemicals Code Regulations 1995* and the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995* made under agvet chemical legislation to:

- prescribe certain kinds of information the Australian Pesticides and Veterinary Medicines Authority (the APVMA) may take into account during the assessment period for an

application which would otherwise not be permitted to be taken into account under subsection 8C(2) of the Agvet Code

- authorise the APVMA to set, in a disallowable legislative instrument, application fees and assessment periods for applications made under sections 14C, 14D and 14E of the Agvet Code for the approval and registration for prescribed active constituents, chemical products or labels
- require the APVMA, when publishing the summary of relevant applications, to include a statement that relevant protection periods or limitation periods may be extended as a result of granting the application
- provide the APVMA with the ability to issue infringement notices for alleged contraventions of civil penalty provisions relating to:
    - failing to comply with annual return reporting or record keeping requirements (subsections 35(4) and 37(3) of the Levy Act, respectively)
    - providing the APVMA with false or misleading information or documents (subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and (4) of the Agvet Code)
    - failing to notify the APVMA of a voluntary recall (subsection 106(2) of the Agvet Code)
- declare that certain voluntary recall notices submitted to the APVMA under subsection 106(7) of the Agvet Code do not need to be published.

ACRONYMS, ABBREVIATIONS AND COMMONLY USED TERMS

Term	Meaning
Administration Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
Administration Regulations	Agricultural and Veterinary Chemicals (Administration) Regulations 1995
agvet	agricultural and veterinary
Agvet Code	the Agricultural and Veterinary Chemicals Code, as set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*
APVMA	Australian Pesticides and Veterinary Medicines Authority
APVMA Board and Other Improvements Act	*Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021*
Code Regulations	*Agricultural and Veterinary Chemicals Code Regulations 1995*
Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
Crimes Act	*Crimes Act 1914*
the Guide	*Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*
Levy Act	*Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*
NRS	National Registration Scheme
the Regulations	*Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021*

Background

Agvet chemicals are regulated through a cooperative National Registration Scheme (NRS). The NRS is a partnership between the Commonwealth and the states and territories with an agreed division of responsibilities. The states and territories apply the Commonwealth law as a law of their own jurisdiction, supported by an intergovernmental agreement.

The Administration Act established the APVMA, including its role as the independent Commonwealth regulator for agvet chemical products (including active constituents contained in the product and the label for the product container). The APVMA assesses, approves and registers agvet chemicals for use in Australia. The APVMA is responsible for regulating these chemicals up to and including, the point of supply – for example, retail sale. The control of use of agvet chemicals after supply is the responsibility of individual states and territories.

The NRS is implemented, in part, through the Code Act (including 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 Agvet Code provides for the APVMA to assess, approve, and register active constituents and agvet chemical products and their associated labels. It also allows the APVMA to issue permits for supply and use and to license the manufacture of agvet chemical products. The Agvet Code also provides for the APVMA to regulate the supply of agvet chemical products and to ensure compliance with (and enforce) the Agvet Code – including suspending and cancelling approvals and registrations.

The Levy Act contains measures that allow for levies to be assessed, calculated and collected on the sale of agvet chemical products registered for use in Australia.

Impact and Effect

These Regulations will improve the efficiency and effectiveness of agvet chemical regulation, while maintaining human, environmental, plant and animal health and trade safeguards. It will do this, for example, by increasing flexibility for the APVMA when it is undertaking assessments of applications and ensuring that the APVMA has a graduated suite of compliance tools to allow it to take proportionate action if a person contravenes certain requirements.

Consultation

This package of amendments was developed in consultation with the APVMA.

The department consulted the affected plant protection chemicals and veterinary medicines industries, farmers and other users in several stages. Initially, a broad range of regulation amendments was consulted on via peak bodies throughout 2018. These peak bodies included CropLife Australia, Animal Medicines Australia, the Veterinary Manufacturers and Distributors Association and the National Farmers' Federation (NFF). The department hosted teleconferences and meetings to ensure industry and users were aware of, and had the opportunity to shape, the proposed changes. Two consultation papers were developed that described these amendments (along with others that were included in the *Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019*):

- The first supported consultation, from 11 July 2018 to 22 August 2018, on the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 which included details of the removal of annual operational plans (set out in Part 7 of these Regulations).
    - Sixteen submissions were received.
- The second supported consultation, from 12 December 2018 to 20 February 2019, on a broad package of proposed changes including those measures set out in Parts 1, 4, 5 and 6 of these Regulations.
    - In addition to particulars of the measures in the consultation paper, stakeholders were also provided with an exposure draft of most of the proposed Regulations, including those set out in Parts 4 and 5 of these Regulations.
    - Five submissions were received.

The submissions received through these consultation processes largely supported the measures in the Regulations and, where applicable, suggestions for improvements were incorporated.

The department also consulted on a further two measures, set out in Parts 2 and 3 of these Regulations. This included discussions with the affected plant protection chemicals and veterinary medicines industries, farmers and other users via peak bodies. In 2021 the department developed a consultation paper that described these amendments. Stakeholders were also provided with an exposure draft of the proposed Regulations. These documents were made available for public consultation from 14 July 2021 to 27 August 2021 – 17 submissions were received. Submitters included ACCORD, Animal Medicines Australia, CropLife Australia, Grain Producers Australia and the Veterinary Manufacturers and Distributors Association. These submissions largely supported the measures in the Regulations and, where applicable, suggestions for clarification were incorporated into the explanatory material.

Relevant state and territory agencies were also consulted and provided with the opportunity to comment and make suggestions about all measures set out in the Regulations.

The Office of Best Practice Regulation (OBPR) was consulted in the preparation of the Regulations (ID 23790, 25277 and 25893). The OBPR advised a Regulation Impact Statement was not required, as the measures appear to have only minor regulatory impacts on business, community organisations or individuals.

Details/ Operation

Details of the Regulations are set out in Attachment A.

Other

Sunsetting does not apply to the Regulations due to paragraph 54(1)(a) of the *Legislation Act 2003*. This is because the enabling legislation for the Regulations (which also authorises the creation of the Regulations) facilitates the establishment or operation of an intergovernmental body or scheme (the NRS).

The Regulations are compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011.* A full statement of compatibility is set out in Attachment B.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT A

Details of the *Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021*

Section 1 – Name

This section provides that the name of the Regulations is the *Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021*.

Section 2 – Commencement

Subsection 2(1) provides that each provision of the Regulations 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 to 4, as well as anything in the Regulations not elsewhere covered by the table, will commence on the day after the Regulations are registered as an instrument.

Item 2 in the table provides that Part 1 of Schedule 1 to the Regulations will commence on the later of the day after the Regulations are registered as an instrument or the day on which Part 1 of Schedule 1 to the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021* (the APVMA Board and Other Improvements Act) commences.

Item 3 in the table provides that Part 2 of Schedule 1 to the Regulations will commence on the later of the day after the Regulations are registered as an instrument or the day on which Part 2 of Schedule 1 to the APVMA Board and Other Improvements Act commences.

Item 4 in the table provides that Part 3 of Schedule 1 to the Regulations will commence on the later of the day after the Regulations are registered as an instrument or the day on which Part 3 of Schedule 1 to the APVMA Board and Other Improvements Act commences.

Item 5 in the table provides that Part 4 of Schedule 1 to the Regulations will commence on the later of the day after the Regulations are registered as an instrument or the day on which Part 4 of Schedule 1 to the APVMA Board and Other Improvements Act commences.

Item 6 in the table provides that Part 5 of Schedule 1 to the Regulations will commence on the later of the day after the Regulations are registered as an instrument or the day on which Part 9 of Schedule 1 to the APVMA Board and Other Improvements Act commences.

Item 7 in the table provides that Part 6 of Schedule 1 to the Regulations will commence on the later of the day after the Regulations are registered as an instrument or the day on which Part 11 of Schedule 1 to the APVMA Board and Other Improvements Act commences.

Item 8 in the table provides that Part 7 of Schedule 1 to the Regulations will commence on the later of the day after the Regulations are registered as an instrument or the day on which Part 13 of Schedule 1 to the APVMA Board and Other Improvements Act commences.

The note to subsection 2(1) highlights that the table only relates to the provisions of this instrument as originally made. The table will not be amended to deal with any later amendments of this instrument.

Subsection 2(2) provides that any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument. Column three allows for the insertion of relevant dates and details.

