EXPLANATORY STATEMENT

Australia New Zealand Food Standards Code—
Standard 1.4.2—Maximum Residue Limits
Amendment Instrument No. APVMA 9, 2015

Subsection 82(1) of the *Food Standards Australia New Zealand Act 1991* provides that the Australian Pesticides and Veterinary Medicines Authority (APVMA) may vary Schedule 1 of the Maximum Residue Limits Standard to include or change a permitted maximum residue limit. The Maximum Residue Limits Standard in the *Australia New Zealand Food Standards Code* (Food Standards Code) is *Standard 1.4.2 — Maximum Residue Limits*.

Standard 1.4.2 is the Principal Instrument being amended by this Amendment Instrument. It has existed in various forms since before the Food Standards Code was first published in 1997.

Section 82 was part of amendments to the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), which were proclaimed to commence on 1 March 2011, that implemented a 2008 reform agreed to by the Council of Australian Governments (COAG) calling for the recognition by Food Standards Australia New Zealand (FSANZ) of the APVMA's residue risk assessment and the promulgation of the resulting MRLs in the Food Standards Code, for domestically grown produce. The reform was designed to streamline current regulatory processes and to eliminate duplication by allowing the APVMA to directly vary Standard 1.4.2.

The 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 due to residues in food.

Subsection 11(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* provides that the APVMA may, by writing under its common seal, delegate to a member of the staff of the APVMA all or any of its powers. By written instrument under the seal of the APVMA of 7 June 2011, the APVMA has delegated to the holder of the office of Executive Director, Scientific Assessment and Chemical Review its powers under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* excludes MRLs for residues of agvet chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agvet chemicals in food.

Assessment and Determination of MRLs

MRLs are regulatory standards which help to monitor that the agvet chemical product has been used in accordance with the approved label 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* (available at http://www.comlaw.gov.au).

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 chemical products indicate that the MRL variations being made by the Amendment Instrument do not present any public health and safety concerns.

Schedule 1 of Standard 1.4.2 lists the maximum level of the residues of an agvet chemical that may occur in foods. Including limits for residues of agvet chemicals in foods in the Food Standards Code has the effect of allowing the sale of food containing legitimate residues, where any residues do not exceed these limits. Variations in MRLs reflect the changing use patterns of agvet chemicals available to chemical users including food producers. These changes include both the development of new products and crop uses, and the withdrawal of older products following review by the APVMA.

Regulatory Impact Assessment

The proposed changes to regulation are minor and machinery in nature involving necessary technical variations to the Food Standards Code. In November 2010, the Office of Best Practice Regulation provided a standing exemption from the need to assess if a Regulatory Impact Statement is required for applications relating to variations to MRLs.

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 and its incorporation in the Food Standards Code 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 proposal to vary MRLs in the Food Standards Code is 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. In doing so, produce grown will be within the MRL set by the APVMA and, with the incorporation of those MRLs into the Food Standards Code by this Amendment Instrument, the sale of the produce containing residues that do not exceed the MRL will be lawful. To this extent, the incorporation of APVMA approved MRLs into Schedule 1 of Standard 1.4.2 of the Food Standards Code benefits rather than burdens primary producers and consumers.

Consultations

The APVMA seeks the wider community's involvement through public consultation as part of its evaluation process for the registration of new agvet chemical products 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 addressed any concerns that were raised at the time as part of the registration and approval process.

More specifically, by way of notice in the Agricultural and Veterinary Chemicals *Gazette* (No. APVMA 16) on 11 August 2015 the APVMA notified that it was proposing to incorporate these variations to MRLs into Standard 1.4.2 and it invited public comment on the proposals. The APVMA did not receive any comments during this stage of the consultations.

FSANZ also made Sanitary and Phytosanitary notification to the World Trade Organization (WTO) in relation to the variations to MRLs in Standard 1.4.2. Comment was received in response to that notice and consultations are continuing.

Variations to MRLs are Legislative Instruments

Pursuant to subsection 82(2) of the FSANZ Act, the variations to MRLs made by the Amendment Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*, but it is neither subject to the disallowance nor sunsetting provisions.

NOTES ON ITEMS

Item 1 Name of Instrument

1. This item states that the full name of the Amendment Instrument is the *Australia New Zealand Food Standards Code — Standard 1.4.2 — Maximum Residue Limits Amendment Instrument No. APVMA 9, 2015.*

Item 2 Commencement

2. Subsection 82(8) of the *Food Standards Australia New Zealand Act 1991* has the effect that, despite the provisions in the *Legislative Instruments Act 2003*, a legislative instrument made by the APVMA varying Standard 1.4.2 commences on the day a copy of the variation is published in the *Gazette*.

3. A Note to the item records that a copy of the variations made by the Amendment Instrument was published in *Gazette* No. APVMA 22 of 3 November 2015.

Item 3 Object

4. This item provides that the object of this Amendment Instrument is for the APVMA to vary Schedule 1 of Standard 1.4.2 of the Food Standards Code to include or change MRLs pertaining to agricultural and veterinary chemical products.

Item 4 Interpretation

5. This item defines the APVMA and the Principal Instrument.

6. The APVMA is the Australian Pesticides and Veterinary Medicines Authority established by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

7. The Principal Instrument is Standard 1.4.2 — Maximum Residue Limits of the *Australia New Zealand Food Standard Code* as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the code published in *Gazette* No. P 27 on 27 August 1987 together with any amendments of the standards in that code.

8. The definition of Principal Instrument also notes that the whole of the *Australia New Zealand Food Standard Code* (including Standard 1.4.2) was further published in *Gazette* P 30 of 20 December 2000. This was specifically included as the amendment history at the beginning of the Food Standards Code dates only from that time.

Item 5 Variations to Standard 1.4.2

9. This item provides that the Schedule to this Amendment Instrument sets out the variations to Standard 1.4.2 – Maximum Residue Limits of the Food Standards Code.

10. The variations to MRLs made by the Amendment Instrument include variations made by the APVMA to the *MRL Standard* for August 2015 comprising amendments numbered (Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2015 (No. 7)) inclusive.

By Authority:
Executive Director, Scientific Assessment and Chemical Review
Delegate of the APVMA
29 October 2015

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

***Australia New Zealand Food Standards Code* — Standard 1.4.2 —**

Maximum Residue Limits Amendment Instrument No. APVMA 9, 2015

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 Legislative Instrument made by the APVMA is not a disallowable instrument pursuant to section 82(2) of the *Food Standards Australia New Zealand Act 1991* and therefore the Statement of Compatibility with Human Rights is not strictly required. 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 makes variations to Standard 1.4.2 — Maximum Residue Limits of the *Australia New Zealand Food Standards Code* to include or change maximum residue limits (MRLs) pertaining to agricultural and veterinary chemical products. The variations made to Standard 1.4.2 in this Amendment Instrument put into the Food Standards Code MRLs previously approved by the APVMA as part of the registration of the relevant chemical products. The variations have the effect of allowing the sale of food containing residues within the approved maximum limits but do not present any public health or safety concerns. The variations also 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, Scientific Assessment and Chemical Review, APVMA