

## **EXPLANATORY STATEMENT**

Issued by Authority of the Minister for Agriculture and Northern Australia

*Agricultural and Veterinary Chemicals Code Act 1994*

*Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2022*

### **Legislative Authority**

Section 7 of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act) provides that the Minister may, by legislative instrument, make orders with respect to a matter that are consistent with the regulations if:

- provision may be made by the regulations for or in relation to a matter; and
- the regulations declare that this section applies to that matter.

Regulation 2 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (the Code Regulations) in turn provides that the matters covered by subsections 6(1), (2) and (3) of the Code Act (other than paragraph 6(2)(i)) are matters to which section 7 of the Code Act applies. This authorises the Minister to make orders with respect to a matter which may be made by the regulations except for the prescribing of penalties (paragraph 6(2)(i) of the Code Act allows regulations to prescribe penalties up to 50 penalty units).

### **Purpose**

The purpose of the *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2022* (the Order) is to support the implementation of the limits on use of information measures introduced into the Code Act by Part 3 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). The APVMA Board and Other Improvements Act amends the Agricultural and Veterinary Chemicals Code (the Agvet Code), which is in Schedule 1 to 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 during which the Australian Pesticides and Veterinary Medicines Authority (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.

The Order supports this by ensuring that the APVMA can provide extensions to certain protection periods and limitation periods when registration of certain uses occur by setting the conditions and qualifying criteria – such as the eligible application types and the prescribed uses that may trigger an extension – that apply in order to obtain an extension, and how large this extension will be.

The Order will restrict the extensions of certain protection periods and limitation periods to those associated with agricultural chemical products only, however the Order includes the ability to include active constituent approvals or veterinary chemical products if, in the future, it is desirable.

## **Background**

Agricultural and veterinary (agvet) chemicals (active constituents and chemical products) are regulated through a cooperative National Registration Scheme (the 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 APVMA was established by the Commonwealth under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* as the independent Commonwealth regulator for agvet chemical products (including active constituents contained in the product and the label for the product container). It assesses, registers and approves 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 ensure compliance with (and enforce) the Agvet Code – including suspending and cancelling approvals and registrations.

## **Impact and Effect**

The Order will improve access to agvet chemicals by incentivising the registration of certain uses through extensions to certain protection periods and limitation periods.

## **Consultation**

The Order was developed in consultation with the APVMA and to support the *Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021* (the Improvements Regulations).

The department consulted on these measures with affected stakeholders (plant protection chemicals and veterinary medicines industries, farmers and other users). In 2021, the department developed a consultation paper that described these amendments along with other unrelated amendments. Stakeholders were also provided with an exposure draft of the proposed Order. These documents were made available for public consultation from 14 July 2021 to 27 August 2021 – seventeen submissions were received. These 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 Order and, where applicable, suggestions for clarification were incorporated into the explanatory material.

Subsection 7(6) of the Code Act sets out matters the Minister must consider when making an order which includes the effect that the order would have for the purposes of the Agvet Code of each jurisdiction. Relevant state and territory agencies were consulted and provided with the opportunity to comment and make suggestions about the measures in the Order.

The Office of Best Practice Regulation (OBPR) was consulted in the preparation of the order (ID 25893). The OBPR advised a Regulation Impact Statement was not required as the measure appears to only have a minor economic and regulatory impact.

### **Details/ Operation**

Details of the Order are set out in Attachment A.

### **Other**

Subsection 7(3) of the Code Act provides that, despite subsection 44(1) of the *Legislation Act 2003*, section 42 (disallowance) of that Act applies to the order. That the Order is disallowable is a matter under subsection 7(6) of the Code Act that the Minister must have regard to when making the Order.

Sunsetting does not apply to the Order due to paragraph 54(1)(a) of the *Legislation Act 2003*. This is because the enabling legislation (that is, the Code Act) for the Order facilitates the establishment or operation of an intergovernmental body or scheme involving the Commonwealth and one or more States or Territories (that is, the NRS), and authorises the Order to be made by the body or for the purposes of the body or scheme.

The Order is 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 Order is a legislative instrument for the purposes of the *Legislation Act 2003*.

**Details of the *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2022***

**Part 1—Preliminary**

Section 1 – Name

This section provides that the name of the Order is the *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2022*.

Section 2 – Commencement

This section provides for the Order to commence at the same time as Part 3 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.

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 3 allows for the insertion of relevant dates and details.

Section 3 – Authority

This section provides that the Order is made under the *Agricultural and Veterinary Chemicals Code Act 1994*. The note to this section states that section 7 of that Act permits the Minister to make orders with respect to most matters that may be dealt with by regulations under section 6 of that Act.

**Part 2—Extension of protection periods and limitation periods**

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

Part 3 of Schedule 1 to the APVMA Board and Other Improvements Act amended the Agvet Code to provide for extensions to particular protection periods and limitation periods to encourage more registered uses of agvet chemical by incentivising certain novel chemistries and/or particular kinds of prescribed uses of chemicals. Where extensions are made, the

APVMA must not use an innovator's information to support the registration, variation or reconsideration of another chemical product or active constituent.