Section 3 – Authority

This section provides that the Regulations are made under the following Acts:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992*
- *Agricultural and Veterinary Chemicals Code Act 1994.*

Section 4 – Schedules

This section provides that the Regulations are amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule has effect according to its terms. This is a technical provision to give operational effect to the amendments contained in the Schedules.

Schedule 1 – Amendments

Part 1—Information to be taken into account in determining applications

Part 1 of Schedule 1 to these Regulations amends the *Agricultural and Veterinary Chemicals Code Regulations 1995* (the Code Regulations) to prescribe new kinds of information the APVMA may consider during the assessment period for an application made under the Agvet Code.

The APVMA is prevented from considering new information provided by an applicant after an application has been made, except in limited circumstances. Subsection 8C(2) of the Agvet Code prevents the APVMA from considering information provided by, or on behalf of, the applicant during the assessment period unless:

- the information was in or accompanied the application as required under section 8B of the Agvet Code; or
- the information was given to the APVMA as required under section 157, 159 or 160A of the Agvet Code in relation to the application; or
- a submission has been made in response to an invitation given by the APVMA in relation to the application.

Prior to passage of the APVMA Board and Other Improvements Act, the only mechanism available for the APVMA to seek additional information about an application was by issuing a notice (at its discretion), to the applicant under section 159 of the Agvet Code. The first such notice issued during the course of an assessment triggers a mandatory one-off extension to the statutory assessment period in which the application must be assessed – the assessment period ranges from 3 months to 18 months. 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.

The APVMA Board and Other Improvements Act refined this approach in order to increase efficiency. It introduced subsection 8C(2A) into the Agvet Code which provides for the regulations to prescribe certain additional kinds of information that the APVMA may consider during the assessment period for an application and the circumstances in which such information may be given – that is, it provides that subsection 8C(2) of the Agvet Code does not apply to information so prescribed. This removes the need for a notice under section 159 of the Agvet Code in these prescribed circumstances, thus avoiding the associated extension of the assessment period and the impacts caused by lengthy extensions.

This amendment will enhance the efficient, effective and timely assessment of applications by the APVMA.

Agricultural and Veterinary Chemicals Code Regulations 1995

Item 1 – At the end of Division 1.2 of Part 1

This item adds new regulation 8AHAA to the end of Division 1.2 of Part 1 of the Code Regulations which, for the purposes of subsection 8C(2A) of the Agvet Code, prescribes information that may be taken into account by the APVMA in determining applications and the circumstances under which this information could be provided.

New subregulation 8AHAA(1) of the Code Regulations provides that the information that may be taken into account by the APVMA in determining applications is information that clarifies or updates information referred to in subparagraph 8C(1)(a)(i) or (ii) of the Agvet Code. Paragraph 8C(1)(a) prescribes information the APVMA must have regard to in determining an application. Subparagraph 8C(1)(a)(i) prescribes that this includes information in, or accompanying, the application as required by section 8B (information to be provided with applications) or any other provision of the Agvet Code.
Subparagraph 8C(1)(a)(ii) extends this to any information (or thing) given to the APVMA under sections 157 (samples for analysis required by the APVMA) or 159 (information, samples for analysis, or results of a trial or analysis required by the APVMA or another prescribed authority in certain circumstances) of the Agvet Code.

New subregulation 8AHAA(2) of the Code Regulations prescribes the circumstances under which this information must be provided. The circumstances are that the information is provided by, or on behalf of, the applicant:

- on the request of the APVMA; and
- the information is provided before the end of the period of 14 days beginning on the day the request is made.

New regulation 8AHAA provides the APVMA with the ability to request clarifying information without the need to issue a notice under section 159 of the Agvet Code, therefore not triggering an automatic extension to the assessment period. This will assist in the efficient, effective and timely assessment of applications. If the APVMA requests the information prescribed through this mechanism and the applicant does not provide it within the requested timeframe, the APVMA may still issue a notice under section 159 of the Agvet Code requesting the information.

Part 2—Approval and registration for prescribed active constituents, chemical products or labels

Part 2 of Schedule 1 to these Regulations amends the Code Regulations to authorise the APVMA to set, in a disallowable legislative instrument, application fees and assessment periods for applications made under sections 14C, 14D and 14E of the Agvet Code for the approval and registration for prescribed active constituents, chemical products or labels.

Part 2 of the APVMA Board and Other Improvements Act provides the APVMA with greater flexibility to manage applications and to align regulatory effort with risk by providing for streamlined application processes for both:

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

The use of simple regulation processes for these approvals and registrations, where minimal or no assessment of technical information occurs, aligns regulatory effort with risk and will improve access to safe and effective chemical products.

Part 2 of the APVMA Board and Other Improvements Act amended the Code Act to provide that, for the purposes of certain approvals and registrations, active constituents, chemical products or labels may be prescribed in the Code Regulations or determined by the APVMA in a disallowable legislative instrument.

Section 164 of the Agvet Code enables the Code Regulations, amongst other things, to set the fees (or a method of working out the fees) payable in respect of making applications to the APVMA, while subsection 165(1) allows the Code Regulations to stipulate the assessment period for an application. These fees and assessment periods are stipulated through the table in clause 2.1 of Schedule 6 to the Code Regulations. This table groups applications with certain common characteristics into application items. These application items provide the necessary legislative mechanism for stipulating the application fees and assessment periods. The Code Regulations are amended to authorise the APVMA to develop the necessary application fees and assessment period for prescribed approvals and registrations through a disallowable legislative instrument developed in consultation with stakeholders in accordance with the whole-of-government cost recovery guidelines.

Agricultural and Veterinary Chemicals Code Regulations 1995

Items 2, 3 and 7 – After subregulation 70(2), after subregulation 70(4) and at the end of regulation 76A

These items insert subregulation 70(2A), 70(4AA) and 76A(5) into the Code Regulations. These subregulations, like those at item 4, provide minor clarifications to regulations about fees and assessment periods to support the amendment made by item 8 in Schedule 1 to the Regulations. As described below, item 8 amends the table in clause 2.1 of Schedule 6 to provide that the assessment periods and fees for applications for applications made under sections 14C, 14D and 14E of the Agvet Code, for approval or registration for prescribed active constituents, chemical products or labels, will be specified in, or worked out in accordance with, a legislative instrument made by the APVMA.

Subregulations 70(2A), 70(4AA) and 76A(5), respectively, clarify that the:

- fee (in column 5)
- maximum pre-application assistance rebate (column 4), and
- extended application assessment period (column 3)

in the table in clause 2.1 of Schedule 6 to the Code Regulations (which sets out assessment periods and fees for types of applications) may, in addition to a specific figure, be expressed as an amount or period specified in, or worked out in accordance with, a legislative instrument made by the APVMA.

Item 4 – Subregulations 76(1) and (1A)

This item repeals and substitutes subregulations 76(1) and (1A) of the Code Regulations and substitutes new subregulations 76(1) and 76(1A) of the Code Regulations.

The new subregulation 76(1) is a minor amendment to consolidate and simplify previous subregulations 76(1) and 76(1A), which were duplicative. New subregulation 76(1) provides that the period for determining an application of a kind specified in column 1 of an item of the table in clause 2.1 of Schedule 6 to the Code Regulations is the period (if any) specified in column 2 of that item, subject to regulations 76A and 76B (which deal with certain extended assessment periods). This has the same substantive effect as previous subregulations 76(1) and (1A) of the Code Regulations.

The new subregulation 76(1A), like items 2, 3 and 7, supports the amendment made by item 8. Specifically, subregulation 76(1A) clarifies the application assessment period specified in column 2 of the table in clause 2.1 of Schedule 6 may (in addition to a specific figure) be expressed as a period specified in, or worked out in accordance with, a legislative instrument made by the APVMA.

Item 5 – Subregulation 76(1B)

This item makes a consequential amendment to subregulation 76(1B) of the Code Regulations because of the amendment made by item 4. It omits from subregulation 76(1B) the previous reference to subregulations 76(1) and 76(1A) of the Code Regulations and substitutes it with ‘applicable under subregulation (1)’.

Item 6 – Subregulation 76A(1)

This item makes a consequential amendment to subregulation 76A(1) of the Code Regulations because of the amendment made by item 4. It omits from subregulation 76A(1) the previous reference to subregulation 76(1A) of the Code Regulations.

