

Agricultural and Veterinary Chemicals Code (Prescribed Variations) Amendment Instrument 2020

EXPLANATORY STATEMENT

Issued by the Australian Pesticides and Veterinary Medicines Authority

INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (**APVMA**) is a statutory authority established under section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. Its functions and powers include administering the national system for regulation of agricultural and veterinary chemicals, and exercising the powers and functions conferred on it by the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994 (Code)*.

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 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](#).

Disallowance and Sunsetting

Although the *Agricultural and Veterinary Chemicals Code (Prescribed Variations) Amendment Instrument 2020* is a legislative instrument for the purposes of the *Legislation Act 2003*, pursuant to subsection 54(1) it is not subject to sunsetting. The Code is part of a co-operative scheme involving the Commonwealth and all States and Territories; and the *Agricultural and Veterinary Chemicals Code (Prescribed Variations) Amendment Instrument 2020* is authorised by the Code.

This instrument is made subject to disallowance pursuant to section 42 of the *Legislation Act 2003*, because of the operation of section 163A of the Code.

OTHER ISSUES

Matter incorporated by reference

This Instrument incorporates by reference definitions contained in Part 1, Division 1 of the Code.

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 (Prescribed Variations) 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 to enable the APVMA to assess changes to overseas sites of manufacture in a similar way to changes to Australian sites of manufacture. 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) 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 26B(6) 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 4 into the Agricultural and Veterinary Chemicals Code (Prescribed Variations) Instrument 2019.

The new Section 4 includes the definitions from the *Agricultural and Veterinary Chemicals Code Act 1994* and the *Agricultural and Veterinary Chemicals Code Regulations 1995*. It also includes new definitions of ‘*Primary steps of manufacture*’ and ‘*Secondary steps of manufacture*’.

Item 2

This item inserts a new Section 5 that includes a new item 2 and 3 in the prescribed variations table.