The Agvet Code deals with two types of information that can be subject to a protection period or a limitation period:

- 'Protected information' is defined in section 3 of the Agvet Code. In practice protected information is certain kinds of information provided as part of a reconsideration by the APVMA (sometimes referred to as a chemical review) that relates to either an active constituent that has been approved or a chemical product that has been registered. The 'protection period' (defined in section 3 of the Agvet Code) commences from the time the information is provided to the APVMA for a reconsideration and ends 8 years after the APVMA makes its decision on the reconsideration. If the active constituent or chemical product being reconsidered (noting a reconsideration may encompass multiple approved active constituents or registered chemical products) is a protected active constituent or protected chemical product (also defined in section 3 of the Agvet Code), the APVMA's use of protected information is constrained during the protection period. Specifically, during the protection period the APVMA may not use the information to assess or make a decision on another reconsideration or application unless an exception applies (for example, the protection period has expired, or the information shows the active constituent or product may not meet the statutory criteria). Since new uses are not a consequence of an APVMA reconsideration process there is no linkage between information obtaining the benefit of a protection period and the policy intent of incentivising the inclusion of particular uses on labels. However, a registered chemical product might have information associated with it that has an existing protection period. The possibility of extending this protection period is also an incentive to add prescribed uses to an existing product registration.
- 'Limits on use of information' relates to information provided to the APVMA as part of an application for approval, registration or variation of an active constituent, chemical product, or label. If the information provided to the APVMA in an application is relied on by the APVMA in making a decision, then that information receives a 'limitation period'. The limitation periods for this information are set out in the table to section 34M of the Agvet Code and range from 3 to 10 years depending on the type of information. During the limitation period the APVMA may not use the information to assess or make a decision on another application unless an exception prescribed in section 34J of the Agvet Code applies (for example, the authorising party has provided consent for the information to be used). As such, the information relied on is associated with an application and an active constituent or product may have multiple sets of information with separate limitation periods.

Specifically, Part 3 of Schedule 1 to the APVMA Board and Other Improvements Act amends the Agvet Code to specify a protection period or limitation period can only be extended if an application is:

- lodged under a provision of Part 2 of the Agvet Code (which deals with active constituent or label approval, chemical product registration and variation to an approval or a registration);
- prescribed by the regulations; and
- made at least 3 years before the protection period or limitation period ends - the purpose of this three year period is to reduce the impact on potential applicants (by providing certainty as to when a protection or limitation period will end) and to mirror similar practices used in other countries.

This means any uses already registered would not be eligible to trigger an extension to an existing protection period or limitation period.

Part 3 of Schedule 1 to the APVMA Board and Other Improvements Act also amended the Agvet Code to constrain extensions to protection or limitation periods by:

- imposing a maximum total of 5 years extension (this is a separate maximum for both limitation and protection period extensions rather than a cumulative maximum); and
- specifying provisions may be made to end the extension.

Only information with an existing protection period, or a new or existing limitation period that relate to item 1, 2, 3, or 4 of the table at subsection 34M(1) of the Agvet Code, may be extended for up to 5 years if certain other requirements are met. Information with a new or existing limitation period that relate to item 5 or 6 of the table at subsection 34M(1) of the Agvet Code is not eligible for an extension. The extension of a limitation period for information provided in connection with a variation application is also less valuable to industry than being able to extend the limitation period of information provided in connection with a registration application (item 1, 2, 3, or 4 of the table at subsection 34M(1) of the Agvet Code).

A variation application (under section 26B or section 27 of the Agvet Code) is an eligible application for the purposes of extending an existing protection or limitation period (that relates to item 1, 2, 3 or 4 of the table at subsection 34M(1) of the Agvet Code).

Additionally, if there is both an eligible protection period and limitation period for the information (and the application meets the prescribed requirements), the extension period applies equally to both the protection period and the limitation period. The extension period is to be cumulative based on *each use* for which an extension to the limitation period is eligible as set out in the tables in Part 3 of the Order.

Where an extension has been applied to a limitation period, and consent has been given to the APVMA to use that information in deciding on another application (known operationally by the APVMA as 'inherited data') – any extension applied to the original information would also apply to where consent has been given to use that information.

An extension only applies where making a prescribed use available in Australia is enduring. Where this outcome is frustrated by a change in circumstance, it is appropriate to withdraw any remaining portion of the extended period. This frustration could occur if a protection period or limitation period were extended on the basis of a prescribed use being made available in Australia and then for the use to be lost – for example where a registration holder decides to vary or cancel the product registration to remove the relevant use that led to the extension.

#### Example of an extension to a limitation period

For example, an application made under section 10 of the Agvet Code for a new agricultural product registration and label approval is granted under section 14 of the Agvet Code and includes an instruction for use on citrus fruits. Item 2 of the table in subsection 34M(1) of the Agvet Code provides the information relied on to grant the application is given a limitation period of 10 years (limitation period A). As use on citrus fruits is one of the prescribed uses

eligible for an extension (see subsection 12(1) and subsection 17(2) of Division 2 of Part 3 of the Order) and the application is an eligible application (see section 10 of the Order), limitation period A is extended by 6 months (the extension period for citrus fruits).

- Limitation period A is now 10 years and 6 months.
- The total extension period applied to limitation period A is 6 months.

Two years after the initial registration and label approval, a new application under section 27 of the Agvet Code is lodged to vary the product registration and label approval to include 5 additional prescribed uses from the Order (each with a 6-month extension). The application is granted under section 29 of the Agvet Code, and item 5 of the table at subsection 34M(1) of the Agvet Code provides the information relied on to grant the variation application is given a limitation period of 5 years (limitation period B). As the prescribed uses are each eligible for a 6-month extension (see subsection 12(1) and Division 2 of Part 3 of the Order) and the application is an eligible application (see section 11 of the Order), limitation period A is extended by a further 2 years and 6 months (five lots of 6-month extensions).