Item 8 – Clause 2.1 of Schedule 6 (after table item 10A)

This item inserts a row into the table in clause 2.1 of Schedule 6 to the Code Regulations. This creates application item 10B for applications for approval or registration for prescribed active constituents, chemical products or labels. Part 2 of the APVMA Board and Other Improvements Act authorises such applications under sections 14C, 14D and 14E of the Agvet Code. The inserted row also sets out that the:

- assessment period (column 2, see also item 4)
- extended assessment period (column 3, see also item 7)
- maximum pre-application assistance rebate (column 4, see also item 3)

- fee (column 5, see also item 2)

will be specified in, or worked out in accordance with, a legislative instrument made by the APVMA.

Part 3—Limits on use of information

Part 3 of Schedule 1 to these Regulations amends the Code Regulations to require the APVMA, when publishing the summary of relevant applications, to include a statement that relevant protection periods or limitation periods may be extended as a result of granting the application.

Part 3 of the APVMA Board and Other Improvements Act amended the Code Act to provide incentives for the chemicals industry to seek approval of certain kinds of active constituents or to register certain uses of chemical products. This involves extending the period of time (up to a maximum of 5 additional years) during which the APVMA must not use an 'innovator's' (that is, the holder who provided the original information to the APVMA) information to support the registration, variation or reconsideration of another chemical product or active constituent – sometimes known as data restriction periods. A ministerial order, the Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2021, set outs the technical details for these incentives such as eligible application types, the prescribed uses that may trigger an extension and the extension periods.

The Agvet Code provides for two kinds of data restriction periods:

- A 'protection period' is defined in section 3 of the Agvet Code. This period provides 8 years of protection from the time certain kinds of 'protected information' (that relate to either an active constituent that has been approved or a chemical product that has been registered) are first given to the APVMA 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. 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.
- A 'limitation period' is defined in section 34M of the Agvet Code and relates to the limits on use of information provided to the APVMA as part of certain applications. It also includes relevant information under section 161 of the Agvet Code (notification of certain new information to the APVMA). If the information is relied on by the APVMA in making a decision, it receives a limitation period which ranges from 3 years to 10 years depending on the type of information relied on (as set out in the table in section 34M of the Agvet Code). 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.

Competing chemical companies require transparency about the expiry date of a protection period or a limitation period. Knowledge of such expiry dates allows these competitors to determine when they may be able to submit an application referencing that information to progress the development of their own generic products.

Regulations 8AM and 8AN of the Code Regulations set out, respectively, the information that must be published by the APVMA in relation to the approval (or approval variation) of an active constituent or registration (or registration variation) of a chemical product. This includes certain details for each item of information the APVMA relied on to make its decision on an application (which is also what triggers a limitation period). The APVMA, in publishing this information about approvals and registrations on its publicly available

database, PubCRIS, also publishes the limitation periods associated with this information. It is the publication notice of the APVMA's decision on an application that normally triggers competitors to examine PubCRIS to find out about the new information (including any limitation period).

The potential for the extensions allowed for by the amendments made to the Agvet Code by Part 3 of the APVMA Board and Other Improvements Act may interfere with this long established trigger. While extensions applied to new products will be able to rely on the above notification process for transparency, this will not be the case for extensions arising from variations of an existing product registration. It is these existing product registrations that will have been the focus of competitor chemical companies' plans for developing their own generic products. In this case, the competitor company will have likely taken the original protection or limitation period into account in plans for developing their products and would have no reason to realise that these periods may be changing in the near future. This issue would only be exacerbated if the competitor company were required to wait until any extensions are determined and published by the APVMA. It is fairer and more transparent to alert competitor companies of the potential for extensions early in the application assessment process – at the preliminary assessment stage.

For transparency, paragraph 28(2)(b) of the Agvet Code and regulation 19AD of the Code Regulations require the APVMA to publish summaries of applications for variation for chemical products. The APVMA must complete a preliminary assessment of such applications within one month and, if it appears from the preliminary assessment that the application meets the application requirements, the APVMA only has a further 14 days to publish the summary of the variation application.

Agricultural and Veterinary Chemicals Code Regulations 1995

Item 9 – After paragraph 19AD(2)(i)

This item inserts a provision in subregulation 19AD(2) setting out that if the APVMA were to make a variation as a result of an application that may also result in the extension of a protection period or limitation period, then a statement in relation to this matter is to be included in the summary of the application. Specifically, read together with subsections 34KA(3) and 34MA(3) of the Agvet Code, this means a statement will be needed where:

- there are three years remaining on the protection period or limitation period when the variation application is lodged
- the variation application contains an instruction for use that would trigger an extension (set out in the *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2021*).

This provides appropriate transparency where granting a variation application may result in an extension of an existing protection period or limitation period.

It is not necessary for the summary of application for a new product registration (under section 11(2)(b) of the Agvet Code) to include a similar statement as there is no existing protection period and the limitation period (including if extended) does not commence until the application is granted.

Item 10 – In the appropriate position in Part 10

This item inserts regulation 94 to add an application provision. This provision specifies the amendment of regulation 19AD (made by item 9) only applies in relation to applications made under section 27 of the Agvet Code on or after the commencement of these Regulations.

Part 4—Annual returns and record-keeping

Part 4 of Schedule 1 to these Regulations amends the Administration Regulations to maintain the APVMA's ability to issue infringement notices for contravening annual reporting and record-keeping requirements.

Part 4 of Schedule 1 to the APVMA Board and Other Improvements Act amended the Administration Act and the Levy Act in order to simplify annual reporting requirements. This will assist in reducing 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. Previously, annual returns and associated records were required for the import, export and manufacture of active constituents (both active constituents in chemical products, and those for proposed or existing chemical products) under the now repealed section 69E of the Administration Act. The APVMA Board and Other Improvements Act repealed section 69E of the Administration Act and introduced an annual returns and record keeping framework into the Levy Act. This framework is set out in sections 35 and 37 of the Levy Act and aligns with levy reporting about product disposals such that interested persons (as defined in section 3 of the Levy Act) now report on, and record, the quantity of agvet chemical product covered by a leviable disposal (as defined in section 3 of the Levy Act).

Sections 35 and 37 of the Levy Act include civil penalty provisions for contravening the annual return reporting and record-keeping requirements in those sections, respectively. These are equivalent to the offences and civil penalty provisions in the now repealed section 69E of the Administration Act.

Part 4 of Schedule 1 to these Regulations provide for infringement notices to be issued for alleged contraventions of the civil penalty provisions in subsections 35(1) and 37(1) of the Levy Act and set the applicable number of penalty units for an individual and a body corporate in any such infringement notices.

- Subsection 35(1) of the Levy Act sets out the annual reporting requirements in relation to chemical products. Subsection 35(3) then provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty, if that person contravenes subsection 35(1). Subsection 35(4) in turn provides that subsection 35(1) is also a civil penalty provision.
- Similarly, subsection 37(1) of the Levy Act sets out related record keeping requirements. Subsection 37(2) then provides that a person commits an offence of strict liability, which is subject to a criminal pecuniary penalty, if that person contravenes subsection 37(1). Subsection 37(3) in turn provides that subsection 37(1) is also a civil penalty provision.

By providing for infringement notices for allegedly contravening these provisions, the APVMA will maintain access to a graduated suite of compliance measures relating to annual return reporting and record-keeping requirements.

Agricultural and Veterinary Chemicals (Administration) Regulations 1995

Item 11 – Regulation 4.10

This item repeals regulation 4.10 of the Administration Regulations. Regulation 4.10 stipulated requirements for providing annual return information for active constituents (for the

purpose of previous paragraph 69E(2)(a) of the Administration Act). The APVMA Board and Other Improvements Act repealed section 69E of the Administration Act and therefore the repeal of regulation 4.10 is consequential to that.

Item 12 – After Part 4

This item inserts a new Part 5 into the Administration Regulations to prescribe application, saving and transitional provisions relating to the repeal of regulation 4.10 (discussed in item 11) and of item 8 of the table in Schedule 5 (discussed in item 13) to the Administration Regulations.

Subregulation 5.1(1) supports the savings provisions in subitem 35(1) of Schedule 1 to the APVMA Board and Other Improvements Act. Those savings provisions provide that section 69E of the Administration Act, as in force immediately before the commencement of subitem 35(1), continues to apply on and after that commencement in respect of the import, manufacture or export of certain active constituents and chemical products that occurred in the financial year that ended before the repeal of section 69E of the Administration Act. As a consequence of this saving provision, subregulation 5.1(1) similarly provides that Regulation 4.10 of the Administration Regulations, as in force immediately before the commencement of these Regulations, continues to apply on and after that commencement for the purposes of the continued application of section 69E of the Administration Act, as described above.

