

# ***AGRICULTURAL AND VETERINARY CHEMICALS (MRL STANDARD FOR RESIDUES OF CHEMICAL PRODUCTS) INSTRUMENT 2023***

## **EXPLANATORY STATEMENT**

Issued by the Australian Pesticides and Veterinary Medicines Authority

### **PURPOSE**

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The *Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019* (2019 Instrument) previously provided for the maximum residue limits under subsection 6(2), for the purposes of subparagraph 5A(3)(b)(iii) of the Agricultural and Veterinary Chemicals Code (the Code) scheduled to the *Agricultural and Veterinary Chemicals Code 1994* (the Code Act). The purpose of the *Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023* (2023 Instrument) is to approve by legislative instrument, standards for residues of chemical products in protected commodities in accordance with recent amendments made to section 7A of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Admin Act).

The standards approved for residues of chemical products in protected commodities under the 2023 Instrument are identical to the standards previously provided for by the 2019 Instrument. The 2023 Instrument also provides for the repeal of the 2019 Instrument.

Previously, subsection 7A(1) of the Admin Act required the APVMA to publish the standards every calendar year. New subsection 7A(1) makes clear that the APVMA is authorised to *approve* standards for residues of chemical products in protected commodities and not merely *publish* such standards. This means that the APVMA may approve, and hence publish these residues standards as often as it finds necessary.

### **BACKGROUND**

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Agricultural and veterinary (Agvet) chemicals are regulated through a cooperative ‘National Registration Scheme for Agricultural and Veterinary Chemicals’ (the NRS). The NRS is a partnership between the Commonwealth and the states and territories, with an agreed division of responsibilities.

The NRS is implemented, in part, through the Admin Act, and the Code Act (including the Code). The Code, in part, provides for the APVMA to assess, approve, register and reconsider active constituents, and agvet chemical products and their associated labels. The states and territories apply the Commonwealth law (the Code) as a law of their own jurisdiction, supported by an intergovernmental agreement.

The APVMA MRL standard is referenced by various state laws, so the Maximum Residue Limits (MRLs) become standards that are used in determining whether approved directions for use of agricultural and veterinary chemicals have been followed.

The *Australia New Zealand Food Standards Code – Schedule 20 – Maximum residue limits* (under the *Food Standards Australia New Zealand Act 1991*)—defined in section 3 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Code) as the Maximum Residue Limits Standard, is adopted by various state laws for setting the maximum concentration of a residue in food. It covers food from any source (domestic or overseas), so includes residues of chemicals equivalent to those established in the APVMA MRL standard in addition to chemicals not authorised for use in Australia.

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 of the Code.

Subsection 5A(3)(b) of the Code 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. These matters 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.

### *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 an MRL may be determined to be unacceptable based on anticipated human dietary exposure.

### **Regulatory impact analysis**

A Regulatory Impact Statement has not been prepared. The Office of Best Practice Regulation (OBPR), now the Office of Impact Analysis (OIA) was consulted before the 2019 Instrument was made.

The 2023 Instrument is machinery in nature as its sole purpose is to implement the recent legislative change to the manner in which the APVMA is able to approve standards for residues of chemical products in protected commodities in accordance with its new powers under section 7A of the Admin Act. To this end, the 2023 Instrument does not alter existing arrangements in relation to standards for residues of chemical products in protected commodities previously provided for under the 2019 Instrument. For this reason, the 2023 Instrument will have no more than minor regulatory impact on business, community organisations or individuals. Noting this, and the fact that this initiative is not being considered by Cabinet, a Regulatory Impact Statement is not required.

### **Consultation before making**

Public consultation was not considered necessary as the 2023 Instrument is machinery in nature as it implements the recent legislative change made to the manner in which the APVMA is able to exercise its powers under section 7A of the Admin Act and does not alter existing arrangements in relation to standards for residues of chemical products in protected commodities previously provided for under the 2019 Instrument. For this reason, the 2023 Instrument will have no more than minor regulatory impact on business, community organisations or individuals.

Full public consultation was undertaken at the time of the making of the 2019 Instrument. This consultation covered that which ordinarily occurs through the evaluation process of applications for registration and approval, which ultimately informs the maximum residue limits.

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 addressed all concerns that were raised at that time, 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 is a legislative instrument for the purposes of the *Legislation Act 2003*, but it is not subject to the disallowance nor sunsetting provisions.

Although the 2023 Instrument is a legislative instrument 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 which is an intergovernmental body and scheme; and authorises the 2023 Instrument to be made for the purposes of the NRS.

The Admin Act gives effect to an intergovernmental scheme (the National Registration Scheme for Agricultural and Veterinary Chemicals) and facilitates the establishment or operation of an intergovernmental scheme (national uniform regulation of agvet chemicals). For these purposes, the Act establishes the APVMA to develop standards for residues of chemical products and these standards are then administered, applied and enforced by the jurisdictions who regulate the use of chemical products.

## **OTHER ISSUES**

### **Matter incorporated by reference**

This instrument incorporates the Australian Standard SAA 2706-2003 (Standard) by reference. The incorporated document is the Australian Standard SAA 2706-2003 which is referred to in subsection 1(7) of Part 1 of the Schedule to the 2023 Instrument. The manner in which this material is incorporated is as in force at the time the 2023 Instrument is made. 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://store.standards.org.au/product/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 (MRL Standard for Residues of Chemical Products) Instrument 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 approve by legislative instrument standards for residues of chemical products in protected commodities in accordance with section 7A of the Agricultural and Veterinary Chemicals (Administration) Act 1992 (Admin Act).

#### **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) Instrument 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 – Repeal**

This section provides for the repeal of the *Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019*.

### **Preamble to Schedule**

Item I to the Preamble provides for the Instrument to be named as the *Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023*.

Item II to the Preamble provides that the Instrument is made under section 7A of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Item III to the Preamble provides the background to the MRL Standard.

Item IV to the Preamble sets out definitions for terms used in the Instrument.

### **Schedule 1**

Schedule 1 contains the MRL Standards for residues of chemical products.