EXPLANATORY STATEMENT

Australia New Zealand Food Standards Code—
Schedule 20—Maximum Residue Limits
Variation Instrument No. APVMA 1, 2022

Subsection 82(1) of the *Food Standards Australia New Zealand Act 1991* provides that the Australian Pesticides and Veterinary Medicines Authority (APVMA) may vary 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 *Schedule 20 — Maximum Residue Limits*.

Schedule 20 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 Schedule 20.

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.

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 20 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 20 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 18) on 07 September 2021, (No. APVMA 21) on 19 October 2021 and (No. APVMA 24) on 30 November 2021 the APVMA notified that it was proposing to incorporate these variations to MRLs into Schedule 20 and it invited public comment on the proposals. The APVMA received one comment during this stage of the consultations and that comment has been addressed.

A Sanitary and Phytosanitary notification to the World Trade Organization (WTO) was also made in relation to the variations to MRLs in Schedule 20 and comment was received in response to that notice which have been addressed.

Following the consultation process, it was determined that proposed MRL changes relating to Prothioconazole in pulse commodities would not proceed at this time. An additional change has been included the Amendment Instrument to amend an inconsistency in the description of the commodity name for cane berries for Afidopyropen.

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 *Legislation Act 2003*, but it is neither subject to the disallowance nor sunsetting provisions.

The MRLs made by the Amendment Instrument will not be subject to the disallowance or sunsetting provisions of the Legislation Act 2003. Subsections 44(1) and 54(1) of the FSANZ Act provides that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ 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. Regulation 11 of the Legislation (Exemptions and other Matters) Regulation 2015 also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement, and consists of Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth and State and Territory food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions regulators as part of those food laws.

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 — Schedule 20 — Maximum Residue Limits Variation Instrument No. APVMA 1, 2022* (Amendment Instrument).

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 *Legislation Act 2003*, a legislative instrument made by the APVMA varying Schedule 20 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 the Commonwealth of Australia Agricultural and Veterinary Chemicals Gazette.

Item 3 Object

4. This item provides that the object of this Amendment Instrument is for the APVMA to vary Schedule 20 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 Schedule 20 — 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 Schedule 20 was published in the *Food Standards Gazette* FSC 96 on Thursday 10 April 2015 and was registered as a legislative instrument on 1 April 2015 F2015L00468.

Item 5 Variations to Schedule 20

9. This item provides that the Schedule to this Amendment Instrument sets out the variations to Schedule 20 – 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 September, October and November 2021 comprising amendments numbered Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument (No. 7) 2021, (No. 8) 2021 and (No. 9) 2021.

By Authority:
Delegate of the Chief Executive Officer
of the Australian Pesticides and Veterinary Medicines Authority
16 February 2022

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* — Schedule 20 —**

Maximum Residue Limits Variation Instrument No. APVMA 1, 2022

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 Schedule 20 — 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 Schedule 20 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.

Name,
Executive Director, Risk Assessment Capability, APVMA