

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 Amendment (Miscellaneous Measures)
Regulations 2021*

Legislative Authority

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 Code Act also includes 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 Code Act does not specify any conditions that need to be satisfied before the power to make regulations may be exercised.

Purpose

The purpose of the *Agricultural and Veterinary Chemicals Code Amendment (Miscellaneous Measures) Regulations 2021* (the Regulations) is to improve access to agricultural and veterinary (agvet) chemicals. Access to safe agvet chemicals is vital for supporting sustainable agriculture – benefiting primary production, management of the environment, veterinary care (including animal health and welfare), trade, and the community. The Regulations amend the *Agricultural and Veterinary Chemicals Code Regulations 1995* made under the Code Act to:

- change the definition of ‘minor use’ to implement an agreed approach by Australia’s Commonwealth, state and territory agricultural ministers to improve the harmonisation of off-label access to agvet chemicals
 - off-label refers to a specific use of a registered chemical product which is not a use the product is registered for by the Australian Pesticides and Veterinary Medicines Authority (APVMA), and therefore does not appear on the product label. The APVMA approves an off-label use through a permit.
- provide for the APVMA to develop a standard setting out the allowed differences for constituents in a registered chemical product
- exclude a limited range of enzyme products from regulation as agvet chemical products.

Background

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, 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 ensure compliance with (and enforce) the Agvet Code – including suspending and cancelling approvals and registrations.

Impact and Effect

These Regulations will improve access to agvet chemicals, while maintaining human, environmental, plant and animal health and trade safeguards. Access to safe agvet chemicals is vital for supporting sustainable agriculture – benefiting primary production, management of the environment, veterinary care (including animal health and welfare), trade, and the community. It will do this, for example, by expanding what the APVMA can classify as a minor use when issuing a permit and excluding certain enzyme products from regulation as agvet chemicals.

Consultation

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

The department developed a consultation paper that described these amendments and consulted the affected stakeholders (plant protection chemicals and veterinary medicines industries, farmers and other users). 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. These included ACCORD, Animal Medicines Australia, CropLife Australia, Grain Producers Australia and the Veterinary Manufacturers and Distributors Association. In response to these submissions, some 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 the measures set out in the Regulations.

The Office of Best Practice Regulation (OBPR) was consulted in the preparation of the Regulations (ID 25893 and 42543). In relation to the measure to change the definition of ‘minor use’, a COAG Regulation Impact Statement (RIS) was prepared in 2013 covering the change (OBPR decision ID 117025). Due to the size of the RIS and on the advice of the OBPR, the RIS is not attached but can be found online at obpr.pmc.gov.au/published-impact-analyses-and-reports/national-scheme-assessment-registration-and-control-use-0.

The OBPR advised a RIS was not required for the remaining amendments as they appear to have only minor economic and regulatory impact.

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 (that is, the Code Act) for the Regulations 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 Regulation to be made by the body or for the purposes of the body or scheme.

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*.

Details of the *Agricultural and Veterinary Chemicals Code Amendment (Miscellaneous Measures) Regulations 2021*

Section 1 – Name

This section provides that the name of the Regulations is the *Agricultural and Veterinary Chemicals Code Amendment (Miscellaneous Measures) 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 the whole of the Regulations will commence on the day after the Regulations are registered as an instrument.

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 Regulations are made under the *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 any other item in a Schedule to this instrument 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 to the *Agricultural and Veterinary Chemicals Code Regulations 1995*

Schedule 1 to the Regulations deals with three matters: a change to the definition of ‘minor use’; permitting the APVMA to develop a standard for the allowed differences for a constituent in a chemical product; and excluding a limited range of enzyme products from regulation as agvet chemicals.

Definition of ‘minor use’ – Items 1, 2 and 4 of Schedule 1 to these Regulations

Items 1, 2 and 4 of Schedule 1 to the Regulations amend the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Code Regulations) to prescribe a new definition of ‘minor use’. These amendments are discussed below.

Part 7 of the Agvet Code creates a framework which allows a person to obtain a permit from the APVMA to do something in respect of an active constituent for a proposed or existing chemical product, or in respect of a chemical product, that would otherwise be prohibited by the Agvet Code or another law. Regulation 57 of the Code Regulations allows for a permit to be issued for the use of the active constituent or chemical product, as proposed in the application for the issue of the permit, where such use is for a minor use. These minor use permits are the primary means to access a use of an active constituent or agvet chemical product where there is no commercial incentive for approval of the constituent, registration of the product or including a specific use in the registration of the product and therefore on the approved label (permitting a use that is not on the approved label is known as off-label use). Chemical access issues are most keenly felt in new and emerging industries where economic returns are insufficient to justify corporate investment. Chemical access issues also exist in major commodities, often as the result of an increase in pest resistance or smaller/infrequent pest emergence. Off-label use allows industry to quickly respond to an immediate need where a registered product use is not available.

