



Agricultural and Veterinary Chemicals Code (Application Requirements) 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

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1 Name

This instrument is the *Agricultural and Veterinary Chemicals Code (Application Requirements) 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. <i>The whole of this instrument</i>	<i>The day after this instrument is registered</i>	<i>Leave blank unless a date is stated in column 2 In that case, insert the date here also.</i>

Note: This table relates only to the provisions of this instrument as originally made.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 8B(1) 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Application Requirements) Instrument 2014

1 Section 35B

Repeal the section, substitute:

35B Application requirements for prescribed variations

- (1) This section specifies, for subsection 8B(1) of the Code, that an application for a prescribed variation of the kind set out in item 2 of the table in the *Agricultural and Veterinary Chemicals Code Act (Prescribed Variations) Instrument 2019* must include a statement that the applicant holds:
- (a) evidence that each secondary 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
- (2) This section specifies, for subsection 8B(1) of the Code, that an application for a prescribed variation of the kind set out in item 3 of the table in the *Agricultural and Veterinary Chemicals Code Act (Prescribed Variations) Instrument 2019* must include a statement that the applicant holds:
- (a) evidence that 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
 - (b) evidence that each primary 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
- (3) This section specifies, for subsection 8B(1) of the Code, that an application for a prescribed variation of the kind set out in item 4 of the table in the *Agricultural and Veterinary Chemicals Code Act (Prescribed Variations) Instrument 2019* must include a statement that the applicant holds:
- (a) evidence that the physical properties and storage stability of the product, as varied and relevant to the product's formulation type or dosage form, are the same as the product's existing physical properties and storage stability, when measured using the same methodology used for the product before being varied; and
 - (b) if the application relates to a veterinary chemical product—the following evidence about the product, as varied:
 - (i) a dissolution profile (if relevant) of at least 2 pilot scale batches that is comparable to the formulation of the product immediately before the application is made;

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- (ii) at least 3 consecutive months of data on the storage stability of the product.