Subregulation 5.1(2) ensures that, despite its repeal by these Regulations, item 8 of the table in Schedule 5 to the Administration Regulations (which provides for infringement notices), as in force immediately before the commencement of these Regulations, continues to apply on and after that commencement in relation to a contravention of subsection 69E(1) of the Administration Act that occurs before, on or after that commencement (see item 13).

Together, these amendments ensure that the repeal of section 69E of the Administration Act, Regulation 4.10 of the Administration Act and table item 8 of Schedule 5 to the Administration Act and the insertion of the new annual returns and record keeping framework in sections 35 and 37 of the Levy Act (together with civil penalty provisions) and Part 4 of Schedule 1 to these Regulations do not apply in relation to the import, manufacture or export of certain active constituents and chemical products that occurred in the financial year that ended before the relevant repeal provisions.

Item 13 – Schedule 5 (table item 8)

This item repeals item 8 of the table in Schedule 5 to the Administration Regulations. This provided for infringement notices for alleged contraventions of the civil penalty provisions in section 69E of the Administration Act. As section 69E of the Administration Act was repealed by the APVMA Board and Other Improvements Act, item 8 of the table in Schedule 5 is no longer required.

Items 14 and 15 – Schedule 5 (after table item 12 and at the end of the table)

These items insert new items 12A and 14 into the table in Schedule 5 to the Administration Regulations. These provide, respectively, for infringement notices to be issued for alleged

contraventions of the civil penalty provisions in subsections 35(1) and 37(1) of the Levy Act which relate to reporting and keeping records in relation to annual returns.

The amounts for both these infringement notices are 15 penalty units for an individual and 125 penalty units for a body corporate. The value of a penalty unit is set in subsection 4AA(1) of the *Crimes Act 1914* (the Crimes Act). These are half the maximum amount that could be prescribed under the legislation, as described below. The amounts of these penalty units depart from the recommendations in the *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* (the Guide) which states that the amount payable for an infringement notice should not exceed 12 penalty units for an individual and 60 for a body corporate. This is justified because these amounts are appropriate to deter non-compliance by individuals and bodies corporate (for example as a cost of doing business) and are proportionate to the likely harm that may result from such contraventions. Further, these amounts are appropriate because the civil penalty amounts specified in table items 12A and 14 of the table at Schedule 5 to the Administration Regulations are the same amounts as for contravening the corresponding requirements previously in section 69E (which was repealed by the APVMA Board and Other Improvements Act) and 69EA (which was amended by the APVMA Board and Other Improvements Act to no longer refer to section 69E) in the Administration Act, which previously dealt with annual return reporting and annual return record-keeping requirements, prior to the amendments made by the APVMA Board and Other Improvements Act. Setting the amounts for these infringement notices at half the maximum amount that could be prescribed under the legislation also allows for penalties to be increased in the future if this is considered necessary and appropriate.

Maximum infringement notice amount allowed under the legislation

Subsections 35(3) and 37(2) of the Levy Act provide that a person commits an offence, which is subject to a criminal pecuniary penalty of 50 penalty units, if that person contravenes, respectively, subsection 35(1) or subsection 37(1) of the Levy Act. This is the maximum criminal pecuniary penalty that a relevant court could impose on an individual.

The maximum criminal pecuniary penalty that a relevant court can impose on a body corporate for a contravention of subsections 35(1) or 37(1) of the Levy Act is 250 penalty units, due to the application of subsection 4B(3) of the Crimes 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.

Subsections 35(4) and 37(3) of the Levy Act provide that, respectively, subsections 35(1) and 37(1) of the Levy Act are also civil penalty provisions. Section 4 of the Administration Act defines a civil penalty provision as a provision declared by the Administration Act or the Levy Act to be a civil penalty provision. Importantly, Part 7AB of the Administration Act creates a framework for the use of civil penalty orders to underpin the civil penalty provisions of the Administration Act and the Levy Act. Notes after both subsection 35(4) and 37(3) of the Levy Act advise of the need to refer to the Administration Act for the use of both civil penalties and infringement notices.

Subsection 69EJA(1) in Part 7AB 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, the offences prescribed by subsections 35(3) and 37(2) of the Levy Act and the application of subsection 4B(3) of the Crimes Act, the maximum civil pecuniary penalty for a contravention of subsections 35(1) and 37(1) of the Levy Act is 150 penalty units for individuals and 1,250 penalty units for a body corporate.

Subsection 69EKA(2) of the Administration Act provides that the amount to be stated in an infringement notice for the alleged contravention of the relevant civil penalty provision must not exceed one-fifth of the maximum penalty that a court could impose on the person for that contravention.

Therefore, the maximum amount in an infringement notice for an alleged contravention of subsections 35(1) and 37(1) of the Levy Act for an individual is 30 penalty units ($50 \times 3 \div 5$). The maximum amount in an infringement notice for an alleged contravention of subsections 35(1) and 37(1) of the Levy Act for a body corporate is 250 penalty units ($50 \times 5 \times 5 \div 5$).

Infringement notices 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. The ability to issue an infringement notice for alleged contraventions of subsections 35(1) and 37(1) of the Levy Act allows the notice with the stated amount to be issued immediately and to be effective in managing alleged non-compliance. The amount to be stated in an infringement notice for such alleged contraventions is appropriate to deter non-compliance by individuals and bodies corporate (for example as a cost of doing business) and is proportionate to the likely harm that may result from such contraventions.

Part 5—False and misleading information

Part 5 of Schedule 1 to these Regulations amends both the Administration Regulations and Code Regulations to provide for the APVMA to issue infringement notices for alleged contraventions of civil penalty provisions in the Administration Act and the Agvet Code for providing false or misleading information to the APVMA.

Subsections 69ER(1) and (2) of the Administration Act provide that a person commits an offence if, 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 (described below), that person knowingly gives false or misleading information, or produces false or misleading documents, which are false or misleading in a material particular. If a person gives a document which that person knows is false or misleading in a material particular, the person must indicate 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. The person must also provide correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information. If the person does not do these things, that person will commit an offence.

Similarly, subsections 146 (1) and (2) of the Agvet Code provide that a person commits an offence 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 in relation to certain matters (described below), that person knowingly gives false or misleading information or produces false or misleading documents, which are false or misleading in a material particular. If a person gives a document which that person knows is false or misleading in a material particular, the person must indicate 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. The person must also provide correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information. If the person does not do these things, that person will commit an offence.

Noting the above, subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and (4) of the Agvet Code introduced civil pecuniary penalty provisions for persons engaging in substantially similar conduct as outlined in the descriptions of subsections 69ER(1) and (2) of the Administration Act and subsections 146 (1) and (2) of the Agvet Code. Subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and (4) of the Agvet Code relate to a person knowingly giving false or misleading information or documents which are false or misleading in a material particular. They also provide that, if a person gives a document which that person knows is false or misleading in a material particular, the person must indicate 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. The person must also provide correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information. Subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and (4) of the Agvet Code relate to such information or documents given in respect to:

- information given in respect to a consent to import an unapproved active constituent or unregistered chemical product (subsection 69ER(3) of the Administration Act)
- information given to an inspector in relation to Parts 7A (importation, manufacture and exportation of chemicals other than importation under section 69B), 7AA (investigative

powers) or 7AB (enforcement) of the Administration Act (subsection 69ER(4) of the Administration Act)
- information given in respect to the safety, efficacy, trade or labelling criteria (at sections 5A, 5B, 5C or 5D of the Agvet Code) or a licence to manufacture (section 123 of the Agvet Code) (subsection 146(3) of the Agvet Code)
- information given in respect to the APVMA's performance of functions and exercise of powers other than that in subsection 146(3) (subsection 146(4) of the Agvet Code).

While subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and (4) of the Agvet Code create the civil penalty provisions, the amendments to the Administration Regulations and the Code Regulations made by Part 5 of Schedule 1 to these Regulations (read together with Division 2 of Part 7AB of the Administration Act and regulation 3A.01 of the Administration Regulations as it relates to the amendments set out in item 16, and read together with Division 3 of Part 9A of the Agvet Code as it relates to the amendments set out in item 17) provide for the APVMA to issue infringement notices for alleged contraventions of these civil penalty provisions.

