Agricultural and Veterinary Chemicals Code (Prescribed 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.

A holder may also apply under Division 2A of Part 2 for one or more prescribed variations of the relevant particulars of an approval or registration. Prescribed variations are minor changes to the particulars of an existing registration of a chemical product, or approval of an active constituent or label. They are made through a simplified application process, rather than the technical assessment process under Division 3.

This Instrument determines the kinds of variations which are prescribed variations, pursuant to subsection 26B(6) 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 prescribed variations contained in item 6 was previously contained in regulation 19AF of the Agricultural and Veterinary Chemicals Code Regulations 1995. This Instrument reproduces those in the same terms. The operation of the former regulation 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

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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 prescribed variations, and in what circumstances. Prescribed variations are minor variations of relevant particulars, which are made through a simplified application process, rather than the technical assessment process under Division 3 of Part 2 of the Code.

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 (Prescribed 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 26B(6) 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 6 – Prescribed variations

This item determines 3 types of variations to be prescribed variations for the purpose of subparagraph 26B(4)(a) 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.