



# **Agricultural and Veterinary Chemicals Code (Prescribed Variations) Instrument 2019**

made under subsection 26B(6) of the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

## **Compilation No. 1**

**Compilation date:** 19 August 2020

**Includes amendments up to:** F2020L01027

Prepared by the Australian Pesticides and Veterinary Medicines Authority

## About this compilation

### This compilation

This is a compilation of the *Agricultural and Veterinary Chemicals Code (Prescribed Variations) Instrument 2019* that shows the text of the law as amended and in force on 19 August 2020 (the *compilation date*).

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

### Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register ([www.legislation.gov.au](http://www.legislation.gov.au)). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

### Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

### Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

### Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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## 1 Name

This instrument is the *Agricultural and Veterinary Chemicals Code (Prescribed Variations) Instrument 2019*.

## 2 Commencement

This instrument commences on the day after the day it is registered.

## 3 Authority

This instrument is made under subsection 26B(6) of the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

## 4 Definitions

(1) Unless the contrary intention appears:

- (a) words and expressions that are used in the Code have the same meaning in this Instrument; and
- (b) words and expressions that are used in the Regulations have the same meaning in this Instrument.

(2) In this Instrument:

**Code** means the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

**Primary steps of manufacture** means all steps in the manufacturing process that result in direct contact with the veterinary chemical product.

**Regulations** means the *Agricultural and Veterinary Chemicals Code Regulations 1995* and a reference to subregulations has a corresponding meaning.

**Secondary steps of manufacture** means labelling or relabelling or secondary/supplementary labelling; secondary packaging; storage; release for supply; analysis and testing; or manufacturing steps that do not result in direct contact with the veterinary chemical product released to market.

## 5 Prescribed variations

The following table prescribes, for the purposes of paragraph 26B(4)(a) of the Code, prescribed variations of the relevant particulars that are listed in an item in the table, for the registrations listed in the table for that item.

<b>Prescribed variations</b>
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Item	Prescribed variation of relevant particular	Registration
1	<p>A variation of either or both of the following particulars:</p> <ul style="list-style-type: none"> <li>(a) the name of a manufacturer of a chemical product in Australia;</li> <li>(b) the address of each site in Australia at which the chemical product is manufactured by a manufacturer;</li> </ul> <p>but only if, under the varied particulars:</p> <ul style="list-style-type: none"> <li>(c) the manufacturer and the address of each manufacturing site are in Australia; and either: <ul style="list-style-type: none"> <li>(a) the manufacturer is the holder of a valid licence under Part 8 of the Code that authorises carrying out a step in the manufacture of the chemical product at premises at the site; or</li> <li>(b) the manufacturer is an exempt person as mentioned in paragraph 121(4)(a) of the Code in relation to the manufacture of the chemical product</li> </ul> </li> </ul>	<p>any registration of a chemical product other than a chemical product that is prescribed under subregulation 59(1)</p>
2	<p>A variation of either or both of the following particulars:</p> <ul style="list-style-type: none"> <li>(a) the name of a manufacturer of a chemical product outside Australia;</li> <li>(b) the address of each site outside Australia at which the chemical product is manufactured by a manufacturer that conducts secondary steps of manufacture (excluding the step of a biological assay for an immunobiological product) in relation to the chemical product, but only if, under the varied particulars: <ul style="list-style-type: none"> <li>(i) the holder of the registration of the chemical product possesses evidence that each step in the manufacture of the chemical product by the manufacturer at the site of manufacture</li> </ul> </li> </ul>	<p>a registration of a chemical product, other than a chemical product that is prescribed under subregulation 59(1)</p>