As noted above, Division 2 of Part 7AB of the Administration Act creates a framework for the use of infringement notices for the alleged contravention of prescribed civil penalty provisions in the Administration Act. Regulation 3A.01 of the Administrative Regulations provides that each civil penalty provision mentioned in Schedule 5 of the Administrative Regulations is a prescribed civil penalty provision. Similarly, Division 3 of Part 9A of the Code Act creates a framework for the use of infringement notices for the alleged contravention of prescribed civil penalty provisions in the Agvet Code. Regulation 64 of the Code Regulations provides that each civil penalty provision mentioned in Schedule 5A of the Code Regulations is a prescribed civil penalty provision.

Part 5 of Schedule 1 to these Regulations will ensure the APVMA has a graduated suite of compliance tools to allow it to take proportionate action if a person knowingly provides false or misleading information or documents in a way that contravenes subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and (4) of the Agvet Code. It would authorise the APVMA to issue an infringement notice, in those circumstances where this is a more appropriate sanction than prosecution of the offence or applying to a court for an order that a person, who is alleged to have contravened one these civil penalty provisions, pay the Commonwealth a pecuniary penalty.

Agricultural and Veterinary Chemicals (Administration) Regulations 1995

Item 16 – Schedule 5 (table item 10)

This item inserts new items 10A and 10B into the table at Schedule 5 to the Administration Regulations. These provide, respectively, for infringement notices to be issued for alleged contraventions of the civil penalty provisions in subsections 69ER(3) and 69ER(4) of the Administration Act.

The amounts for the infringement notices, which are authorised under the Administration Act (section 69EKA) are:
- 90 penalty units for an individual, and 750 penalty units for a body corporate, for an alleged contravention of subsection 69ER(3)

- 18 penalty units for an individual, and 150 penalty units for a body corporate, for an alleged contravention of subsection 69ER(4).

The amounts of these penalty units depart from the recommendations in the Guide which states that the amount payable for an infringement notice should not exceed 12 penalty units for an individual and 60 for a body corporate. This is justified because these amounts are appropriate to deter non-compliance by individuals and bodies corporate (for example as a cost of doing business) and are proportionate to the likely harm that may result from such contraventions. Further, these amounts are half the maximum amount that could be prescribed under the legislation (as described below) and are consistent with the amounts set for similar alleged contraventions of agvet chemical legislation (see the table of infringement notice penalty amounts in Schedule 5 to the Administration Regulations). Setting the amounts for these infringement notices at half the maximum amount that could be prescribed under the legislation also allows for penalties to be increased in the future if this is considered necessary and appropriate.

Maximum infringement notice amount allowed under the legislation

As described in more detail above, subsections 69ER(1) and (2) of the Administration Act provide that a person commits an offence if that person knowingly gives false or misleading information or produces false or misleading documents in respect of certain matters. The associated criminal pecuniary penalty depends on the nature of the information as follows:

- 300 penalty units for information given in respect to a consent to import an unapproved active constituent or unregistered chemical product (subsection 69ER(1) of the Administration Act)
- 60 penalty units for information given to an inspector in relation to Parts 7A (importation, manufacture and exportation of chemicals – other than importation under section 69B), 7AA (investigative powers) or 7AB (enforcement) (subsection 69ER(2) of the Administration Act).

These are the maximum criminal pecuniary penalties 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 subsections 69ER(1) or (2) of the Administration Act will be 1,500 and 300 penalty units respectively, due to the application of subsection 4B(3) of the Crimes 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.

Subsections 69ER(3) and (4) of the Administration Act introduce, respectively, civil pecuniary penalties for persons allegedly engaging in the type of conduct described in subsections 69ER(1) or (2) of the Administration Act so as to contravene subsections 69ER(3) and (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.

By virtue of section 69EJA of the Administration Act, and the matters prescribed by subsections 69ER(3) and (4) of the Administration Act (including the application of subsection 4B(3) of the Crimes Act in relation to bodies corporate), the maximum civil pecuniary penalties for a contravention of subsections 69ER(3) and (4) of the Administration Act are:

- for individuals – 900 and 180 penalty units for subsections 69ER(3) and (4) of the Administration Act respectively
- for a body corporate – 7,500 and 1,500 penalty units for subsections 69ER(3) and (4) of the Administration Act respectively.

Subsection 69EKA(2) of the Administration Act provides that the amount to be stated in an infringement notice for the alleged contravention of the relevant civil penalty provision must not exceed one-fifth of the maximum penalty that a court could impose on the person for that contravention.

Therefore the maximum amount in an infringement notice for an alleged contravention of subsections 69ER(3) and (4) of the Administration Act for an individual is 180 (300 × 3 ÷ 5) and 36 (60 × 3 ÷ 5) penalty units, respectively.

The maximum amount in an infringement notice for an alleged contravention of subsections 69ER(3) and (4) of the Administration Act for a body corporate is 1,500 (300 × 5 × 5 ÷ 5) and 300 (60 × 5 × 5 ÷ 5) penalty units, respectively.

Infringement notices 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. The ability to issue an infringement notice for alleged contraventions of subsections 69ER(3) and (4) of the Administration Act allows the notice with the stated amount to be issued immediately and to be effective in managing alleged non-compliance. The amount to be stated in an infringement notice for such alleged contraventions is appropriate to deter non-compliance by individuals and bodies corporate (for example as a cost of doing business) and is proportionate to the likely harm that may result from such contraventions.

Agricultural and Veterinary Chemicals Code Regulations 1995

Item 17 – Schedule 5A (after table item 54)

This item inserts new items 54A and 54B into the table in Schedule 5A to the Code Regulations. These provide, respectively, for infringement notices to be issued for alleged contraventions of the civil penalty provisions in subsections 146(3) and 146(4) of the Agvet Code.

The amounts for the infringement notices, which are authorised under the Agvet Code (section 145DB) are:

- 90 penalty units for an individual, and 750 penalty units for a body corporate, for an alleged contravention of subsection 146(3)
- 18 penalty units for an individual, and 150 penalty units for a body corporate, for an alleged contravention of subsection 146(4).

The amounts of these penalty units depart from the recommendations in the Guide which states that the amount payable for an infringement notice should not exceed 12 penalty units for an individual and 60 for a body corporate. This is justified because these amounts are appropriate to deter non-compliance by individuals and bodies corporate (for example as a cost of doing business) and are proportionate to the likely harm that may result from such contraventions. Further, these amounts are half the maximum amount that could be prescribed (as described below) under the legislation but are consistent with the amounts set for similar alleged contraventions of agvet chemical legislation (as set out in the table of infringement notice penalty amounts in Schedule 5A to the Code Regulations). Setting the amounts for these infringement notices at half the maximum amount that could be prescribed under the legislation also allows for penalties to be increased in the future if this is considered necessary and appropriate.

These amounts are an appropriate balance between being low enough to provide the incentive for the party to not go to court for the alleged contravention while being high enough to be an adequate deterrent (rather than the infringement notice penalty being paid as a cost of doing business).

Maximum infringement notice amount allowed under the legislation

As described above in more detail, section 146 of the Agvet Code provides that a person commits an offence if that person knowingly gives false or misleading information or produces false or misleading documents. The associated criminal pecuniary penalty depends on the nature of the information as follows:

- 300 penalty units for information given in respect to the safety, efficacy, trade or labelling criteria (at sections 5A, 5B, 5C or 5D of the Agvet Code) or an application for a licence to manufacture (section 123(1) of the Agvet Code)—subsection 146(1) of the Agvet Code
- 60 penalty units for information given in respect to the APVMA's performance of functions and exercise of powers other than those matters referred to in subsection 146(1) – subsection 146(2) of the Agvet Code.

These are the maximum criminal pecuniary penalties 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 subsections 146(1) or (2) of the Agvet Code is 1,500 and 300 penalty units respectively, due to the application of subsection 170(5) of the Agvet Code. Subsection 170(5) 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.

Subsections 146(3) and (4) of the Agvet Code introduce, respectively, civil pecuniary penalties for persons allegedly engaging in the type of conduct described in

subsections 146(1) or (2) of the Agvet Code so as to contravene subsections 146(3) and (4) 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.

