

Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2019

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

Dated 21 March 2019

Chris Parker

Chief Executive Officer

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1 Name

 This instrument is the *Agricultural and Veterinary Chemicals Code (Notifiable 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 26AB(5) 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 in Part 1, Division 1 of the Code, including the following:

(a) active constituent;

(b) agricultural chemical product;

(c) chemical product;

(d) instruction;

(e) notifiable variation;

(f) Register;

(g) relevant particulars;

(h) variations;

(i) veterinary chemical product.

 In this instrument:

***Agricultural Labelling Code*** means the *Agricultural Labelling Code* made by the APVMA, as in force from time to time.

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

***FAISD Handbook*** means the document entitled *Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals*, published by the Office of Chemical Safety in the Therapeutic Goods Administration of the Department of Health, as in force from time to time.

***interchangeable constituent determination*** means that term as defined in the Regulations.

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

***Veterinary Labelling Code*** means the *Veterinary Labelling Code* made by the APVMA, as in force from time to time.

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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

6 Notifiable variations

 (1) The following table determines, as notifiable variations for the purposes of subparagraph 26AB(3)(a)(i) of the Code, variations of the relevant particulars that are listed in an item in the table, for approvals or registrations listed in the table for that item.

| Notifiable variations |
| --- |
| Item | Notifiable variation of relevant particular | Approval or registration |
| 1 | A variation of the name of the manufacturer of an active constituent for a chemical product | any approval of an active constituent |
| 2 | A variation of the distinguishing name of a chemical product | any registration of a chemical product |
| 3 | A variation of the net contents of an agricultural chemical product, but only if:(a) the variation will not result in the instructions for use, or disposal, of the product or containers for the products, being modified or affected; and | any registration of an agricultural chemical product |
|  | (b) the net contents is in the range recorded in the Register for the product |  |
| 4 | A variation of the instructions for a use of a chemical product if:(a) the variation is to remove the use of the chemical product from the instructions; and(b) the variation of the instructions will not otherwise modify or affect the instructions for another use of the product | any registration of a chemical product |
| 5 | A variation of either or both of the following particulars:(a) the name of a manufacturer of a chemical product;(b) the address of each site at which the product is manufactured by a manufacturer | any registration of a chemical product that is prescribed under subregulation 59(1) |
| 6 | A variation of an approved label as a result of a notifiable variation mentioned in items 3 and 4, but only if a label for the chemical product as varied would not include any misleading or deceptive information about the use, safety, environmental impact or efficacy of the chemical product | any approval of a label for containers of chemical products |
| 7 | A variation of the name of a chemical product that is to appear on an approved label as mentioned in paragraph 17(1)(b) of the Regulations, but only if a label for the chemical product as varied would not include any misleading or deceptive information about the use, safety, environmental impact or efficacy of the chemical product | any approval of a label for containers of chemical products |
| 8 | A variation of one or more constituents of a chemical product if:(a) the variation is to replace one or more constituents with a constituent or constituents listed for the product in an interchangeable constituent determination; and(b) 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(c) 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 | any registration of a chemical product |
| 9 | A variation to the address of a site at which the approved active constituent is manufactured by the manufacturer if there is no physical change of location | any approval of an active constituent |
| 10 | A variation to the name of any other registered products referred to within the instructions for use on the label (provided the referred to product has the same APVMA distinguishing number). This item includes a variation of an approved label but only if a label for the chemical product as varied would not include any misleading or deceptive information about the use, safety, environmental impact or efficacy of the chemical product | any registration of a chemical product; approval of a label for containers of a chemical product |
| 11 | A variation to the instructions for storage and disposal of containers of products, in line with the relevant requirements for the type of container as specified in the Agricultural Labelling Code or Veterinary Labelling Code made by the APVMA. But only if the variation will not result in other instructions for use being modified or affected. This item includes a variation of an approved label but only if a label for the chemical product as varied would not include any misleading or deceptive information about the use, safety, environmental impact or efficacy of the chemical product | any registration of a chemical product; approval of a label for containers of a chemical product |
| 12 | A variation to safety directions and first aid instructions appearing on a label to reflect the current FAISD Handbook. This item includes a variation of an approved label but only if a label for the chemical product as varied would not include any misleading or deceptive information about the use, safety, environmental impact or efficacy of the chemical product | any registration of a chemical product; approval of a label for containers of a chemical product |
| 13 | A variation of the net contents of a veterinary chemical product but only if:(a) the variation will not result in the instructions for use, or disposal, of the product or containers for the product, being modified or affected; and(b) the net contents is in the range recorded in the Register for the product.This item includes a variation of an approved label but only if a label for the chemical product as varied would not include any misleading or deceptive information about the use, safety, environmental impact or efficacy of the chemical product | any registration of a veterinary chemical product;approval of a label for containers of a chemical product |

             (2)  However, a variation listed in item 3 or 4 of the table is only a notifiable variation for a product listed in the item if, at the time the notice for the notifiable variation is lodged, notice is also lodged for a notifiable variation listed in item 6 of the table for any approved label for the product.

Schedule 1

Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2016

1 The whole of the instrument

Repeal the instrument.