

Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument (No. 9) 2021

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)*.

A requisite to the exercise of many of the APVMA's powers under the Code in relation to registrable chemical products is its satisfaction that a product meets the safety criteria, among others. 'Meets the safety criteria' is defined at section 5A.

Subsection 5A(3)(b) provides a number of matters to which the APVMA may have regard for the purpose of being satisfied as to whether a chemical product meets the safety criteria. Those include (at subparagraph (iii))—

whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves.

'Residues' is defined in section 3 of the Code to include, in relation to an active constituent for a proposed or existing chemical product or in relation to a chemical product, 'any remains, persisting in or on a protected commodity' of the active constituent or chemical product.

Section 6 provides that if a provision of the Code makes reference to an approval or other thing done by the APVMA, and no other provision of the Code expressly authorises the APVMA to give such an approval or do such a thing, the APVMA is authorised to give such an approval or do such a thing either unconditionally or subject to conditions.

This instrument relies on subsection 6(2) of the Code, which permits the APVMA to vary an approval given under subsection (1).

How the maximum residues limits are determined

As part of its consideration in deciding whether or not to register a chemical product, the APVMA undertakes a comprehensive health and safety assessment. An essential part of this is a residue risk assessment by the APVMA, which includes a dietary risk assessment. A key outcome of these assessments is the setting of a maximum residue limit (MRL) for a particular chemical in relation to nominated crops and animals. An MRL is the maximum amount of a residue which would be expected if the agvet chemical product was used according to its label instructions approved by the APVMA.

The setting of an MRL by the APVMA is a science-based outcome arising from these regulatory decisions and for which there is only limited discretion on the part of the APVMA decision-maker.

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 25328).

On the basis of the information provided, OBPR considered that the principal 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 for the principal instrument or any subsequent amendments.

Consultation before making

No public consultation further to that which ordinarily occurs through the evaluation process of applications for registration and approval, which ultimately informs the maximum residue limits, was undertaken prior to making this instrument.

During evaluation of a proposed chemical product or active constituent, any person may comment or raise concerns about any relevant aspect of the intended registration, sale and use of the chemical product, including proposed maximum residue limits and the dietary exposure assessment. The APVMA addresses any concerns that are raised then, as part of that process.

Statement of compatibility with human rights obligations

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

Disallowance and Sunsetting

Although the MRL Standard 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 MRL Standard 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 the Australian Standard SAA 2706-2003 (Standard) by reference. The Standard sets out procedures for the rounding of numbers in circumstances where figures beyond the number of significant figures can be rejected and the relevant adjustment made to the last retained figure.

The Standard is available for viewing at the APVMA offices, during business hours. For details of locations and hours, please visit <https://apvma.gov.au/>. The Standard is subject to copyright. The terms of the copyright preclude the ability to make free copies and limit the amount of handwritten notes a person viewing it can make of material contained in it to a maximum of 10% (e.g. 1.5 pages if the Standard is 15 pages). Full details of the viewing conditions will be provided upon attending the office.

The Standard can also be accessed via the Standards Australia website for a fee (see <https://www.standards.org.au/standards-catalogue/sa-snz/publicsafety/me-071/as--2706-2003>).

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 (MRL Standard) 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 to amend the maximum residue limits in relation to which the APVMA may have regard in its consideration of whether chemical products meet the safety criteria pursuant to section 5A of the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994 (Code)*.

Human rights implications

This instrument engages the right to the enjoyment of the highest attainable standard of physical and mental health, contained in article 12 of the International Covenant on Economic, Social and Cultural Rights ([1976] ATS 5). In particular, it engages the imperative on the States Parties to take steps for the improvement of all aspects of environmental and industrial hygiene (article 12.2(b)).

This instrument safeguards public health, and promotes environmental and industrial hygiene, by setting the maximum levels which the APVMA approves for residues of agricultural and veterinary chemical products being present in food and animal feedstuff. Those values may be considered in relation to the APVMA's consideration of whether a chemical product meets the safety criteria for the purposes of section 5A of the Code. They are scientifically determined, having regard to risk and the best available information; particularly any dietary exposure assessments submitted for consideration.

It is intended that the values contained in this instrument will continue to be regularly reviewed for currency, and to ensure they continue to be appropriate to protect human health.

Conclusion

This instrument protects and promotes the recognised human rights to health, and environmental and industrial hygiene. It does not engage with any other recognised rights.

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 (MRL Standard) Amendment Instrument (No. 9) 2021*.

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 6(2) for the purposes of subparagraph 5A(3)(b)(iii) of the Agricultural and Veterinary Chemicals Code, as scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Code).

This instrument relies on the power contained in subsection 6(2) to vary an approval given by the APVMA under subsection 6(1). It is considered that the approval referred to in subparagraph 5A(3)(b)(iii) does not expressly confer a power on the APVMA to give it.

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

Schedule 1 contains the amendments to the MRL Standards in Schedule 1 of the principal instrument.