Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Amendment Instrument (No. 1) 2023

EXPLANATORY STATEMENT

Issued by the Australian Pesticides and Veterinary Medicines Authority

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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* (Admin Act). The Admin Act implements the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) which is an intergovernmental scheme which facilitates the establishment and operation of the intergovernmental scheme for the national uniform regulation of agvet chemicals.

The APVMA's functions and powers include administering the NRS, 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 prerequisite 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 7A of the Admin Act authorises the APVMA to approve standards for residues of chemical products in protected commodities. These standards are then administered, applied and enforced by the jurisdictions who regulate the use of chemical products.

The *Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023* (2023 Instrument) approves by legislative instrument, standards for residues of chemical products in protected commodities in accordance with recent amendments made to section 7A of the Admin Act. The purpose of this instrument is to amend the 2023 Instrument so that it contains maximum residue limits required to support uses of agvet chemicals which have recently been approved by the APVMA.

How the maximum residues limits are determined

As part of its consideration in deciding whether to register a chemical product, the APVMA undertakes a comprehensive safety assessment. An essential part of this is a residue risk assessment by the APVMA based on the uses proposed on the label. 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 acceptability of an MRL associated with a product use is based on a dietary risk assessment.

The setting of an MRL by the APVMA is a science-based outcome arising from these regulatory decisions. There is only limited discretion on the part of the APVMA decision-maker in the establishment of an MRL, however a proposed MRL may be determined to be unacceptable based on anticipated human dietary exposure.

PROCESS BEFORE INSTRUMENT WAS MADE

Regulatory impact analysis

A Regulatory Impact Statement has not been prepared as the purpose of this instrument to amend the 2023 Instrument so that it contains maximum residue limits required to support uses of agvet chemicals which have recently been approved by the APVMA is machinery in nature.

The proposed MRL amendments are an essential consequence of the decision by the APVMA to register agvet chemical products (or to vary and extend their approved label instructions); or to issue a permit in relation to an agvet chemical product; or an outcome of a review decision by the APVMA to withdraw or restrict older agvet chemical products. The setting of an MRL is a science-based outcome arising from these decisions and for which there is only very limited discretion on the part of the APVMA decision maker.

The amendments to the 2023 Instrument are likely to have negligible impacts on business, individuals, regulatory agencies or the economy. Primary producers understand the need to use only registered agvet chemical products and to use those products strictly in accordance with approved label instructions and in doing so, residues will be within the MRL recommended by the APVMA.

Consultation before making

No additional public consultation was undertaken other than 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. Jurisdictions who regulate the use of chemical products, and reference the 2023 Instrument, are consulted as part of the evaluation process of applications for registration and approval.

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

Pursuant to subsection 7A of the Admin Act, the 2023 Instrument and any subsequent amendments are legislative instruments for the purposes of the Legislation Act 2003, but it is not subject to the disallowance nor sunsetting provisions.

Although the 2023 Instrument and any subsequent amendments are legislative instruments for the purposes of the Legislation Act 2003, pursuant to subsections 44(1) and 54(1) it is not subject to the disallowance or sunsetting provisions of the Legislation Act 2003. Subsections 44(1) and 54(1) of the

Legislation Act respectively provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the Admin Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States and (b) authorises the instrument to be made for the purposes of the scheme.

In accordance with sections 44(1) and 54(1) of the Legislation Act, the Admin Act is: part of a co-operative scheme involving the Commonwealth and all States and Territories which facilitates the establishment and operation of the NRS for Agricultural and Veterinary Chemicals which is an intergovernmental body and scheme; and authorises the 2023 Instrument to be made for the purposes of the NRS.

OTHER ISSUES

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 (MRL Standard for Residues of Chemical Products) Amendment Instrument (No. 1) 2023

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 (MRL Standard for Residues of Chemical Products) Amendment Instrument (No. 1) 2023*

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 section 7A of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

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.