Previously, the Code Regulations defined a ‘minor use’ as:

- in relation to a chemical product or an active constituent, a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose).

The ‘sufficient economic return’ test presents a significant barrier to those wanting a permit where the use is already registered (and therefore is a use that appears on a chemical product label) – this is usually taken as strong evidence that there is a sufficient economic return to register a chemical product for that use. This barrier is a deliberate feature of the minor use permit scheme and provides an incentive for holders to register chemical products and register specific minor uses of agvet chemical products so those uses can be included in the approved product label.

However, this existing framework for minor use permits did not address the circumstance where a use exists in one or more registered chemical products, but none of those registered chemical products is available for sale in Australia – as might arise from a supply chain disruption. If a similar registered chemical product was available but did not have the use registered and therefore included on its approved label, then users would likely not previously

have been able to access this through a minor use permit. Without such access, users could be left without suitable agvet chemical tools to support sustainable agriculture – with impacts on primary production, management of the environment, veterinary care (including animal health and welfare), trade, and the community.

In response to a 2017 Productivity Commission report, the Agriculture Senior Officials' Committee tasked the Agvet Chemical Task Group (subsequently called the Harmonised Agvet Chemical Control of Use Task Group (HACCUT)) to consider off-label use of agvet chemicals. At the 25 October 2019 Agriculture Ministers' Forum (AGMIN) meeting, after two rounds of public consultation (in November 2017 and August 2018), ministers agreed that changes were needed to the definition of 'minor use' in the Code Regulations to address where 'a lack of sufficient and suitable chemical options exists'.

Item 1 – Subregulation 3(1)

This item repeals the definition of 'minor use'. This amendment is consequential upon the insertion of the proposed new definition of 'minor use' as set out in item 2 of Schedule 1 to the Regulations.

Item 2 – After regulation 3

This item inserts regulation 3AA that contains two definitions of 'minor use' – the previous definition of 'minor use' (now in subregulation 3AA(1)) and an additional definition of 'minor use' in subregulation 3AA(2). The additional definition provides for a 'minor use' to include a use of the product where instructions for that use are in the Register of Agricultural and Veterinary Chemical Products (the Register) as kept by the APVMA in accordance with section 18 of the Agvet Code in relation to one or more registered chemical products and none of those registered chemical products is available for sale anywhere in Australia.

A minor use, for the purposes of seeking a permit, must meet *either* of the two definitions set out in subregulations 3AA(1) and (2) – it is not necessary for both definitions in both subregulations to apply to the minor use.

This additional definition in subregulation 3AA(2) does not include the 'sufficient economic return' test where there is already a registered use but the associated registered chemical products are not available for sale anywhere in Australia.

For example, there are 5 registered chemical products with an instruction for use that includes treating pineapples for mealy bugs. There are no other chemical products registered for use on pineapples to treat mealy bugs. If all 5 registered chemical products become unavailable for sale anywhere in Australia, then under the additional definition in subregulation 3AA(2), the APVMA will be able to issue a minor use permit to use a different registered (or unregistered) chemical product for use on pineapples to treat mealy bugs.

The existing requirements for a permit (particularly those under section 112 of the Agvet Code including safety criteria and fit and proper person tests) will all continue to apply.

Subsection 115(2) of the Agvet Code provides the APVMA with the ability to time limit any permit it issues. To ensure a minor use permit issued where there is a lack of sufficient and suitable agvet chemical options for sale in Australia does not undermine the registration of

any relevant chemical products, the APVMA will consider when the registered chemical product(s) will become available again and place an appropriate expiry date on the permit.

Item 4 – In the appropriate position in Part 10

This item inserts an application provision through regulation 91. This provision specifies regulation 3AA (the amended ‘minor use’ definition made by item 2) only applies in relation to applications made under section 110 (applications for permits) of the Agvet Code on or after the commencement of the regulation.

Supply etc. of substances with constituents differing from registered particulars – Item 3 of Schedule 1 to these Regulations

Item 3 of Schedule 1 to these Regulations replaces regulation 41 of the Code Regulations. These amendments are discussed below.

Due to manufacturing processes there can be variations in:

- the constituents contained in a chemical product (such as trace amounts of another constituent in the end product)
- the concentration of constituents in a chemical product
- the composition or purity of constituents in a chemical product.

These variations are often routine and reasonable, resulting only in minor differences which, in many cases, do not affect the safety or efficacy of the registered chemical product.

