Agricultural and Veterinary Chemicals Code (Application Requirements) Amendment Instrument 2020

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.

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.

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 42542).

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 does not make any substantive change to existing law or procedure.

The Instrument does not increase regulatory burden; it is arguable, in fact, that it reduces it by allowing overseas manufacturers to make changes to their sites as a prescribed variation rather than a full application. 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

Agricultural and Veterinary Chemicals Code (Application Requirements) Amendment Instrument 2020

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 2020.*

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 Section 35B into the Agricultural and Veterinary Chemicals Code (Application Requirements) Instrument 2014, after section 35A, comprising one item.

The new item 35B specifies the additional application requirements that apply for prescribed variations. These requirements specify that the applicant must hold certain evidence that the site of manufacture is comparable to the manufacturing principles and the Australian GMP code. It also requires the applicant to 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.