By virtue of section 145AA of the Agvet Code, and the matters prescribed by subsections 146(3) and (4) of the Agvet Code (and the application of subsection 170(5) in relation to bodies corporate), the maximum civil pecuniary penalty for a contravention of subsections 146(3) and (4) of the Agvet Code are:

- for individuals – 900 and 180 penalty units for subsections 146(3) and (4) of the Agvet Code respectively
- for a body corporate – 7,500 and 1,500 penalty units for subsections 146(3) and (4) of the Agvet Code respectively.

Subsection 145DB(2) of the Agvet Code provides that the amount to be stated in an infringement notice for the alleged contravention of the provision must not exceed one-fifth of the maximum penalty that a court could impose on the person for that contravention.

Therefore, the maximum amount in an infringement notice for an alleged contravention of subsections 146(3) and (4) of the Agvet Code for an individual is 180 (300 × 3 ÷ 5) and 36 (60 × 3 ÷ 5) penalty units, respectively.

The maximum amount in an infringement notice for an alleged contravention of subsections 146(3) and (4) of the Agvet Code for a body corporate is 1,500 (300 × 5 × 5 ÷ 5) and 300 (60 × 5 × 5 ÷ 5) penalty units, respectively.

Infringement notices 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. The ability to issue an infringement notice for alleged contraventions of subsections 146(3) and (4) of the Agvet Code allows the notice with the stated amount to be issued immediately and to be effective in managing alleged non-compliance. The amount to be stated in an infringement notice for such alleged contraventions is appropriate to deter non-compliance by individuals and bodies corporate (for example as a cost of doing business) and is proportionate to the likely harm that may result from such contraventions.

The infringement amounts are an appropriate balance between being low enough to provide the incentive for the party to not go to court for the alleged contravention while being high enough to be an adequate deterrent (rather than being paid as a cost of doing business).

Part 6—Voluntary recalls

Part 6 of Schedule 1 to these Regulations amends the Code Regulations to:

- prescribe circumstances in which the APVMA does not need to publish a notice about a voluntary recall; and
- provide for the APVMA to issue infringement notices for failing to notify the APVMA about voluntary recalls.

Section 106 of the Agvet Code (as amended by Part 11 of the APVMA Board and Other Improvements Act) provides that, if a person voluntarily proposes to take action to recall a chemical product in the circumstances specified in subsection 106(1) of the Agvet Code (described below), the person must, pursuant to subsection 106(2) of the Agvet Code, give a notice of this to the APVMA within two days of the recall in an approved form with the information required by that form. If a notice is given to the APVMA, then subsection 106(6) of the Agvet Code requires the APVMA to publish the notice. Subsection 106(7) provides, however, that the regulations may prescribe circumstances in which subsection 106(6) does not apply.

For the purposes of subsection 106(1) of the Agvet Code, the circumstances in which a person conducting a voluntary recall must notify the APVMA are those where it appears to the person that either:

- the chemical product does not meet the safety, trade or efficacy criteria, or the label for containers of the chemical product does not meet the labelling criteria
- 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 differs by more than the prescribed extent from those set out in the Register of Agricultural and Veterinary Chemical Products – the APVMA is required to keep this register under section 18 of the Agvet Code).

Subsection 106(4) of the Agvet Code provides that a person commits an offence if that person is required to give a notice under subsection 106(2) of the Agvet Code, but refuses or fails to do so. Subsection 106(3) of the Agvet Code provides that subsection 106(2) is also a civil penalty provision.

Allowing the APVMA to issue an infringement notice for failing to notify the APVMA about voluntary recalls, instead of pursuing criminal or civil proceedings in the courts, will provide the APVMA with a graduated suite of compliance options for this conduct.

Agricultural and Veterinary Chemicals Code Regulations 1995

Item 18 – After Part 5

This item inserts new Part 5A into the Code Regulations. As noted above, subsection 106(7) provides that the regulations may exempt the APVMA from publishing a notice about a recall. New Part 5A of the Code Regulations will prescribe that the only circumstances in which the APVMA does not need to publish a notice about a voluntary recall is where both of the following apply:

- the chemical product has not been supplied to premises where a person can purchase the product; and
- the chemical product has not been supplied to a user of the product.

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 for the APVMA to contact these persons directly rather than publicise the recalls of the relevant chemical products.

Item 19 – Schedule 5A (after table item 44)

This item inserts new item 44A into the table in Schedule 5A to the Code Regulations. This provides for an infringement notice to be issued for alleged contraventions of subsection 106(2) of the Agvet Code which subsection 106(5) of the Agvet Code provides is a civil penalty provision. The amounts for the infringement notice, which is authorised under the Agvet Code (section 145DB) are:

- 36 penalty units for an individual
- 300 penalty units for a body corporate.

The amounts of these penalty units depart from the recommendations in the Guide which states that the amount payable for an infringement notice should not exceed 12 penalty units for an individual and 60 for a body corporate. This is justified because these amounts are appropriate to deter non-compliance by individuals and bodies corporate (for example as a cost of doing business) and are proportionate to the likely harm that may result from such contraventions. These amounts are the maximum amounts that could be prescribed (as described below) under the legislation and are consistent with existing amounts prescribed for infringement notices in the Code Regulations (as set out in the table of infringement notice penalty amounts in Schedule 5A to the Code Regulations).

<u>Maximum infringement notice amount allowed under the legislation</u>

As described above in more detail, section 106 of the Agvet Code provides that a person commits an offence if that person refuses or fails to give a notice to the APVMA about certain voluntary recall actions. The associated criminal pecuniary penalty is 60 penalty units (subsection 106(4)).

This 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 subsection 106(4) of the Agvet Code is 300 penalty units due to the application of subsection 170(5) of the Agvet Code. Subsection 170(5) 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.

Subsection 106(5) of the Agvet Code provides that failing to comply with subsection 106(2) is also a civil penalty.

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.

By virtue of section 145AA of the Agvet Code, and the matters prescribed by subsection 106(5) of the Agvet Code, the ,maximum civil pecuniary penalty for a contravention of subsection 106(2) of the Agvet Code is:

- 180 penalty units for individuals
- 1,500 penalty units for bodies corporate.

Subsection 145DB(2) of the Agvet Code provides that the amount to be stated in an infringement notice for the alleged contravention of the provision must not exceed one-fifth of the maximum penalty that a court could impose on the person for that contravention.

Therefore, the maximum amount in an infringement notice for an alleged contravention of subsection 106(2) of the Agvet Code for an individual is 36 (60 × 3 ÷ 5) penalty units. For a body corporate it is 300 (60 × 5 × 5 ÷ 5) penalty units.

Infringement notices 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.

The ability to issue an infringement notice for an alleged contravention of subsection 106(2) of the Agvet Code allows the notice with the stated amount to be issued immediately and to be effective in managing alleged non-compliance. The amount to be stated in an infringement notice for such alleged contraventions is appropriate to deter non-compliance by individuals and bodies corporate (for example as a cost of doing business) and is proportionate to the likely harm that may result from such contraventions.

Part 7—Annual operational plans

Part 7 of Schedule 1 to these Regulations amends the Administration Regulations to make minor consequential changes that arise from the APVMA Board and Other Improvements Act repealing sections 55, 56 and 57 of the Administration Act which had required the APVMA to prepare and publish an annual operational plan.

Agricultural and Veterinary Chemicals (Administration) Regulations 1995

Item 20 – Regulation 1A.2

This item repeals regulation 1A.2 of the Administration Regulations. Regulation 1A.2 was made for the purposes of repealed paragraph 55(2)(c) of the Administration Act. It describes information for inclusion in the annual operational plan, which is unnecessary following the repeal of section 55 of the Administration Act which had required the APVMA to develop an annual operational plan.

Item 21 – Regulation 1A.3

This item amends regulation 1A.3 of the Administration Regulations, which sets out particulars that must be included in the APVMA's annual report. Amended regulation 1A.3 provides that regulation 1A.3 is made for the purposes of subsection 61(b) of the Administration Act, rather than paragraph 61(b)(ii) of the Administration Act.

Subsection 61(b) of the Administration Act sets out performance indicators against which the APVMA must report. With the removal of annual operation plan requirements, subsection 61(b) of the Administration Act was recast to omit reference to the annual operational plan. This resulted in the omission of paragraph 61(b)(i) and the incorporation of paragraph 61(b)(ii), which provides the authority for regulation 1A.3, into the 'main' text of subsection 61(b). The amendment in item 21 captures this change in authority.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021

This Legislative Instrument 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*.