Section 83 of the Agvet Code provides that a person must not supply, or cause or permit to be supplied, a substance or mixture of substances in a container to which is attached a label containing a name of a registered chemical product if:

- the constituents of the substance or mixture differ by more than the prescribed extent from the constituents of the registered chemical product that were shown in the particulars of the registered chemical product contained in the Register (paragraph 83(1)(a)); or
- the concentration of the constituents of the substance or mixture differs by more than the prescribed extent from the concentration of the constituents of the registered chemical product that was shown in those particulars (paragraph 83(1)(b)); or
- the composition or purity of any constituent of the substance or mixture differs by more than the prescribed extent from the composition or purity of the corresponding constituent of the registered chemical product that was shown in those particulars (paragraph 83(1)(c)).

This, for example, allows for routine variations in constituent concentration arising in manufacturing to be prescribed.

Section 102 of the Agvet Code deals with the recall of registered chemical products in certain circumstances. Relevantly, paragraphs 102(1)(b)-(d) of the Agvet Code provide that if it appears to the APVMA that:

- the constituents of stocks of a registered chemical product or of a particular batch of a registered chemical product differ by more than the prescribed extent from the constituents stated in relation to the product in the Register (paragraph 102(1)(b)); or
- the concentration of the constituents of stocks of a registered chemical product or of a particular batch of a registered chemical product differs by more than the prescribed extent from the concentration of the constituents stated in relation to the product in the Register (paragraph 102(1)(c)); or
- the composition or purity of any constituent of stocks of a registered chemical product or of a particular batch of a registered chemical product differs by more than the prescribed extent from the composition or purity of that constituent stated in relation to the product in the Register (paragraph 102(1)(d)),

the APVMA may give written notice to any person who has, or has had, possession or custody of any of the stocks or of the batch, requiring that person to do any one or more of the things mentioned in subsection 102(2) of the Agvet Code, which includes not supplying or destroying any of such stocks or batch.

For the purposes of sections 83 and 102 of the Agvet Code, previous regulation 41 of the Code Regulations operated with regulation 42 of the Code Regulations to prescribe the extent to which some constituents (and the concentration, composition and purity of some constituents) of a registered chemical product can differ from the particulars for that product in the Register. Specifically:

- previous regulation 41 set out the following extents to which a constituent may differ from the registered particulars:
 - for the purpose of paragraphs 83(1)(a) and 102(1)(b) of the Agvet Code, in the case of an active constituent of a registered chemical product, the extent is nil; and
 - for the purposes of paragraphs 83(1)(b) and 102(1)(c) of the Agvet Code, for a constituent of a registered product that is an active constituent and in respect of which a standard is prescribed under section 87 of the Agvet Code, the extent (if any) of any variation of concentration is permitted by that standard.
- regulation 42 (which was not amended) sets out what the standards are (as authorised by section 87 of the Agvet Code), which allows for products to be required to conform to a standard).

The previous regulation 41, whilst providing for variations to the concentration of an active constituent, did not provide for differences in composition or purity of a constituent. Further, minor differences were only provided for in relation to the active constituent of a registered chemical product, and did not address the non-active constituents. The new regulation 41 addresses these gaps.

Item 3 – Regulation 41

This item repeals and substitutes regulation 41 of the Code Regulations. New regulation 41 provides that:

- for the purposes of paragraphs 83(1)(a) and 102(1)(b) of the Agvet Code, the prescribed extent is:
 - the extent to which a difference of constituents is permitted by the standards prescribed by regulation 42; or
 - if those standards do not permit a difference of constituents—nil;
- for the purposes of paragraphs 83(1)(b) and 102(1)(c) of the Agvet Code, the prescribed extent in relation to a constituent is:
 - the extent to which a difference of concentration of the constituent is:
 - (i) permitted by the standards prescribed by regulation 42 (including the standard set out in subregulation 42(4)); or
 - (ii) necessary because of a difference of concentration of another constituent; or
 - if those standards do not permit any such difference of concentration, and no difference is necessary as mentioned in subparagraph (a)(ii)—nil;
- for the purposes of paragraphs 83(1)(c) and 102(1)(d) of the Agvet Code, the prescribed extent is:
 - the extent to which a difference of composition or purity is permitted by the standards prescribed by regulation 42; or
 - if those standards do not permit a difference of composition or purity—nil.

The purpose of regulation 41 is to clarify that the APVMA may make a standard (through regulation 42 of the Code Regulations) in relation to the supply of substances with constituents differing from the registered particulars for the purposes of section 83 (supply of

a product with differing constituents) and 102 (recall of products in certain circumstances) of the Agvet Code. This includes the extent to which the constituents, concentration of any constituents, or composition and purity of any constituents of the registered chemical product can differ from the registered particulars – for both active and non-active constituents, which regulation 41 did not previously provide for.