- Limitation period A is now a total of 13 years (the commencement date does not change).
- Limitation period B (established by item 5 of the table at subsection 34M(1)) is not eligible for an extension and remains at 5 years.
- The total extension period applied to limitation period A is now 3 years.

Nine years after the initial registration and label approval, another application under section 27 of the Agvet Code is lodged to vary the product registration and label approval to include 5 further prescribed uses from the Order (each with a 6-month extension). The application is granted under section 29 of the Agvet Code, and item 5 of the table at subsection 34M(1) of the Agvet Code provides the information relied on to grant the variation application is given a limitation period of 5 years (limitation period C). As the prescribed uses are each eligible for a 6-month extension (see subsection 12(1) of the Order and Division 2 of Part 3 of the Order) and the application is an eligible application (see section 11 of the Order), limitation period A is extended by 2 more years. This is because only 2 years remain of the 5 year maximum extension period (i.e. 6 months was used to extend limitation period A on the initial registration, and 2 years and 6 months used to extend limitation period A as triggered by the second application – see subsection 11(5) and subsection 12(2) of the Order), the 6 month extension from the last of the 5 additional uses cannot be applied.

- Limitation period A is now a total of 15 years (the commencement date does not change).
- Limitation period C (established by item 5 of the table at subsection 34M(1)) is not eligible for an extension and remains at 5 years.
- The total length of all extensions applied to limitation period A is 5 years, no more extensions can be granted to limitation period A (new subsection 34MA(4) of the Agvet Code).

	Limitation period years															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
New registration (limitation period A)																
First extension to limitation period A (initial registration)											6 mths					
Second extension to limitation period A (first variation)											2.5 yrs					
Third extension to limitation period A (second variation)															2 yrs	

The approach detailed in the example above would also apply to extending an existing protection period.

### **Division 1—Extension of protection periods**

Division 1 of Part 2 of the Order sets out circumstances for extending a protection period for an active constituent, or an agvet chemical product, as well as the circumstances for ending such an extension.

#### Section 4 – Extension of protection period—approved active constituents

Subsection 4(1) sets out that the section deals with extending the protection period in relation to protected information that relates to an approved active constituent.

Subsection 4(2) provides that for the purposes of paragraph 34KA(3)(a) of the Agvet Code (which provides for the application provisions that are relevant to an extension of the protection period), the relevant application provisions are subsection 26B(1) (applications for prescribed variations of relevant particulars of approvals and registrations) or 27(1) or 27(2) (applications for variations of the relevant particulars or conditions) of the Agvet Code.

Subsection 4(3) provides that for the purposes of paragraph 34KA(3)(b) of the Agvet Code (which provides for the requirements an application must satisfy that are relevant to an extension of the protection period), the application lodged under subsection 26B(1) or 27(1) or 27(2) of the Agvet Code must be seeking to vary instruction for use of the approved active constituent to add a new use covered by Division 1 of Part 3 of the Order.

No uses of an active constituent have been identified for the purposes of Division 1 of Part 3 of the Order.

Subsection 4(4) sets out, subject to subsection 4(5) of the Order, that the protection period is only extended if the APVMA varies the instructions of use of the approved active constituent to add the new use that is covered by Division 1 of Part 3 of the Order.

Subsection 4(5) constrains the extension period (consistent with subsection 34KA(4) of the Agvet Code which prescribes an extension of a protection period must not be more than 5 years) so the total length of all extensions, including any previous extensions, of that protection period cannot exceed 5 years.

#### Section 5 – Extension of protection period—registered agricultural chemical product

Subsection 5(1) sets out that this section deals with extending the protection period in relation to protected information that relates to a registered agricultural chemical product.

Subsection 5(2) provides that for the purposes of paragraph 34KA(3)(a) of the Agvet Code (which provides for the application provisions that are relevant to an extension of the protection period), the relevant application provisions are subsection 26B(1) (applications for prescribed variations of relevant particulars of approvals and registrations) or 27(1) or 27(2) (applications for variations of the relevant particulars or conditions) of the Agvet Code.

Subsection 5(3) provides that for the purposes of paragraph 34KA(3)(b) of the Agvet Code (which provides for the requirements an application must satisfy that are relevant to an



extension of the protection period), the application lodged under subsection 26B(1) or 27(1) or 27(2) of the Agvet Code must be seeking to vary instruction for use of the registered agricultural chemical product to add a new use covered by Division 2 of Part 3 of the Order.

Subsection 5(4) sets out, subject to subsection 5(5) of the Order, that the protection period is only extended if the APVMA varies the instructions of use of the registered agricultural chemical product to add the new use that is covered by Division 2 of Part 3 of the Order. The note in subsection 5(4) clarifies that subsection 5(6) sets out the period of the extension.

Subsection 5(5) constrains the extension period (consistent with paragraph 34KA(4) of the Agvet Code which prescribes an extension of a protection period must not be more than 5 years) so the total length of all extensions, including any previous extensions, of that protection period cannot exceed 5 years.

