

Agricultural and Veterinary Chemicals Code (Application Requirements) Amendment Instrument 2019

EXPLANATORY STATEMENT

Issued by the Australian Pesticides and Veterinary Medicines Authority

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.

The Agricultural and Veterinary Chemicals Code (Application Requirements) Instrument 2014 (**Application Requirements Instrument**) specifies, pursuant to section 8B of the Code, formal requirements for applications in addition to those set out in subsection 8A(a) of the Code and in Division 1.2 of the *Agricultural and Veterinary Chemicals Code Regulations 1995 (Regulations)*.

Once a chemical product is registered, or an active constituent or label is approved, the registration or approval holder may apply in certain circumstances to the APVMA to make a prescribed variation. A prescribed variation is a minor type of change which is made through a simplified application process, rather than the full technical assessment process under Division 3.

This Instrument amends the Application Requirements Instrument by inserting provisions specific to applications for prescribed variations. The substance of those provisions was formerly contained in regulation 8AFB.

Inclusion of the information specified in the Instrument, or its continued inclusion, is necessary for the APVMA to determine applications for prescribed variations. The Instrument therefore meets the requirement of subsection 8B(2).

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 application requirements for prescribed variations was previously contained in regulation 8AFB. This Instrument reproduces those in the same terms. The operation of the former regulation has not been 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 does not incorporate any matter by reference.

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 specify the information that must be included in applications for prescribed variations. 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 (Application Requirements) Amendment 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 8B(1) of the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Code).

Item 4 – Schedules

This item gives the amendments their legal effect, by providing that each instrument specified in the Schedule is amended as set out in the applicable items of the Schedule.

Schedule 1

Item 1

This item inserts a new Part 4A into the Agricultural and Veterinary Chemicals Code (Application Requirements) Instrument 2014, after section 35, comprising two items.

The new item 35A provides that Part 4A applies to all applications for one or more prescribed variations made under section 26B of the Code.

The new item 35B specifies the additional application requirements that apply for prescribed variations. These requirements specify that the applicant must hold certain evidence about the product, including its storage stability and physical properties. This information is relevant to managing the risks of the replacement constituent to the safety to people, animals, plants or the environment or Australia's trade or the product efficacy.