Regulation 41 deals with 3 different situations:

- the constituents allowed in a registered chemical product; that is, the substances found in a product
- the concentration of constituents allowed in a registered chemical product; that is, the amount and proportion of substances in a product
- the composition or purity of any constituents in a registered chemical product; that is, the make up of the constituent and any trace amounts of contaminants in a product.

Regulation 41 does not allow for fundamental changes in a product's constituents, concentration, composition or purity. If the holder wishes to vary the product beyond the prescribed extent set out in an APVMA standard, this continues to require a variation application to the APVMA. The APVMA will develop standards in consultation with stakeholders.

Substances or mixtures declared to be veterinary chemical products – Item 5 of Schedule 1 to these Regulations

Item 5 amends clause 2 of Schedule 3AA (table item 3) of the Code Regulations. These amendments are discussed below.

Paragraph 5(4)(b) of the Agvet Code provides for the regulations to declare substances or mixtures of substances not to be a veterinary chemical product. Substances that are declared not to be a veterinary chemical product are not regulated by the APVMA. These substances are set out in the table at Part 3 of Schedule 3AA (declared not to be veterinary chemical products) to the Code Regulations.

Previously item 3 of the table in Division 3.1 of Part 3 of Schedule 3AA of the Code Regulations declared products containing defined nutritional or digestive ingredients (set out in Division 3.2 of Part 3 of Schedule 3AA of the Code Regulations) not to be veterinary chemical products. However, this was limited to when such products were for consumption by an animal (paragraph 4(1)(a) of Division 3.2 of Part 3 of Schedule 3AA of the Code Regulations). The same ingredients when used topically however, such as in certain animal cleaning products, did not fall within the definition of an excluded nutritional or digestive product.

There is a topical products exclusion in item 6 of the table in Division 3.1 of Part 3 of Schedule 3AA of the Code Regulations. This excludes any product applied topically to the teeth, hair, fur or intact skin of an animal to cosmetically alter the animal's appearance or odour. However, in the case of enzyme topical products there was a previous conflicting entry in the Code Regulations that declared certain substances or mixtures to be veterinary chemical products. Specifically, previous item 3 of the table in Part 2 of Schedule 3AA of the Code Regulations stipulated that enzymes administered to an animal by any means were declared to be veterinary chemical products, unless these were excluded nutritional or digestive products. As described above, the exemption for nutritional or digestive products was limited to when such products were for consumption by an animal – that is, it did not include topical use. This created a potential contradiction for certain topical enzyme products between the two declarations (of what is, and is not, a veterinary chemical product).

Item 5 – Clause 2 of Schedule 3AA (table item 3)

This item omits 'except excluded nutritional or digestive products', and substitutes 'except an enzyme that is an excluded nutritional or digestive product or that is a product covered by item 6 of the table in clause 3 of this Schedule' in table item 3 of Clause 2 of Schedule 3AA of the Code Regulations.

This substitution ensures enzyme products that are:

- excluded nutritional or digestive products or
- a product applied topically to the teeth, hair, fur or intact skin of an animal to cosmetically alter the animal's appearance or odour, that:
 - contains no antiseptic, antimicrobial, or antibiotic active constituent, and
 - is solely for cosmetic purposes; and
 - is not claimed to have any benefits other than cosmetic benefits; and
 - is not supplied or used for any therapeutic benefit other than to cosmetically alter the animal's appearance or odour

are not considered veterinary chemical products.

The low risks associated with these particular enzyme cleaning product uses can be sufficiently addressed under other laws controlling chemicals in Australia (such as the workplace safety, poisons scheduling, consumer protection, environment, food and public health laws) without need for additional specific controls under agvet chemical legislation.

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 Amendment (Miscellaneous Measures)
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 Code Regulations 1995* to improve access to agricultural and veterinary (agvet) chemicals. Access to safe agvet chemicals is vital for supporting sustainable agriculture – benefiting primary production, management of the environment, veterinary care (including animal health and welfare), trade, and the community. The instrument amends regulations made under the Code Act to:

- change the definition of ‘minor use’ to implement an agreed approach by Australia’s Commonwealth, state and territory agricultural ministers to improve the harmonisation of off-label access to agvet chemicals
 - off-label refers to a specific use of a registered chemical product which is not a use the product is registered for by the Australian Pesticides and Veterinary Medicines Authority (APVMA), and therefore does not appear on the product label. The APVMA approves an off-label use through a permit.
- provide for the APVMA to develop a standard setting out the allowed differences for constituents in a registered chemical product
- exclude a limited range of enzyme products from regulation as agvet chemicals.

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**