EXPLANATORY STATEMENT

Issued by the authority of the Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority

Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012

Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2013 (No. 7)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority of the Commonwealth. Amongst other things, the APVMA is responsible for ensuring agricultural and veterinary (agvet) chemicals used in Australia are not harmful to public health as a result of residues.

Subsection 6(1) of the Agricultural and Veterinary Chemicals Code (Agvet Code), which is a Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, expressly authorises the APVMA to give an approval where the Agvet Code merely refers to an approval given by the APVMA. Paragraph 14(5)(f) of the Agvet Code refers to limits that the APVMA has approved or approves for residues of agvet chemical products. Residues are defined in the relevant part in s 3(1) of the Agvet Code as remains persisting in or on a protected commodity. Section 7A of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) requires the APVMA to publish in each calendar year approved standards for residues of chemical products in protected commodities. These limits are referred to by the APVMA and known as maximum residue limits (MRLs).

The *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012* (MRL Standard) is made under the Agvet Code for the purposes of subsection 6(1) and the reference in paragraph 14(5)(f) of the Agvet Code, and published as a legislative instrument having regard to s 7A of the Administration Act. Subsection 32(1) of the Administration Act provides that the Chief Executive Officer is to manage the affairs of the APVMA and in doing so, may exercise any of the powers and perform any of the functions of the APVMA.

Purpose

The purpose of the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2013 (No. 7)* (the Amendment Instrument) is to amend the Tables in the Schedule to set new and varied MRLs and make other changes to the Tables.

Assessment and Determination of MRLs

MRLs are regulatory standards which assist in monitoring whether agvet chemical products are used in accordance with the approved instructions. If an MRL is exceeded, it usually indicates a misuse of the chemical but does not normally indicate a public health or safety concern.

In evaluating the safety and performance of agvet chemicals, the APVMA's assessment also includes a determination of an MRL for the chemical in relation to relevant crops and animals. The APVMA uses data from a series of residue trials and calculates whether the application of the minimum amount of chemical that is required to achieve effective pest or disease control will leave any residue in the plant or animal commodity. In order to legitimise the presence of these residues, MRLs are established by the APVMA by entry

into the APVMA's MRL Standard, which is regularly updated when new assessments indicate the need to establish new or varied MRLs.

If there are small amounts of chemical residue in produce, the APVMA uses the toxicological evaluation and the dietary exposure assessment to examine the potential occurrence of adverse effects on human health when the produce is consumed.

Dietary exposure assessments undertaken by the APVMA as part of the registration of the relevant agvet chemical products indicate that the MRLs approved by the APVMA and included in the MRL Standard do not present any public health and safety concerns.

Regulatory Impact Assessment

On 22 November 2012, the Office of Best Practice Regulation provided an exemption from the need to assess if a Regulatory Impact Statement is required for the approvals of MRLs by the APVMA. The MRLs are an essential consequence of the decision by the APVMA to register agvet chemical products (or to extend their approved label instructions) or to issue a permit in relation to an agvet chemical product. The setting of an MRL and its inclusion in the MRL Standard 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 setting of MRLs by the APVMA and their inclusion in the MRL Standard is unlikely to have any impact on the States, other regulatory agencies, business including primary producers, individuals, 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 instructions. In doing so, produce grown will be within the MRLs set by the APVMA and included in the APVMA's MRL Standard.

Consultation

The APVMA seeks the wider community's involvement through public consultation as part of its evaluation process for the registration of new agvet chemicals or a major extension of the use of existing products to new crops and target animals. During this consultation phase any person may comment or raise concerns about any relevant aspect of the intended registration, sale and use of the chemical product, including proposed MRLs and the dietary exposure assessment. The APVMA addresses any concerns that are raised as part of the registration and approval process.

Disallowance and Sunsetting and the Updating of the MRL Standard

Although the MRL Standard is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*, pursuant to subsections 44(1) and 54(1) it is neither subject to disallowance nor sunsetting. The Agvet Code is part of a co-operative scheme involving the Commonwealth and all States and Territories; and the MRL Standard is authorised by the Agvet Code. The APVMA proposes to amend the MRL Standard on a monthly basis to incorporate new and varied MRLs.

Details of the Amendment Instrument are set out below:

Section 1

This section provides that the Amendment Instrument is named the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2013 (No. 7)*.

Section 2

This section provides that the Amendment Instrument commences on the day after it is registered.

Section 3

This section provides that Schedule 1 of the Amendment Instrument amends the MRL Standard.

SCHEDULE 1 Amendments

Item 1

Item 1 amends Table 1 of the Schedule to vary the MRLs of agricultural and veterinary chemicals and associated substances in food commodities. These variations are made consequent upon the results of recent assessments by the APVMA of the safety and performance of agvet chemicals.

Item 2

Item 2 amends Table 5 of the Schedule to vary the uses to which certain substances may be put for which MRLs are not necessary. These variations are made consequent upon the results of recent assessments by the APVMA of the safety and performance of agvet chemicals.

STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2013 (No. 7)

This legislative instrument made by the Australian Pesticides and Veterinary Medicines Authority (APVMA) 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*.

Requirement for a Statement of Compatibility with Human Rights

This Statement is not strictly required. Disallowable legislative instruments within the meaning of section 42 of the *Legislative Instruments Act 2003* (LI Act) must be accompanied by a statement of compatibility. Section 44(1) of the LI Act provides that section 42 does not apply in relation to this legislative instrument, as the enabling legislation for the instrument facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States. Nonetheless, to accord with the spirit of the *Human Rights (Parliamentary Scrutiny) Act 2011,* the APVMA provides this Statement of Compatibility.

Overview of the legislative instrument

This legislative instrument amends the MRL Standard to set new and varied maximum residue limits (MRLs), and to make other minor amendments to the MRL Standard to clarify its object and provide guidance concerning the use of residue definitions. The MRL Standard contains the MRLs for agvet chemicals approved by the APVMA. MRLs are regulatory standards which help to monitor that agvet chemical products are used in accordance with the approved instructions. If an MRL is exceeded, it usually indicates a misuse of the chemical but does not normally indicate a public health or safety concern.

The APVMA evaluates the safety and performance of agvet chemicals before they are registered for sale in Australia. A part of this assessment also includes a determination of an MRL for the chemical in relation to relevant crops and animals. The assessments undertaken by the APVMA indicate that the MRLs approved by the APVMA and included in the MRL Standard as amended by this legislative instrument do not present any public health and safety concerns.

The approval of MRLs do not affect the rights or freedoms of any humans.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Dr Rajumati Bhula, Executive Director, Pesticides Program, and delegate of the Chief Executive Officer of the APVMA