



Agricultural and Veterinary Chemicals Code (Application Requirements) Amendment 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 (Application Requirements) Amendment Instrument 2019*.

2 Commencement

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

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Agricultural and Veterinary Chemicals Code (Application Requirements) Instrument 2014

1 After section 35

Insert:

Part 4A—Requirements for applications for prescribed variations

35A Application of this Part

This Part applies to applications for one or more prescribed variations of the relevant particulars of an approval or registration made under section 26B of the Code.

35B Application requirements for prescribed variations

This section specifies, for subsection 8B(1) of the Code, 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 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;
 - (ii) at least 3 consecutive months of data on the storage stability of the product.