

## EXPLANATORY STATEMENT

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

The *Agricultural and Veterinary Chemicals Code Act 1994* (Act) provides, within a Code set out in the Schedule to the Act (Agvet Code), a regulatory scheme for agricultural and veterinary chemicals.

If a person makes an application to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for assistance (pre-application assistance) in preparing or making an application to the APVMA under the Agvet Code or the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Regulations), the APVMA may provide the pre-application assistance: regulation 8AT of the Agvet Regulations.

The Agvet Regulations may prescribe the fees to be paid in respect of the doing of any thing by the APVMA under the Agvet Code or the Agvet Regulations: subsection 164(1) of the Agvet Code. Regulation 69B of the Agvet Regulations provides for the fees payable in respect of pre-application assistance provided by the APVMA under regulation 8AT. In particular, subregulation 69B(3) of the Agvet 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.

The APVMA may make a legislative instrument setting out criteria for working out which fee applies under the Agvet Regulations in a particular case: subsection 164(1A) of the Agvet Code. This instrument, the *Agricultural and Veterinary Chemicals Code (Pre-application Assistance Fee) Instrument 2015* (Instrument), is made under subsection 164(1A).

The Instrument revokes the *Agricultural and Veterinary Chemicals Code Regulations (Pre-application Assistance Fee) Instrument 2014* (2014 Instrument) in respect of applications for pre-application assistance made on and after the commencement of the Instrument. The 2014 Instrument continues to apply in respect of applications for pre-application assistance made before the commencement of this Instrument.

The new Instrument sets out, in a table, the criteria for working out which unit-based fee applies under the Agvet Regulations in a particular case. It also provides examples of the application of the criteria in particular cases. The fee that applies in a particular case depends, in part, on whether Tier 1, Tier 2 or Tier 3 pre-application assistance is provided by the APVMA.

#### ***Tier 1 pre-application assistance***

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. It aims to provide assistance to applicants in:

- a) the types of regulatory assessments that may be likely to be conducted in a particular application as it relates to the item, module levels, timeframes and fees for assessment.

- b) relevance of the efficacy criteria.
- c) clarification of guidance documents available on the APVMA website.

Tier 1 pre-application assistance **DOES NOT provide assistance** on specific aspects of information or data that may be contained in a submission. Technical assistance in the relevance of particular studies, study design and generating data are provided by Tiers 2 and 3 as described below.

### *Tier 2 pre-application assistance*

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. It aims to provide assistance to applicants on:

- a) the types of supporting information and data that may be appropriate in a particular application.
- b) the types of trials that may be undertaken, including specific guidelines that could be considered in generating data.
- c) the relevance or suitability of overseas data and/or assessment reports.
- d) a scientific matter relevant to a specific application.
- e) a specific aspect of the conduct and design of a study.
- f) development of an agreed project plan for a timeshift application (including Global Joint Review applications).

### *Tier 3 pre-application assistance*

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. It aims to provide assistance to applicants on:

- a) appraisal of a trial protocol(s) before commencement of studies.
- b) a proposed new methodology or variations to an existing guideline in generating data to support an application.
- c) finalisation of project plans for Global Joint Reviews.

**Regulatory impact**

No Regulatory Impact Statement has been prepared for the Instrument. The Office of Best Practice Regulations was consulted about this Instrument and has advised that no further analysis (in the form of a Regulatory Impact Statement) is required (OBPR ID: 19488).

**Public consultation**

This Instrument was released as a draft for consultation on the APVMA website. Public consultation was sought from 7 September 2015 to 28 September 2015. Industry and community stakeholder groups were informed of the release. Comments provided with respect to the content of the Instrument were taken into account in finalising the Instrument.

## **STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

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

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of the Legislative Instrument**

The purpose of this Instrument is to:

- (a) revoke the *Agricultural and Veterinary Chemicals Code Regulations (Pre-application Assistance Fee) Instrument 2014* – which does not engage any of the applicable rights of freedoms – in respect of applications for pre-application assistance made before the commencement of this Legislative Instrument; and
- (b) set out the criteria for working out which pre-application assistance fee applies under the *Agricultural and Veterinary Chemicals Code Regulations 1995* in a particular case.

#### **Human rights implications.**

The Instrument does not engage any of the applicable rights or freedoms.

#### **Conclusion**

The Instrument is compatible with human rights as it does not raise any human rights issues.