

# **Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2019**

## **EXPLANATORY STATEMENT**

Issued by the Australian Pesticides and Veterinary Medicines Authority

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### **INTRODUCTION**

The Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994 (Code)*, establishes a regulatory scheme for agricultural and veterinary chemicals. Under the Code, persons may apply to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for registration of a chemical product, approval of an active constituent and approval of a label.

Once a chemical product is registered, or an active constituent or label is approved, the registration or approval holder may apply to the APVMA to vary relevant particulars of their registration or approval either under Division 2AA or Division 3 of Part 2. Relevant particulars include the distinguishing number, any instructions for use, as well as the distinguishing name, composition (if applicable), concentration of the active constituent (if applicable), identifying information of the holder, and the name of the manufacturer.

Division 2AA permits a holder to lodge a notice of one or more notifiable variations of the relevant particulars of an approval or registration. Notifiable variations are minor changes to the details of an approved active constituent, registered product or approved labels made by notice rather than by way of a full application. Multiple changes can be made in one notification to the APVMA for a single fee, using the APVMA online services. A variation which is a notifiable variation cannot also be a prescribed variation.

This Instrument determines the kinds of variations which are notifiable variations, pursuant to subsection 26AB(5) of the Code.

### **PROCESS BEFORE INSTRUMENT WAS MADE**

#### **Regulatory impact analysis**

A Regulatory Impact Statement has not been prepared. The Office of Best Practice Regulation (OBPR) was consulted about this Instrument (OBPR reference 25037).

On the basis of the information provided, OBPR considered that this Instrument is machinery in nature and likely to have no more than minor regulatory impacts on business, community organisations or individuals. Noting this, and the fact that this initiative is not being considered by Cabinet, OBPR considered that a Regulatory Impact Statement was not required.

#### **Consultation before making**

This Instrument is fundamentally machinery in nature, and does not make any substantive change to existing law or procedure. The provision for notifiable variations contained in item 6 was previously contained in regulation 19AE of the Agricultural and Veterinary Chemicals Code Regulations 1995 and the Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2016. This Instrument reproduces those in the same terms, and simply combines them. The operation of the former regulation and instrument has not been substantially altered in this Instrument.

Consultation was not considered appropriate in those circumstances, and was not undertaken.

### **Statement of compatibility with human rights obligations**

A statement of compatibility has been prepared and is at [Attachment A](#).

### **OTHER ISSUES**

#### **Matter incorporated by reference**

This Instrument incorporates by reference a selection of definitions contained in Part 1, Division 1 of the Code. Those definitions are identified in the note of item 4.

#### **More information**

A provision-by-provision explanation of the Instrument is provided in [Attachment B](#).

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

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

### **Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2019**

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 for the APVMA to determine the types of variations which are notifiable variations, and in what circumstances. Notifiable variations are minor variations of relevant particulars, which are made by way of notice to the APVMA.

#### **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.

## NOTES ON ITEMS

## ATTACHMENT B

### **Item 1 – Name of instrument**

This item provides for the Instrument to be named as the *Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2019*.

### **Item 2 – Commencement**

This item provides for the Instrument to commence on the day after the day it is registered.

### **Item 3 – Authority**

This item provides that the Instrument is made under subsection 26AB(5) of the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Code).

### **Item 4 – Definitions**

This item defines certain terms used in the substantive part of the Instrument.

The note in this item contains a list of terms used in the substantive part of the Instrument which are defined in the Code, as well as where to find them.

### **Item 5 – Schedules**

This item gives effect to Schedule 1 by providing that each instrument specified in it is amended or repealed as set out in the applicable items in the Schedule, or otherwise according to its terms.

### **Item 6 – Notifiable variations**

This item determines 13 types of variations to be notifiable variations for the purpose of subparagraph 25AB(3)(a)(i) of the Code. Those variations are set out in a table. Column 2 of the table describes each individual variation and, where appropriate, any condition or conditions applying to it. Column 3 describes the thing or things to which the variation may be made.

Sub-item (2) creates a condition for items 3 and 4 in the table to be classified as notifiable variations.

### **Schedule 1 – Repeals**

#### **Item 1 – The whole of the instrument**

This item repeals the *Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2016* in full.