Agricultural and Veterinary Chemicals Code (Prescribed Variations) Instrument 2019

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

Dated 22 March 2019

Chris Parker
Chief Executive Officer

Contents

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

Note: A number of expressions used in this instrument are defined Part 1, Division 1 of the Code, including the following:

(a) active constituent;
(b) chemical product;
(c) manufacture
(d) notifiable variation;
(e) Register;
(f) variations.

In this instrument:

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

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

5 Prescribed variations

The following table prescribes, as prescribed variations for the purposes of paragraph 26B(4)(a) of the Code, 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
1	A variation of either or both of the following particulars: (a) the name of a manufacturer in Australia of a chemical product; (b) the address of each site in Australia at which the 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 (d) either: (i) 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 product at premises at a site mentioned in paragraph (b); or (ii) the manufacturer is an exempt person as mentioned in paragraph 121(4)(a) of the Code in relation to the manufacture of the product	any registration of a chemical product other than a chemical product that is prescribed under subregulation 59(1)
2	A variation of the name of a manufacturer of a chemical product, if the manufacturer is outside Australia	any registration of a chemical product other than a chemical product that is prescribed under subregulation 59(1)
3	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	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**
	(ii) dissolution profile; and (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	