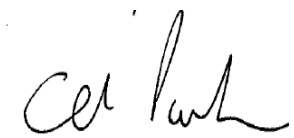
Agricultural and Veterinary Chemicals Code (Prescribed Variations) Amendment Instrument 2020

I, Chris Parker, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, make the following legislative instrument.

Dated 13/08/2020



Chris Parker
Chief Executive Officer

Contents

1 Name

This instrument is the *Agricultural and Veterinary Chemicals Code (Prescribed Variations) Amendment Instrument 2020*.

2 Commencement

(1) Each provision of this instrument 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.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	*The day after this instrument is registered*	*Leave blank unless a date is stated in column 2 In that case, insert the date here also.*

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) 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.

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 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Agricultural and Veterinary Chemicals Code (Prescribed Variations) Instrument 2019

1 Section 4

Repeal the section, substitute:

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.

2 Section 5

Repeal the section, substitute:

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.

Prescribed variations		
Item	**Prescribed variation of relevant particular**	**Registration**

Prescribed variations		
Item	**Prescribed variation of relevant particular**	**Registration**
1	A variation of either or both of the following particulars: (a) the name of a manufacturer of a chemical product in Australia; (b) the address of each site in Australia at which the chemical product is manufactured by a manufacturer; but only if, under the varied particulars: (c) the manufacturer and the address of each manufacturing site are in Australia; and either: (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 (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	any registration of a chemical product other than a chemical product that is prescribed under subregulation 59(1)
2	A variation of either or both of the following particulars: (a) the name of a manufacturer of a chemical product outside Australia; (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: (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 conforms to a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code	a registration of a chemical product, other than a chemical product that is prescribed under subregulation 59(1)

Prescribed variations		
Item	**Prescribed variation of relevant particular**	**Registration**
3	A variation of either or both of the following particulars: (a) the name of a manufacturer of a chemical product outside Australia; (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: (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 (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	a registration of a chemical product, other than (a) a chemical product that is prescribed under subregulation 59(1); or (b) an immunobiological product
4	A variation of one or more constituents of a chemical product if: (a) the constituent (the ***original constituent***) is replaced with another constituent (the ***replacement constituent***); and (b) the original constituent is not an active constituent of the product; and (c) the replacement constituent will not be an active constituent of the product; and (d) the original and replacement constituents have the same purpose in the product; and (e) the original and replacement constituents differ only in solvates or hydrates; and (f) the original and replacement constituents have the same: (i) pH; and (ii) dissolution profile; and	a registration of a chemical product, other than a chemical product that is: (a) an antibiotic product; or (b) an immunobiological product; or (c) a product that is administered through direct injection into an animal

Prescribed variations		
Item	**Prescribed variation of relevant particular**	**Registration**
	(iii) hydrophilic or hydrophobic behaviour; and (iv) hygroscopic behaviour; and (g) neither the original nor replacement constituent are a nanomaterial; and (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 (i) the replacement constituent does not introduce material of human or animal origin into the product; and (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 (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 (l) the variation does not require the formulation type entered in the Register for the product to be varied; and (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 (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 constituents entered in the Register for the product	