



Agricultural and Veterinary Chemicals Code (Pre-application Assistance Fee) Instrument 2015

Agricultural and Veterinary Chemicals Code Act 1994

I, Kareena Arthy, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, make this Instrument under subsection 164(1A) of the Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Kareena Arthy
Chief Executive Officer

Dated this 2 November 2015

(a) Name of Instrument

This Instrument is the *Agricultural and Veterinary Chemicals Code (Pre-application Assistance Fee) Instrument 2015*.

(b) Commencement

This Instrument commences on the day after it is registered.

(c) Revocation and transitional arrangements

- (1) This Instrument revokes the *Agricultural and Veterinary Chemicals Code Regulations (Pre-application Assistance Fee) Instrument 2014 (the 2014 Instrument)*.
- (2) However, the 2014 Instrument continues to apply, and this Instrument does not apply, to applications for pre-application assistance made before the commencement of this Instrument.

4 Overview

This Instrument sets out the criteria for working out which pre-application assistance fee applies under the *Agricultural and Veterinary Chemicals Code Regulations 1995 (the Regulations)* in a particular case.

Subregulation 69B(3) of the Regulations prescribes the fee of \$192.50 (GST inclusive) for one unit, or a part of one unit, that is payable in respect of pre-application assistance provided by the APVMA under regulation 8AT.

Subregulation 69B(4) provides that a 2-unit fee is payable in all cases; additional units attract fees pursuant to subregulation 69B(5). This Instrument sets out the criteria for working out which fees apply in a particular case.

5 Pre-application assistance

The following table sets out the criteria for working out which pre-application assistance fee applies under regulation 69B of the Regulations in a particular case. Each application will fall within a tier and will include one or more elements of assistance. The fee is worked out by working out which tier applies to the application and which elements of assistance are involved.

Pre-application assistance tier	Elements of assistance	Fee under the Regulations
Tier 1	Administration by the APVMA	The 1-unit fee (\$192.50)
	Preparation of a written response to the application, including research	The 2-unit fee (\$385)

	Meeting between the applicant and the APVMA	The 2-unit fee (\$385)
Tier 2	Administration by the APVMA	The 1-unit fee (\$192.50)
	Preparation of a written response to the application, including research	The 4-unit fee (\$770)
	Meeting between the applicant and the APVMA	The 2-unit fee (\$385)
Tier 3	Administration by the APVMA	The 1-unit fee (\$192.50)
	Preparation of a written response to the application, including analysis	The 6-unit fee (\$1,155), per module type*. If the assistance involves more than one module type, more than one 6-unit fee applies.
	Meeting between the applicant and the APVMA	The 2-unit fee (\$385)

* A **module type** is a type of module set out in one of items 2 to 10 of Schedule 7 to the Regulations.

Where:

- (a) **Tier 1 pre-application assistance** is for applicants seeking guidance in the early stages of preparing for the making of an application. It is to assist applicants in clarifying the types of regulatory assessments likely to be conducted for a particular submission to inform that applicant in collating relevant information and data likely to be necessary.
- (b) **Tier 2 pre-application assistance** includes all the aspects of Tier 1 with further provision for applicants who are seeking guidance in matters relating to the types of information and data that may be appropriate in a particular submission.
- (c) **Tier 3 pre-application assistance** includes all the aspects of Tier 1 and Tier 2 with further provision for applicants seeking appraisal of the specifics of conducting studies and finalisation of project plans for Global Joint Reviews.

Examples of the application of the above criteria to particular cases:

- (a) The 3-unit fee of \$577.50 applies for the provision of Tier 1 pre-application assistance consisting of administration and a written response.
- (b) The 5-unit fee of \$962.50 applies for the provision of Tier 2 pre-application assistance consisting of administration and a written response.
- (c) The 7-unit fee of \$1,347.50 applies for the provision of Tier 2 pre-application assistance consisting of administration, a written response and a meeting.

- (d) The 9-unit fee of \$1,732.50 applies for the provision of Tier 3 pre-application assistance consisting of administration, 1 module type (e.g. efficacy and safety) and a meeting.
- (d) The 13-unit fee of \$2,502.50 applies for the provision of Tier 3 pre-application assistance consisting of administration, 2 module types (e.g. efficacy and safety, and residues) and no meeting.