Prescribed variations		
Item	Prescribed variation of relevant particular	Registration
	conforms to a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code	
3	<p>A variation of either or both of the following particulars:</p> <p>(a) the name of a manufacturer of a chemical product outside Australia;</p> <p>(b) the address of each site outside Australia at which the chemical product is manufactured by a manufacturer that conducts primary steps of manufacture in relation to the chemical product, but only if, under the varied particulars:</p> <p>(i) at the time of the holder's application, the site of manufacture is entered in the Register as a site for another chemical product of the holder, and the manufacturer conducts the same steps of manufacture in relation to the other chemical product; and</p> <p>(ii) the holder of the registration of the chemical product possesses evidence that each step in the manufacture of the chemical product by the manufacturer at the site of manufacture conforms to a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code</p>	<p>a registration of a chemical product, other than</p> <p>(a) a chemical product that is prescribed under subregulation 59(1); or</p> <p>(b) an immunobiological product</p>
4	<p>A variation of one or more constituents of a chemical product if:</p> <p>(a) the constituent (the <b>original constituent</b>) is replaced with another constituent (the <b>replacement constituent</b>); and</p> <p>(b) the original constituent is not an active</p>	<p>a registration of a chemical product, other than a chemical product that is:</p> <p>(a) an antibiotic product; or</p> <p>(b) an immunobiological product; or</p> <p>(c) a product that is administered through direct injection into an animal</p>

<b>Prescribed variations</b>		
<b>Item</b>	<b>Prescribed variation of relevant particular</b>	<b>Registration</b>
	<p>constituent of the product; and</p> <p>(c) the replacement constituent will not be an active constituent of the product; and</p> <p>(d) the original and replacement constituents have the same purpose in the product; and</p> <p>(e) the original and replacement constituents differ only in solvates or hydrates; and</p> <p>(f) the original and replacement constituents have the same:</p> <ul style="list-style-type: none"> <li>(i) pH; and</li> <li>(ii) dissolution profile; and</li> <li>(iii) hydrophilic or hydrophobic behaviour; and</li> <li>(iv) hygroscopic behaviour; and</li> </ul> <p>(g) neither the original nor replacement constituent are a nanomaterial; and</p> <p>(h) in the case of the original and replacement constituents being a straight or branched unsaturated hydrocarbon—the change in the length of the hydrocarbon chain is not more than 33% of the length of the original constituent’s hydrocarbon chain; and</p> <p>(i) the replacement constituent does not introduce material of human or animal origin into the product; and</p> <p>(j) the variation does not require variation to the signal words required by the current Poisons Standard to be on the label of the product; and</p> <p>(k) in the case of a product that is a molluscicide in the form of a bait or a product applied to seeds to be stored before planting or sowing—the variation does not change the colour of the product; and</p> <p>(l) the variation does not require the formulation type entered in the Register for the product to be varied; and</p> <p>(m) in the case of a product that has 9 or more constituents entered in the Register for the product—the variation is to no more than 25% of the number of constituents entered in the Register for the product; and</p> <p>(n) in the case of a product that has less than 9 constituents entered in the Register for the product—the variation is to one or 2 of the</p>	

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<b>Prescribed variations</b>		
<b>Item</b>	<b>Prescribed variation of relevant particular</b>	<b>Registration</b>
	constituents entered in the Register for the product	

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## **Endnotes**

### **Endnote 1—About the endnotes**

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

### **Abbreviation key—Endnote 2**

The abbreviation key sets out abbreviations that may be used in the endnotes.

### **Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

### **Misdescribed amendments**

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

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## Endnote 2—Abbreviation key

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
exp = expires/expired or ceases/ceased to have effect	renum = renumbered
F = Federal Register of Legislation	rep = repealed
gaz = gazette	rs = repealed and substituted
LA = <i>Legislation Act 2003</i>	s = section(s)/subsection(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sch = Schedule(s)
(md) = misdescribed amendment can be given effect	Sdiv = Subdivision(s)
(md not incorp) = misdescribed amendment cannot be given effect	SLI = Select Legislative Instrument
mod = modified/modification	SR = Statutory Rules
No. = Number(s)	Sub-Ch = Sub-Chapter(s)
	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

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### Endnote 3—Legislation history

<b>Name</b>	<b>Registration</b>	<b>Commencement</b>	<b>Application, saving and transitional provisions</b>
F2020L01027	18 August 2020	19 August 2020	-

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## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
Section 4.....	F2020L01027
Section 5.....	F2020L01027