Overview of the Legislative Instrument

The Legislative Instrument makes amendments to the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995* (the Administration Regulations) and the *Agricultural and Veterinary Chemicals Code Regulations 1995* (the Code Regulations).

The Legislative Instrument will improve the efficiency and effectiveness of the regulatory framework for agricultural and veterinary chemicals (agvet chemicals). It amends regulations made under the agvet chemical legislation to:

- prescribe certain kinds of information the Australian Pesticides and Veterinary Medicines Authority (the APVMA) may take into account during the assessment period for an application which would otherwise not be permitted to be taken into account under subsection 8C(2) of the Agvet Code
- to authorise the APVMA to set, in a disallowable legislative instrument, application fees and assessment periods for applications made under sections 14C, 14D and 14E of the Agvet Code for the approval and registration for prescribed active constituents, chemical products or labels
- require the APVMA, when publishing the summary of relevant applications, to include a statement that relevant protection periods or limitation periods may be extended as a result of granting the application
- provide the APVMA with the ability to issue infringement notices for alleged contraventions of civil penalty provisions relating to:
    - failing to comply with annual return reporting or record keeping requirements (subsections 35(4) and 37(3) of the Levy Act, respectively)
    - providing the APVMA with false or misleading information or documents (subsections 69ER(3) and (4) of the Administration Act and subsections 146(3) and (4) of the Agvet Code)
    - failing to notify the APVMA of a voluntary recall (subsection 106(2) of the Agvet Code)
- declare that certain voluntary recall notices submitted to the APVMA under subsection 106(7) of the Agvet Code do not need to be published.

Human rights implications

Some parts of the Legislative Instrument engage, or have the potential to engage the International Covenant on Civil and Political Rights (ICCPR). These are identified and assessed below for each part of the Legislative Instrument.

Part 1–Information to be taken into account in determining applications

Item 1 of Part 1 of Schedule 1 to the Legislative Instrument inserts new regulation 8AHAA which prescribes the kinds of information the APVMA may consider during the assessment period for an application made under the Agvet Code and the circumstances in which the information may be given.

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.

Regulation 8AHAA of the Code Regulations may engage the protection against arbitrary or unlawful interference with privacy, as these provisions enable the APVMA to request information from an applicant or a person acting on behalf of an applicant for use by the APVMA. To the extent that new regulation 8AHAA of the Code Regulations may limit the right to privacy, any limitation is reasonable, necessary and proportionate to the achievement of a legitimate objective.

Regulation 8AHAA of the Code Regulations provides (as authorised by subsection 8C(2A) of the Agvet Code) that certain kinds of information could be provided to the APVMA at the APVMA's request in certain circumstances for which it would be appropriate for the APVMA to be able to consider during an assessment without triggering a compulsory extension to the statutory assessment period. Specifically, regulation 8AHAA of the Code Regulations prescribes the kinds of information that may be taken into account in determining applications and the circumstances under which this information could be provided. Before the introduction of section 8C(2A) of the Agvet Code, the only mechanism available for the APVMA to seek additional information about an application was by issuing a notice (at its discretion) to the applicant under section 159 of the Agvet Code. The first such notice issued during the course of an assessment triggers a mandatory one-off extension to the statutory assessment period in which the application must be assessed – the assessment period ranges from 3 months to 18 months. 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.

The kind of information prescribed by subregulation 8AHAA(1) of the Code Regulations is information that clarifies or updates information referred to in subparagraph 8C(1)(a)(i) or (ii) of the Agvet Code. Paragraph 8C(1)(a) prescribes information the APVMA must have regard to in determining an application. Subparagraph 8C(1)(a)(i) prescribes that this includes information that is required in, or to accompany, the application by any provision of the Agvet Code. Subparagraph 8C(1)(a)(ii) extends this to information (or thing) given to the

APVMA under section 157 (samples for analysis) or 159 (which authorises the APVMA to request further information in certain circumstances) or 160A of the Agvet Code.

Subregulation 8AHAA(2) of the Code Regulations provides that the circumstances in which this information must be provided are where:

- the APVMA requests the information from the applicant or a person on behalf of the applicant; and
- such information is provided by, or on behalf of, the applicant before the end of the period of 14 days beginning on the day the request is made.

Regulation 8AHAA of the Code Regulations ensures that the APVMA has the ability to quickly and easily request clarifying information. This information will be used by the APVMA to support is assessment of an application. The information helps to ensure that the assessment is based on accurate data. The APVMA's ability to request clarifying information also allows a more efficient, effective and timely assessment of the application because it will not trigger an extension of time. This potentially benefits the applicant, but it also ensures that the APVMA can fulfil its functions and obligations particularly in relation to its role regulating agvet chemical to advance Australia's agricultural productivity and animal health in a way that is safe for humans, plants and animals.

It is important to note that such information will be treated no different to other information routinely provided as part of an application to the APVMA (including protections against potential disclosure of personal information). Specifically, 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.

Summary

Part 1 of Schedule 1 to the Legislative Instrument is compatible with human rights because, to the extent that regulation 8AHAA of the Code Regulations 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.

Part 2– Approval and registration for prescribed active constituents, chemical products or labels

Part 2 of Schedule 1 to the Legislative Instrument 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* as it does not engage any human rights.

Part 3– Limits on use of information

Part 3 of Schedule 1 to the Legislative Instrument 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* as it does not engage any human rights

Part 4–Annual returns and record-keeping

Items 14 and 15 of Part 4 of Schedule 1 to the Legislative Instrument inserts new items 12A and 14 into the table at Schedule 5 to the Administration Regulations. New table items 12A and 14 provide for the penalty amounts for infringement notices for alleged contraventions of certain civil penalty provisions of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (the Collection Act) relating to annual returns and record keeping requirements. The infringement notice amounts provided by table items 12A and 14 are 15 penalty units for an individual and 125 penalty units for a body corporate.

Right to fair and public hearing

Article 14(1) of the ICCPR ensures that everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law.

The Legislative Instrument engages the right to a fair and public hearing through the insertion of infringement notices. An infringement notice may be issued by an infringement officer for contravening subsection 35(1) or 37(1) of the Collection Act, which are civil penalty provisions enforceable under the Administration Act. The Administration Act ensures against arbitrariness or abuses of power through limitations as to who can issue an infringement notice. The Administration Act limits this exercise of power to APVMA inspectors (see section 69EK of the Administration Act), who are appointed by the APVMA and are members of the staff of the APVMA, persons engaged under the *Public Service Act 1999*, or other persons having appropriate qualifications (see section 69F of the Administration Act).

The right of a person to a fair and public hearing by a competent, independent and impartial tribunal is preserved by the Administration Act. If a person elects not to pay the amount specified in the notice, the APVMA may instead pursue the matter as a civil penalty in court. This effectively presents the person with the ability to have the matter heard in court. Additionally, the Administration Act outlines that this right must be stated in an infringement notice issued to a person, ensuring that a person issued with an infringement notice is aware of their right to have the matter heard by the court (see section 69EKA of the Administration Act).

These powers are reasonable, necessary and proportionate. The Administration Act ensures that relevant courts have sufficient oversight to ensure against arbitrariness and abuses of power. Regulatory functions and powers in the issuing of infringement notices are limited to government officers and a person can elect to have the matter heard by a court.

Criminal process rights

As discussed in the *Guidance Note 2: Offence provisions, civil penalties and human rights* (the Guidance Note 2) published by the Parliamentary Joint Committee on Human Rights, civil penalty provisions may engage criminal process rights under Article 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 Articles 14 and 15 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.

The civil penalty provisions in the Collection Act to which the infringement notices relate, expressly classify the penalties as civil penalties. The civil penalty provisions and the infringement notice amounts are solely pecuniary penalties in the form of a debt payable to the Commonwealth. The civil penalties aim to deter non-compliance with the Collection Act and a finding by a court that they have been contravened does not lead to the creation of a criminal record. The infringement notices apply in a specific regulatory context and do not apply to the general public but to a sector or class of people that deal with registered chemical products. Such persons will reasonably be expected to be aware of their obligations under the Collection Act and Administration Act, because they engage in activity that is regulated under clear conditions. Further, the infringement notice scheme of the Collection Act and Administration Act are regulatory control options. These factors all indicate that the infringement notices amounts inserted by items 14 and 15 of Part 4 of Schedule 1 to the Legislative Instrument are civil rather than criminal in nature.