Subsection 5(6) sets out that, subject to subsection 5(7), if a protection period for information is extended under section 5, the period of extension is:

- for each use that is covered by subsection 17(2) of the Order—6 months (paragraph 5(6)(a))
- for each use that is covered by subsection 17(3) of the Order—12 months (paragraph 5(6)(b))
- for each use that is covered by subsection 17(4) of the Order—18 months (paragraph 5(6)(c))
- for each use that is covered by subsection 17(5) of the Order—6 months (paragraph 5(6)(d))
- for each use that is covered by subsection 17(6) of the Order—6 months (paragraph 5(6)(e))

Subsection 5(7) clarifies if the extension period provided for in subsection 5(6) would result in the total length of all extensions of the protection period being more than 5 years, then the period of the extension is the remainder of that 5-year period.

## Section 6 – Extension of protection period— registered veterinary chemical product

Subsection 6(1) sets out that this section deals with extending the protection period in relation to protected information that relates to a registered veterinary chemical product.

Subsection 6(2) provides that for the purposes of paragraph 34KA(3)(a) of the Agvet Code (which provides for the application provisions that are relevant to an extension of the protection period), the relevant application provisions are subsection 26B(1) (applications for prescribed variations of relevant particulars of approvals and registrations) or 27(1) or 27(2) (applications for variations of the relevant particulars or conditions) of the Agvet Code.

Subsection 6(3) provides that for the purposes of paragraph 34KA(3)(b) of the Agvet Code (which provides for the requirements an application must satisfy that are relevant to an extension of the protection period), the application lodged under subsection 26B(1) or 27(1) or 27(2) of the Agvet Code must be seeking to vary instruction for use of the registered veterinary chemical product to add a new use covered by Division 3 of Part 3 of the Order.

No uses of a veterinary chemical product have been identified for the purposes of Division 3 of Part 3 of the Order.

Subsection 6(4) sets out, subject to subsection 6(5) of the Order, that the protection period is only extended if the APVMA varies the instructions of use of the registered veterinary chemical product to add the new use that is covered by Division 3 of Part 3 of the Order.

Subsection 6(5) constrains the extension period (consistent with paragraph 34KA(4) of the Agvet Code which prescribes an extension of a protection period must not be more than 5 years) so the total length of all extensions, including any previous extensions, of that protection period cannot exceed 5 years.

### Section 7 – Ending extensions of protection period

Section 7 provides that the APVMA must end an extension of a protection period if:

- before the end of the extension period and as a result of a notice lodged under subsection 26AB(1) of the Agvet Code (which provides for the lodging of a notice of notifiable variations of the relevant particulars of an approval or registration) or of an application made under subsection 26B(1), 27(1) or 27(2) of the Agvet Code (providing for various applications for variations), the APVMA varies the instructions for use to remove the use that led to the extension (paragraph 7(1)(a)); and
- the APVMA is satisfied in all the circumstances that it is appropriate to end the extension (paragraph 7(1)(b)).

If the APVMA is not satisfied in all the circumstances, they may decide not to end the extension. For example, if a variation application removes the trigger for the extension for no specific reason, the APVMA is likely to be satisfied in this circumstance to end the extension. However, if the APVMA has requested the holder remove the use that was the trigger for the extension due to a safety concern, the APVMA may not be satisfied in that circumstance to end the extension.

Subsections 7(2) to (5) provide that before ending the extension the APVMA must:

- give written notice to the holder that it proposes to end the extension and invite written submission from the holder within 28 days or such further period as specified in the notice (subsection 7(2))
- have regard to any submissions made by the holder within the period set out in the notice (subsection 7(3))
- give the holder notice if it ends the extension including the specifying the day on which the extension ends (which must not be earlier than the day the notice is given) (subsection 7(4))
- give the holder notice if it decides to not end extension (subsection 7(5)).

Subsection 7(6) provides that for the purposes of paragraph 167(1)(y) of the Agvet Code a decision to end an extension of a protection period extension is reviewable by the AAT.

Paragraph 166(1)(b) of the Agvet Code provides for an internal review of a decision if the decision is also eligible for an AAT review, therefore a decision to end an extension of a protection period is also subject to an internal APVMA review.

## **Division 2—Extension of limitation periods**

Division 2 of Part 2 of the Order sets out circumstances for extending a limitation period for an active constituent or an agvet chemical product, as well as the circumstances for ending such an extension.

### **Subdivision A—Approved active constituents**

#### Section 8 – Extension of initial limitation period

Section 8 provides that for the purposes of paragraph 34MA(1)(a) of the Agvet Code (which provides for extending the limitation period), the limitation period for information covered by item 1 of the table in subsection 34M(1) of the Agvet Code is extended if the information includes instruction for use of the active constituent that is covered by Division 1 of Part 3 of the Order. Item 1 of the table in subsection 34M(1) of the Agvet Code relates to information given in connection with an application under section 10 of the Agvet Code for approval of an active constituent that was not a previously endorsed active constituent on the commencement of this Division and is relied on to approve that active constituent.

As this section refers only to item 1 of the table in subsection 34M(1) of the Agvet Code, it means it only applies the initial (new) limitation period associated with a new active constituent approval.

No uses of an active constituent have been identified for the purposes of Division 1 of Part 3 of the Order.

#### Section 9 – Extension of limitation period for making of applications at least 3 years before end of limitation period

Subsection 9(1) sets out that the section deals with extending the limitation period for information covered by item 1 of the table in subsection 34M(1) of the Agvet Code (which is described above in section 8 of the Order). This relates to an existing limitation period, that was created by item 1 of the table in subsection 34M(1) of the Agvet Code – importantly, it is not the limitation period established by information associated with the variation application that gets the extended limitation period but the limitation period established by the original information. Consistent with the constraint in subsection 34MA(3) of the Agvet Code (which prescribes the circumstances where there may be an extension of the limitation period), there must be three years remaining on the existing limitation period at the time an application seeking to vary the instructions for use is lodged.

