



## **Agricultural and Veterinary Chemicals Code (Prescribed Relevant Particulars) Instrument 2014**

### *Agricultural and Veterinary Chemicals Code*

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I, Kareena Arthy, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, make this Instrument for the purposes of sections 8B and 26B of the Agricultural and Veterinary Chemicals Code, scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Dated [date]

**V1**

**DRAFT**

**13 June 2014**

Kareena Arthy

Chief Executive Officer

# Part 1 Preliminary

## 1 Name of Instrument

This Instrument is the *Agricultural and Veterinary Chemicals Code (Prescribed Relevant Particulars) Instrument 2014*.

## 2 Commencement

This Instrument commences on the commencement of Schedule 1 to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.

## 3 Overview

- (1) This Instrument does 2 things.
- (2) First, in Part 2, the Instrument sets out certain kinds of relevant particulars of approvals of active constituents, registrations of chemical products and approvals of labels. These kinds of relevant particulars are, by reason of Part 2, ‘prescribed relevant particulars’ for the purposes of the Agricultural and Veterinary Chemicals Code. Applications can be made for their variation in accordance with Division 2A of Part 2 of the Code.
- (3) Second, in Part 3, the Instrument specifies the information that must be contained in, or accompany, applications for the variation of prescribed relevant particulars under Division 2A of Part 2 of the Code.
- (4) In the first respect, the Instrument is made for the purposes of section 26B of the Code. In the second respect, the Instrument is made for the purposes of section 8B of the Code.

## Part 2 The prescribed relevant particulars

Note: This Part is made for the purposes of section 26B of the Code.

### 5 Prescribed relevant particulars

- (1) The following kinds of relevant particulars are set out for the purposes of section 26B of the Code:
- (a) the name of the holder of an approval or registration;
  - (b) the name of a manufacturer of an active constituent;
  - (c) the distinguishing name of a chemical product;
  - (d) a relevant particular in relation to the approval of a label, but only if:
    - (i) the variation of that particular for which an application is made under subsection 26B(1) of the Code (the *label variation*) is necessary to give effect to a variation of a relevant particular in relation to the registration of a chemical product (the *product variation*); and
    - (ii) the product variation is of a kind set out by another paragraph of this subsection;
  - (e) the net contents of an agricultural chemical product, but only if:
    - (i) the variation of that particular for which an application is made under subsection 26B(1) of the Code will not result in the instructions for use, or disposal, of the product or containers for the products, being modified or affected; and
    - (ii) the net contents, as varied, is in the range recorded in the Register for the product;
  - (f) the name of a manufacturer, or the addresses of 1 or more sites of manufacture, or both, of a chemical product of a kind prescribed by subregulation 59(1) of the *Agricultural and Veterinary Chemicals Code Regulations 1995*;
  - (g) the name of a manufacturer, or the addresses of 1 or more sites of manufacture in Australia, or both, of a chemical product.
- (2) Paragraphs #(1)(c) and (e) apply only if, at the time the relevant application is made under subsection 26B(1) of the Code, an application is also made for a variation in relation to the approved labels for the chemical product.

## **Part 3 Information contained in, or accompanying, applications**

Note: This Part is made under section 8B of the Code. It is not the only Instrument under section 8B. Other instruments deal with other kinds of applications.

### **6 Information contained in, or accompanying, applications**

- (1) An application under subsection 26B(1) of the Code must contain, or be accompanied by:
- (a) the following information about the applicant:
    - (a) the name of the applicant;
    - (b) if the applicant has an ACN – the ACN;
    - (c) if the applicant is an overseas company and has a number equivalent to an ACN – that number;
    - (d) if the applicant is not an individual – the name of an individual whom the APVMA may contact in relation to the application;
    - (e) the telephone number of the applicant;
    - (f) the facsimile number of the applicant;
    - (g) the street address of the applicant;
    - (h) the postal address of the applicant; and
  - (b) a declaration, made by or on behalf of the applicant, that the information contained in, and accompanying, an application is complete and correct (except that if the particular approved form for the application sets out an alternative form of words for the declaration, the declaration is to use that form of words); and
  - (c) if the application relates to a registered chemical product—the name and distinguishing number of the product; and
  - (d) the details of the proposed variation of the prescribed relevant particular; and
  - (e) for a variation of the net contents of an agricultural chemical product—a declaration that:
    - (i) the variation will not result in the instructions for use, or disposal, of the product or containers for the products, being modified or affected; and
    - (ii) the net contents, as varied, is in the range recorded in the Register for the product; and
  - (f) for a variation of the name of a manufacturer, or the address of a site of manufacture, of an agricultural chemical product, a declaration that the variation will not affect the formulation of the product; and
  - (g) for a variation of the name of a manufacturer, or the address of a site of manufacture, of a veterinary chemical product:

### **Part 3 Information contained in, or accompanying, applications**

#### **Section 6 Information contained in, or accompanying, applications**

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- (i) the number of the relevant licence issued by the APVMA under the Code; and
  - (ii) the steps in the manufacture of the product that will be undertaken at each site affected by the variation; and
  - (h) a declaration that the variation is of a relevant particular of a kind set out in Part 2 of this Instrument.
- (2) For paragraph #(1)(b), if the applicant is not a resident of, and does not carry on business in, Australia, the declaration must be made on behalf of the applicant by the relevant nominated agent.