The infringement notice amount of 15 penalty units for an individual and 125 penalty units for a body corporate, do not exceed the amount of one fifth of the maximum penalty that a court could impose on the person under the relevant offence provision. However, this is inconsistent with the maximum amount of 12 penalty units for an individual and 60 penalty units for a body corporate that an infringement notice should impose, as stipulated in the *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers* (the Guide). While the infringement notice amounts provided for by items 14 and 15 of the Legislative Instrument exceed the amount stipulated by the Guide, this amount provides for a proportionate response to contraventions and deters non-compliance with the return and record keeping requirements of interested persons. This ensures that the APVMA has access to information, including information on the leviable disposal of chemicals, that is necessary for the ongoing regulation of agvet chemicals.

The infringement notices which would apply in a regulatory context, should not be considered severe, noting that they are pecuniary penalties (rather than more severe punishment like imprisonment) and there is no sanction of imprisonment for non-payment of an infringement notice.

Having regard to the severity of the penalty, and the context in which they are applied, the infringement notices should not be considered as criminal in nature under international human rights law. However, in the event that they could be perceived to be criminal in nature, they would be compatible with the criminal process rights in Articles 14 and 15 of the ICCPR. For example, Article 15 of the ICCPR is not engaged by the Legislative Instrument as the Legislative Instrument does not seek to create retrospective criminal offences.

Part 4 of Schedule 1 to the Legislative Instrument 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 because to the extent that table items 12A and 14 of Schedule 5 to the Administration Regulations may limit the fair hearing rights in Article 14 of the ICCPR, that limitation is reasonable, necessary and proportionate.

Part 5–False and misleading information

Items 16 of Part 5 of Schedule 1 to the Legislative Instrument inserts new items 10A and 10B into the table in Schedule 5 of the Administration Regulations, which provides for the penalty amounts for infringement notices for alleged contraventions of certain civil penalty provisions of the Administration Act. Item 17 of Part 5 of Schedule 1 to the Legislative instrument inserts new items 54A and 54B into the table in Schedule 5A to the Code Regulations, which provides for the penalty amounts for infringement notices for alleged contraventions of certain civil penalty provisions of the Agvet Code. These infringement notices are in relation to providing false and misleading information.

Table items 10A and 54A each provide an infringement notice amount of 90 penalty units for an individual and 750 penalty units for a body corporate. Table items 10B and 54B each provide an infringement notice amount of 18 penalty units for an individual and 150 penalty units for a body corporate.

Right to fair and public hearing

Part 5 of Schedule 1 to the Legislative Instrument inserts infringement notices for contraventions of subsections 69ER(3) and (4) of the Administration Act, and subsections 146(3) and (4) of the Agvet Code.

As discussed in detail above, the issue of infringement notices engages the right to a fair and public hearing in Article 14 of the ICCPR. As also discussed in details above, the Administration Act ensures against arbitrariness and abuses of power through limitations as to who can issue an infringement notice and the right to a fair and public hearing is preserved by the Administration Act as it allows the person issued with an infringement notice to elect to have the matter heard by a relevant court. Therefore the fair hearing rights are not circumvented by this measure.

Criminal Process rights

As discussed in the Guidance Note 2, civil penalty provisions may engage criminal process rights regardless of the distinction between criminal and civil penalties in domestic law. Criminal process rights in relation to infringement notices is discussed in detail above. The regulatory context, absence of criminal penalty such as conviction or imprisonment and the purpose of the infringement notices inserted by items 16 and 17 of Part 5 of Schedule 1 to the Legislative Instrument, indicate that they are civil rather than criminal in nature.

While the infringement notice penalty amounts provided by table items 10A of Schedule 5 to the Administration Regulations and 54A of Schedule 5A to the Code Regulations (90 penalty units for an individual, 750 penalty units for a body corporate), and table items 10B of Schedule 5 to the Administration Regulations and 54B of Schedule 5A to the Code Regulations (18 penalty units for an individual, 150 penalty units for a body corporate) are inconsistent with the recommended maximum amount stipulated by the Guide (as discussed above), these amounts provide for a proportionate response to contraventions that involve

providing the APVMA with false and misleading information or false and misleading documents. This reflects the seriousness of the contravening conduct and the risk that contravening behaviour may have on human and animal health, the environment and trade.

As discussed above, the infringement notices which would apply in a regulatory context, should not be considered as criminal in nature under international human rights law and in the event that they could be perceived to be criminal in nature, they would be compatible with the criminal process rights in Articles 14 and 15 of the ICCPR.

Part 5 of Schedule 1 to the Legislative Instrument 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* because to the extent that table items 10A and 10B of Schedule 5 to the Administration Regulations and table items 54A and 54B of Schedule 5A to the Agvet Code Regulations may limit the fair hearing rights in Article 14 of the ICCPR, that limitation is reasonable, necessary and proportionate.

Part 6–Voluntary recalls

Item 19 of Part 6 of Schedule 1 to the Legislative Instrument inserts new item 44A into the table in Schedule 5A to the Code Regulations, which provides the penalty amount for an infringement notice for an alleged contravention of the civil penalty provision in subsection 106(2) of the Agvet Code. Subsection 106(2) of the Agvet Code relates to voluntary recalls. Table item 44A provides an infringement notice amount of 36 penalty units for an individual and 300 penalty units for a body corporate.

Right to fair and public hearing

Part 6 of Schedule 1 to the Legislative Instrument, which inserts an infringement notice for a contravention of subsection 106(2) of the Agvet Code, engages the right to a fair and public hearing in Article 14 of the ICCPR. The right to a fair and public hearing is discussed in detail above.

The Agvet Code ensures against arbitrariness or abuses of power through limitations as to who can issue an infringement notice. The Agvet Code limits this exercise of power to APVMA inspectors (see section 145DA of the Agvet Code), who are appointed by the APVMA and are members of the staff of the APVMA, persons engaged under the *Public Service Act 1999*, or other persons having appropriate qualifications (see section 69F of the Administration Act).

The right of a person to a fair and public hearing by a competent, independent and impartial tribunal is preserved by the Agvet Code as its provisions allow a person to elect to have the matter heard by a court rather than pay the amount specified in the notice. Additionally, the Agvet Code outlines that this right must be stated in an infringement notice issued to a person, ensuring that a person issued with an infringement notice is aware of their right to have the matter heard by the court (see section 145DB of the Agvet Code).

Criminal process rights

As discussed in the Guidance Note 2, civil penalty provisions may engage the criminal process rights regardless of the distinction between criminal and civil penalties in domestic

law. Criminal process rights in relation to infringement notices is discussed in detail above. As above, the regulatory context, absence of criminal penalty such as conviction or imprisonment and the purposes of the infringement notice inserted by item 19 of Part 6 of Schedule 1 to the Legislative Instrument, indicate that they are civil rather than criminal in nature.

While the infringement notice penalty amounts provided by table item 44A of Schedule 5A to the Code Regulations (36 penalty units for an individual, 300 penalty units for a body corporate) are not consistent with the recommended maximum amount stipulated by the Guide (as discussed above), the amount provides for a proportionate response to contraventions of subsection 106(2) of the Agvet Code. This reflects the serious harm that contravening conduct could have on public safety, the environment, animal and plant health or trade.

The infringement notice which would apply in a regulatory context, should not be seen as criminal in nature under international human rights law. In the event that it could be perceived to be criminal in nature, it would be compatible with the criminal process rights in Articles 14 and 15 of the ICCPR.

Part 6 of Schedule 1 to the Legislative Instrument 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* because to the extent that table item 44A of Schedule 5A to the Agvet Code Regulations may limit the fair hearing rights in Article 14 of the ICCPR, that limitation is reasonable, necessary and proportionate.

Part 7–Annual operational plans

Part 7 of Schedule 1 to the Legislative Instrument 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* as it does not engage any human rights.

Conclusion

This Legislative Instrument is compatible with human rights because its provisions either do not engage human rights or, to the extent that they may limit the right to privacy in Article 17 of the ICCPR, or the right to fair and public hearing in Article 14 of the ICCPR, that limitation is reasonable, necessary and proportionate to the achievement of a legitimate outcome.

The Hon. David Littleproud MP
Minister for Agriculture and Northern Australia