Subsection 9(2) provides that for the purposes of paragraph 34MA(3)(a) of the Agvet Code (which provides for the application provisions that are relevant to an extension of the limitation period), the relevant application provisions are subsection 26B(1) (applications for prescribed variations of relevant particulars of approvals and registrations) or 27(1) or 27(2) (applications for variations of the relevant particulars or conditions) of the Agvet Code.

Subsection 9(3) provides that for the purposes of paragraph 34MA(3)(b) of the Agvet Code (which provides for the requirements an application must satisfy that are relevant to an extension of the limitation period), the application (lodged under subsection 26B(1) or 27(1)

or 27(2) of the Agvet Code) must be seeking to vary instruction for use of the active constituent to add a new use covered by Division 1 of Part 3 of the Order.

No uses of an active constituent have been identified for the purposes of Division 1 of Part 3 of the Order.

Subsection 9(4) sets out, subject to subsection 9(5) of the Order, that the limitation period is only extended if the APVMA varies the instructions of use of the approved active constituent, in practice by adding the new use that is covered by Division 1 of Part 3 of the Order.

Subsection 9(5) constrains the extension period (consistent with subsection 34MA(4) of the Agvet Code which prescribes an extension of a limitation period must not be more than 5 years) so the total length of all extensions, including any previous extensions, of that limitation period cannot exceed 5 years.

## **Subdivision B—Registered agricultural chemical products**

### Section 10 – Extension of initial limitation period

Subsection 10(1) provides that for the purposes of paragraph 34MA(1)(a) of the Agvet Code (which provides for extending the limitation period), the limitation period for information covered by item 2 of the table in subsection 34M(1) of the Agvet Code is extended if:

- the chemical product referred to in item 2 of the table in subsection 34M(1) of the Agvet Code is an agricultural chemical product (paragraph 10(1)(a))
- the information includes instruction for use of that agricultural chemical product (paragraph 10(1)(b)) and
- that instruction for use is covered by Division 2 of Part 3 of the Order (paragraph 10(1)(c)).

Item 2 of the table in subsection 34M(1) of the Agvet Code relates to information given in connection with an application made under section 10 of the Agvet Code for:

- registration of a chemical product at least one of whose active constituents was not a previously endorsed active constituent when the application passed preliminary assessment or
- approval of a label for a container for a chemical product at least one of whose active constituents was not a previously endorsed active constituent when the application passed preliminary assessment and

is relied on to register the product or approve the label.

Subsection 10(2) provides that for the purposes of paragraph 34MA(1)(a) of the Agvet Code (which provides for extending the limitation period), the limitation period for information covered by item 3 of the table in subsection 34M(1) of the Agvet Code is extended if:

- the information includes instruction for use of the agricultural chemical product referred to in item 3 of the table in subsection 34M(1) of the Agvet Code (paragraph 10(2)(a))
- that instruction for use is covered by Division 2 of Part 3 of the Order (paragraph 10(2)(b)).

Item 3 of the table in subsection 34M(1) of the Agvet Code relates to information given in connection with an application (except one covered by item 1 of the table in subsection 34M(1) of the Agvet Code) made under section 10 of the Agvet Code for:

- registration of an agricultural chemical product or
- approval of a label for a container for an agricultural chemical product and is relied on to register the product or approve the label.

As section 10 refers only to agricultural chemical products in item 2 or item 3 of the table in subsection 34M(1) of the Agvet Code, it means it only applies the initial (new) limitation period associated with the registration of a new agricultural chemical product.

The notes after both subsection 10(1) and 10(2) clarify that section 12 sets out the period of the extension.

### Section 11 – Extension of limitation period for making of applications at least 3 years before end of limitation period

Subsection 11(1) sets out that the section deals with extending the limitation period for information covered by item 2 or 3 of the table in subsection 34M(1) of the Agvet Code (which are described above in section 10 of the Order). This relates to an existing limitation period for a registered agricultural chemical product, that was created by item 2 or 3 of the table in subsection 34M(1) of the Agvet Code – importantly, it is not the limitation period established by information associated with the variation application that gets the extended limitation period but the limitation period established by the original information relied on for the registration of the agricultural chemical product. Consistent with the constraint in subsection 34MA(3) of the Agvet Code (which prescribes the circumstances where there may be an extension of the limitation period), there must be three years remaining on the existing limitation period at the time an application seeking to vary the instructions for use is lodged.

Subsection 11(2) provides that for the purposes of paragraph 34MA(3)(a) of the Agvet Code (which provides for the application provisions that are relevant to an extension of the limitation period), the relevant application provisions are subsection 26B(1) (applications for prescribed variations of relevant particulars of approvals and registrations) or 27(1) or 27(2) (applications for variations of the relevant particulars or conditions) of the Agvet Code.

Subsection 11(3) provides that for the purposes of paragraph 34MA(3)(b) of the Agvet Code (which provides for the requirements an application must satisfy that are relevant to an extension of the limitation period), the application (lodged under subsection 26B(1) or 27(1) or 27(2) of the Agvet Code) must be seeking to vary instruction for use of the registered agricultural chemical product to add a new use covered by Division 2 of Part 3 of the Order.

