



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

**Agricultural and Veterinary Chemicals
Code Instrument No. 1 (Application Fees)
2010**

I, Eva Bennet-Jenkins, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 32(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, make this instrument for the purposes of subsection 164(1A) of the Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Eva Bennet-Jenkins
Chief Executive Officer

Dated this fifteenth day of July 2010

Part 1 Preliminary

1 Name of Instrument

This Instrument is the *Agricultural and Veterinary Chemicals Code Instrument No. 1 (Application Fees) 2010*.

2 Commencement

This Instrument commences on the day after it is registered.

3 Object

The object of this Instrument is to set out criteria which more fully describe some of the 25 items in Part 2 of Schedule 6 to the *Agricultural and Veterinary Chemicals Code Regulations 1995*. A more detailed description of the items will allow applicants to work out which fee applies to a particular application.

4 Interpretation

- (1) Unless the contrary intention appears, an expression used in the Agvet Code Act or the Agvet Regulations and in this Instrument has the same meaning in this Instrument as in the Agvet Code Act or the Agvet Regulations.

- (2) In this Instrument, unless the contrary intention appears:

Category in relation to an application means an item in Column 1 of Part 2 of Schedule 6 of the Agvet Regulations.

multiple application means an application to vary the particulars or conditions of registration or label approval where the variation is to allow a minor label change (whether or not data of a technical nature is required) and the same type of variation is requested by the same applicant in respect of more than one chemical product.

new active constituent means an active constituent that, at the time an application in respect of that active constituent is lodged with the APVMA, has not been approved.

new chemical product means a chemical product that, at the time an application in respect of that chemical product is lodged with the APVMA, has not been registered.

Part 2

Repeal

5 Repeal of Instrument

The *Agricultural and Veterinary Chemicals Code Instrument No. 1 (Application Fees) 2005* is repealed.

Part 3

Criteria for Working out which Application Category Applies

6 Category 1

- (1) A Category 1 application includes only applications for agricultural chemical products for use on food-crops where the new active constituent in the agricultural chemical product is synthetic or is semi-synthetic or is highly purified or is produced by genetic engineering.
- (2) In the context of a Category 1 application, a **full assessment** means that to grant the application the APVMA must undertake an assessment of the application that is equivalent to the following Schedule 7 modules — 1, 2.1, 3.1, 4, 5.1, 6.1, 7.1, 8.1, 11.1, and 12.

7 Category 2

A Category 2 application includes applications for:

- (a) agricultural chemical products where the active constituent is a commonly used household or industrial chemical with a history of safe use; or
- (b) veterinary chemical products.

8 Category 3

In the context of a Category 3 application, a **full assessment** means that to grant the application the APVMA must undertake an assessment of the application that is equivalent to the following Schedule 7 modules — 1, 2.3, 3.3, 4, 5.1, 6.1, 7.1, 8.1, 11.1, and 12.

9 Category 11

A Category 11 application does not include an application to vary the particulars or conditions of registration where the variation is an extension of use of a chemical product from a non-food-producing use to a food-producing use for the first time for any chemical product containing the active constituent which the chemical product contains.

10 Category 12

A Category 12 application does not include a multiple application.

11 Category 14

A Category 14 application includes multiple applications. The modular assessment fee for multiple applications is to apply in the manner described in subsections 17 (2) and (3) of the *Agricultural and Veterinary Chemicals Code Instrument No. 2 (Modular Assessment Fees) 2010*.

12 Category 15

In the context of a Category 15 application, a *full assessment* means that to grant the application the APVMA must undertake an assessment of the application that is equivalent to either of the following Schedule 7 modules — 2.1 and 3.1; or 2.1 and 3.2.

13 Category 17

A Category 17 application includes an application for a new source of manufacture for the active constituent that is the subject of the application.

14 Category 18

Category 18 applies to applications to vary the particulars or conditions of an approved active constituent where a chemistry assessment is the only assessment required. Variations to the particulars or conditions of approval of biological active constituents (which also involve efficacy and safety assessment, at least) are not included in this Category.

15 Category 20

In the context of a Category 20 application, a previous assessment would remain valid where the application is for the purposes of extending or renewing the duration of a permit.

16 Category 25

A Category 25 application includes an application for assessment of a trial protocol.

Part 4

Fees

17 Fees

Subregulation 70 (2) of the *Agricultural and Veterinary Chemicals Code Regulations 1995* provides that the fee payable in respect of an application of a kind specified in Column 2 of an item in Part 2 of Schedule 6 of the Regulations is the fee (if any) specified for the item in Column 4 of that Schedule.