Subsection 11(4) sets out, subject to subsection 11(5) of the Order, that the limitation period is only extended if the APVMA varies the instructions of use of the registered agricultural chemical product, in practice, by adding the new use that is covered by Division 2 of Part 3 of the Order. The note in subsection 11(4) clarifies that subsection 12 sets out the period of the extension.

Subsection 11(5) constrains the extension period (consistent with subsection 34MA(4) of the Agvet Code which prescribes an extension of a limitation period must not be more than 5 years) so the total length of all extensions, including any previous extensions, of that limitation period cannot exceed 5 years.

## Section 12 – Period of extension

Subsection 12(1) sets out that, subject to section 12, if a limitation period for information is extended under subdivision B, the period of extension is:

- for each use that is covered by subsection 17(2) of the Order—6 months (paragraph 12(1)(a))
- for each use that is covered by subsection 17(3) of the Order—12 months (paragraph 12(1)(b))
- for each use that is covered by subsection 17(4) of the Order—18 months (paragraph 12(1)(c))
- for each use that is covered by subsection 17(5) of the Order—6 months (paragraph 12(1)(d))
- for each use that is covered by subsection 17(6) of the Order—6 months (paragraph 12(1)(e))

Subsection 12(2) clarifies if the extension period provided for in subsection 12(1) of the Order would result in the total length of all extensions of the limitation period being more than 5 years, then the period of the extension is the remainder of that 5-year period.

### **Subdivision C—Registered veterinary chemical products**

## Section 13 – Extension of initial limitation period

Subsection 13(1) provides that for the purposes of paragraph 34MA(1)(a) of the Agvet Code (which provides for extending the limitation period), the limitation period for information covered by item 2 of the table in subsection 34M(1) of the Agvet Code (described above in section 12) is extended if:

- the chemical product referred to in item 2 of the table in subsection 34M(1) of the Agvet Code is a veterinary chemical product (paragraph 13(1)(a));
- the information includes instruction for use of that veterinary chemical product (paragraph 13(1)(b)); and
- that instruction for use is covered by Division 3 of Part 3 of the Order (paragraph 13(1)(c)).

Subsection 13(2) provides that for the purposes of paragraph 34MA(1)(a) of the Agvet Code (which provides for extending the limitation period), the limitation period for information covered by item 4 of the table in subsection 34M(1) of the Agvet Code is extended if:

- the information includes instruction for use of the veterinary chemical product referred to in item 4 of the table in subsection 34M(1) of the Agvet Code (paragraph 13(2)(a)); and
- that instruction for use is covered by Division 3 of Part 3 of the Order (paragraph 13(1)(b)).

Item 4 of the table in subsection 34M(1) of the Agvet Code relates to information given in connection with an application (except one covered by item 2 of the table in subsection 34M(1) of the Agvet Code) made under section 10 of the Agvet Code for:

- registration of a veterinary chemical product or
- approval of a label for a container for a veterinary chemical product, and is relied on to register the product or approve the label.

As section 13 refers only to veterinary chemical products in item 2 or item 4 of the table in subsection 34M(1) of the Agvet Code, it means it only applies the initial (new) limitation period associated with a new veterinary chemical product.

No uses of a veterinary chemical product have been identified for the purposes of Division 3 of Part 3 of the Order.

#### Section 14 – Extension of limitation period for making of applications at least 3 years before end of limitation period

Subsection 14(1) sets out that the section deals with extending the limitation period for information covered by item 2 or 4 of the table in subsection 34M(1) of the Agvet Code (described above in section 13). This relates to an existing limitation period for a registered veterinary chemical product, that was created by item 2 or 4 of the table in subsection 34M(1) of the Agvet Code – importantly, it is not the limitation period established by information associated with the variation application that gets the extended limitation period but the limitation period established by the original information relied on for the registration of the veterinary chemical product. Consistent with the constraint in subsection 34MA(3) of the Agvet Code (which prescribes the circumstances where there may be an extension of the limitation period), there must be three years remaining on the existing limitation period at the time an application seeking to vary the instructions for use is lodged.

Subsection 14(2) provides that for the purposes of paragraph 34MA(3)(a) of the Agvet Code (which provides for the application provisions that are relevant to an extension of the limitation period), the relevant application provisions are subsection 26B(1) (applications for prescribed variations of relevant particulars of approvals and registrations) or 27(1) or 27(2) (applications for variations of the relevant particulars or conditions) of the Agvet Code.

Subsection 14(3) provides that for the purposes of paragraph 34MA(3)(b) of the Agvet Code (which provides for the requirements an application must satisfy that are relevant to an extension of the limitation period), the application (lodged under subsection 26B(1) or 27(1) or 27(2) of the Agvet Code) must be seeking to vary instruction for use of the registered veterinary chemical product to add a new use covered by Division 3 of Part 3 of the Order.

Subsection 14(4) sets out, subject to subsection 14(5), that the limitation period is only extended if the APVMA varies the instructions of use of the registered veterinary chemical product, in practice by adding the new use that is covered by Division 3 of Part 3 of the Order.

No uses of a veterinary chemical product have been identified for the purposes of Division 3 of Part 3 of the Order

Subsection 14(5) constrains the extension period (consistent with subsection 34MA(4) of the Agvet Code which prescribes an extension of a limitation period must not be more than 5 years) so the total length of all extensions, including any previous extensions, of that limitation period cannot exceed 5 years.

## **Subdivision D—Ending extensions of limitation periods**

### Section 15 – Ending extensions of limitation periods

Section 15 provides for the APVMA to end an extension of a limitation period for information covered by item 1, 2, 3 or 4 of the table in subsection 34M(1) of the Agvet Code (which are described above in sections 8, 10 and 13 of the Order) if:

- before the end of the extension period and as a result of a notice lodged under subsection 26AB(1) of the Agvet Code (which provides for the lodging of a notice of notifiable variations of the relevant particulars of an approval or registration) or of an application made under subsection 26B(1), 27(1) or 27(2) of the Agvet Code (providing for various applications for variations), the APVMA varies the instructions for use to remove the use that led to the extension (paragraph 15(1)(a)); and
- the APVMA is satisfied in all the circumstances that it is appropriate to end the extension (paragraph 15(1)(b)).

If the APVMA is not satisfied in all the circumstances they may decide to not end the extension. For example, if the variation application removes the trigger for the extension for no specific reason, the APVMA is likely to be satisfied in this circumstance to end the extension. However, if the APVMA has requested the holder remove the use that was the trigger for the extension due to a safety concern, the APVMA may not be satisfied in that circumstance to end the extension.

Subsections 15(2) to (5) provide that before ending the extension the APVMA must:

- give written notice to the holder that it proposes to end the extension and invite written submission from the holder within 28 days or such further period as specified in the notice (subsection 15(2))
- have regard to any submissions made by the holder within the period set out in the notice (subsection 15(3))
- give the holder notice if it ends the extension including the specifying the day on which the extension ends (which must not be earlier than the day the notice is given) (subsection 15(4))
- give the holder notice if it decides to not end extension (subsection 15(5)).

Subsection 15(6) provides that for the purposes of paragraph 167(1)(y) of the Agvet Code a decision to end an extension of a limitation period is reviewable by the AAT.

Paragraph 166(1)(b) of the Agvet Code provides for an internal review of a decision if the decision is also eligible for an AAT review, therefore a decision to end an extension of a limitation period is also subject to an internal APVMA review.

### **Part 3—Uses tables**

Part 3 sets out the identified uses of active constituents, agricultural chemical products and veterinary chemical products that qualify for an extension to the protection period or limitation period when included in an approval or registration.



## **Division 1—Active constituents**

### Section 16 – Kind of use of an active constituent

Section 16 provides that for the purposes of sections 4, 8 and 9 of the Order there no kinds of use identified for an active constituent.

If in the future, a use of an active constituent is identified it will be included in section 16.

## **Division 2—Agricultural chemical products**

The identified uses of an agricultural chemical product reflect the uses in the existing:

- APVMA established crop groups
  - the APVMA groups crops through similarities in their botanical classification, morphology, growth habit, the portion of the commodity harvested and/or consumed, and cultural practices
  - crop grouping enables formal recognition of data generated in a subset of crops to be extrapolated to other related crops of the same crop group with little or no additional data (or assessment) required.
- agricultural priority uses determined through an annual collaborative forum established under the Improved Access to Agricultural and Veterinary Chemicals Initiative (the collaborative forum)
  - the initiative assists research and development corporations (RDCs) in generating data required to support applications to the APVMA
  - an annual collaborative forum brings together RDCs and grower representatives to discuss specific chemical uses or chemical need and establish the uses' priority ranking.

Inclusion of the use from subsections 17(2), (3) and (4) of the Order (which is equivalent to an APVMA established crop group) in the instructions for use of the product would attract an extension of 6-months, 12-months or 18-months, respectively. These extension periods reflect the difference in effort required to generate data to support a particular crop group as per the 'extrapolation and data waiver guidance within crop groups' table that is set out in the APVMA's document "Representative crops and extrapolation principles for risk assessment and data waivers" available at [apvma.gov.au/node/42471](http://apvma.gov.au/node/42471). The extension is associated purely with the individual prescribed use (equivalent to an APVMA crop group) as opposed to the same use multiple times for different pests or rates. For example, adding a prescribed use such as 'citrus fruit' to the instructions for use of a product three times – once for ladybugs, once for beetles and once for fruit fly – will result in only one extension. However, adding both the prescribed use 'citrus fruits' and the prescribed use 'pome fruits' will result in two cumulative extensions.

Certain priority uses (as determined by the collaborative forum) if included in the instructions for use would attract an extension of 6-months (see subsections 17(5) and (6)).

The specificity of the priority use agreed to at the collaborative forum will be maintained in the Order. This allows for a 6-month extension for each identified use, further encouraging and incentivising chemical companies to register these priority uses for the benefit of

chemical users and Australian agriculture. The Order will be regularly reviewed by the department (in consultation with the collaborative forum and the APVMA) to include relevant new priority uses established through the collaborative forum, and to remove priorities that have been addressed – an appropriate phase out period would apply for any priorities that are removed from the Order. The department will consult with stakeholders on any proposed amendments to the Order.

Importantly, the thing or thing/pest combination mentioned in the instructions for use of the agricultural chemical product must be the same (including written in the same way) as the thing, or thing/pest combination mentioned in these tables for an extension to apply. Additionally, multiple extensions may apply provided there are multiple mentions of a thing or thing/pest combination from the tables also mentioned in the instructions for use of the agricultural chemical product.

### Section 17 – Kind of use of an agricultural chemical product

Subsection 17(1) provides that, for the purposes of section 5, 10 and 11 of the Order (which relate to the use of an agriculture chemical product that may trigger an extension) the kind of use of an agricultural chemical product is one or more of:

- the use of the agricultural chemical product on a thing mentioned in an item of the table in subsection 17(2), 17(3) or 17(4) of the Order (paragraph 17(1)(a))
- the use of the agricultural chemical product on a thing mentioned in column 1 to treat the pest mentioned in column 2 of the table in subsection 17(5) of the Order (paragraph 17(1)(b))
- the use of the agricultural chemical product on a thing mentioned in column 1 to modify the physiology of the thing in the way mention in column 2 of the table in subsection 17(6) of the Order (paragraph 17(1)(c)).

Subsection 17(2) sets out the table of uses of a thing with a 6-month extension. If the thing mentioned in this table is also included as an instruction for use of the agricultural chemical product, a 6-month extension may apply.

Subsection 17(3) sets out the table of uses of a thing with a 12-month extension. If the thing mentioned in this table is also included as an instruction for use of the agricultural chemical product, a 12-month extension may apply.

Subsection 17(4) sets out the table of uses of a thing with an 18-month extension. If the thing mentioned in this table is also included as an instruction for use of the agricultural chemical product, an 18-month extension may apply.

Subsection 17(5) sets out the table of uses of a thing to treat a pest with a 6-month extension. If the thing and pest combination mentioned in this table is also included as an instruction for use of the agricultural chemical product, a 6-month extension may apply.

Subsection 17(6) sets out the table of uses of a thing to modify the physiology of another thing with a 6-month extension. If the combination mentioned in this table is also included as an instruction for use of the agricultural chemical product, a 6-month extension may apply.

## **Division 3—Veterinary chemical products**

### Section 18 – Kind of use of a veterinary chemical product

Section 18 provides that for the purposes of sections 6, 13 and 14 of the Order there are no kinds of use identified for a veterinary chemical product.

If, in the future, a use of a veterinary chemical product is identified, it will be included in section 18.

## **Part 4—Application provisions**

### Section 19 – Application provisions—protection periods

Subsection 19(1) provides that subsection 5(1) of the Order applies in relation to a protection period beginning before, on or after the commencement of this section. This has the effect of ensuring a protection period that exists before the commencement of the Order is eligible for an extension (all other criteria must also be met for an extension to apply). This ensures the incentive to add prescribed uses applies broadly and aligns with how the operation of the provision was described during consultation. Additionally, 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, then a statement in relation to this matter is to be included in the summary of the application (see regulation 19AD of the Code Regulations). This provides appropriate transparency where granting a variation application may result in an extension of an existing protection period or limitation period.

Subsection 19(2) provides that subsection 5(2) of the Order applies in relation to an application made on or after the commencement of this section. This has the effect of ensuring only an application made on or after the commencement of the Order could trigger an extension of the protection period (all other criteria must also be met for an extension to apply). An application already lodged at the commencement of the Order, could not trigger an extension of an existing protection period. An application prescribed for the purposes of subsection 5(2) of the Order includes a variation of a registered agricultural chemical product under subsection 26B(1) or 27(1) or 27(2) of the Agvet Code.

### Section 20 – Application provisions—limitation periods

Subsection 20(1) provides that subsection 10 of the Order applies in relation to applications made under section 10 of the Agvet Code, on or after the commencement of this section. This has the effect of ensuring only an application made on or after the commencement of the Order could trigger an extension of a new limitation period (all other criteria must also be met for an extension to apply). An application already lodged at the commencement of the Order, could not trigger an extension of the new limitation period. An application made under section 10 of the Agvet Code includes an application for registration of an agricultural chemical product.

Subsection 20(2) provides that section 11(1) of the Order applies in relation to a limitation period beginning before, on or after the commencement of this section. This has the effect of ensuring a limitation period that exists before the commencement of the Order is eligible for

an extension (all other criteria must also be met for an extension to apply). This ensures the incentive to add prescribed uses applies broadly and aligns with how the operation of the provision was described during consultation. Additionally, if the APVMA were to make a variation as a result of an application that may also result in the extension of a limitation period, then a statement in relation to this matter is to be included in the summary of the application (see regulation 19AD of the Code Regulations). This provides appropriate transparency where granting a variation application may result in an extension of an existing protection period or limitation period.

Subsection 20(3) provides that subsection 11(2) of the Order applies in relation to an application made on or after the commencement of this section. This has the effect of ensuring only an application made on or after the commencement of the Order could trigger an extension of the limitation period (all other criteria must also be met for an extension to apply). An application already lodged at the commencement of the Order could not trigger an extension of an existing limitation period. An application prescribed for the purposes of subsection 11(2) of the Order includes a variation of a registered agricultural chemical product under subsection 26B(1) or 27(1) or 27(2) of the Agvet Code.

**Statement of Compatibility with Human Rights**

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

**Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2022**

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 *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2022* (the Order) supports the implementation of the limits on use of information measures introduced into the *Agricultural and Veterinary Chemicals Code Act 1994* by Part 3 of the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021*. The Order ensures that the Australian Pesticides and Veterinary Medicines Authority can provide extensions to certain protection periods and limitation periods when registration of certain uses occur.

**Human rights implications**

This Legislative Instrument does not engage any of the applicable rights or freedoms.

**Conclusion**

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

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