Australia New Zealand Food Standards Code – Schedule 20 – Maximum Residue Limits Variation Instrument No. APVMA 2 2025

EXPLANATORY STATEMENT

Issued by the Australian Pesticides and Veterinary Medicines Authority

Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is a statutory authority continued in existence under section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. Its functions and powers include administering the national system for regulation of agricultural and veterinary chemical products (agvet chemicals), 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*.

The APVMA is also responsible for ensuring agvet chemicals used in Australia are not harmful to human health due to residues in food. The APVMA has the powers to set or vary maximum residue limits (MRLs) under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) for this purpose.

Setting MRLs

In evaluating the safety and efficacy of agvet chemicals, the APVMA's assessment includes a determination of MRLs for agvet chemicals in relation to relevant plant and animal commodities.

The APVMA uses data from residue trials to calculate whether the application of the minimum amount of agvet chemical that is required to achieve effective pest or disease control will leave any residue in the plant or animal commodity. The APVMA also uses a toxicological evaluation and a dietary exposure assessment to examine the potential occurrence of adverse effects on human health where the plant or animal commodities will be consumed as food.

If a residue from agvet chemical use is present, the APVMA sets a MRL through the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023 (MRL Standard for Residues of Chemical Products) and the Australia New Zealand Food Standards Code – Schedule 20 – Maximum residue limits (Maximum Residue Limits Standard).

The Maximum Residue Limits Standard identifies agvet chemicals, and their permitted residues for the purposes of section 1.4.2—4 of the *Australia New Zealand Food Standards Code* (**Food Standards Code**). Section 1.4.2—4 provides that a food listed in the Maximum Residue Limits Standard may contain a permitted residue of an agvet chemical that is listed in that Standard for that food.

From time to time the APVMA varies the MRLs it has set. 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 or new uses on crops, and the withdrawal of older products following review by the APVMA.

Authority

Section 82 of the FSANZ Act authorises the APVMA to amend the Maximum Residue Limits Standard to set or vary MRLs.

The APVMA may, in accordance with subsection 82(1) of the FSANZ Act, vary the Maximum Residue Limits Standard to include or change a permitted MRL.

The Maximum Residue Limits Standard only applies to MRLs for agvet chemicals in food in Australia. The Australia New Zealand Joint Food Standards Agreement between the Government of Australia and the Government of New Zealand establishing a system for the development of joint food standards for Australia and New Zealand excludes MRLs for residues of agvet chemicals in food as a joint standard in the joint Australia New Zealand food standards system. Australia and New Zealand independently and separately develop MRLs for agvet chemicals in food.

The Australia New Zealand Food Standards Code – Schedule 20 – Maximum Residue Limits Variation Instrument No. APVMA 2 2025 (Amending Instrument) is a legislative instrument (subsection 82(2) of the FSANZ Act).

Purpose

The purpose of the Amending Instrument is to amend the Maximum Residue Limits Standard to set or vary MRLs. The Amending Instrument will set or vary MRLs in the Maximum Residue Limits Standard to align with MRLs approved by the APVMA as part of the registration of agvet chemical products and published in the MRL Standard for Residues of Chemical Products (available at https://www.legislation.gov.au/F2023L01350/latest/versions).

Recent dietary exposure assessments undertaken by the APVMA as part of the registration of the relevant chemical products indicate that the MRL variations or inclusions being made by the Amending Instrument do not present any human health and safety concerns.

Inclusion of MRLs in foods in the Maximum Residue Limits Standard permits the sale of food containing legitimate residues, where any residues do not exceed these limits.

Impact Analysis

The Office of Impact Analysis (OIA) has granted Food Standards Australia New Zealand (**FSANZ**) a standing exemption for the necessity for the OIA to assess if a full impact analysis is required for variations related to MRLs (OIA23-06225 (formerly 12065)).

Similarly, the OIA has granted the APVMA a standing exemption for the making of an existing MRLs standard as a legislative instrument (OIA23-06119 (formerly 14469)). The proposal to vary MRLs in the Food Standards Code is likely to have negligible impacts on business, individuals, regulatory agencies or the economy.

Consultation

In accordance with section 82(3) of the FSANZ Act, the APVMA notified FSANZ on 14 August 2025 before varying the Maximum Residue Limits Standard by way of the Amending Instrument. In accordance with section 82(4)(b) of that Act, and with FSANZ agreement, the APVMA prepared a dietary exposure assessment in relation to the proposed variation, provided a copy of that assessment to the FSANZ for review. In accordance with section 82(5)(b) of that Act, the APVMA considered the assessment and the comments on the assessment provided by FSANZ.

The APVMA conducted a public consultation as part of its evaluation process for the registration of new agvet chemical products or as part of a major extension of the use of existing products to new crops and target animals. During this consultation phase, any person could comment or raise concerns about any relevant aspect of the intended registration, sale or use of the agvet chemical product, including proposed MRLs and the dietary exposure assessment.

More specifically, by way of notice in the Agricultural and Veterinary Chemicals *Gazette* (No. APVMA 25) on 10 December 2024, the APVMA notified that it was proposing to vary the Maximum Residue Limits Standard to include or change a permitted MRL in that Standard and it invited public comments on the proposal. The APVMA received a number of comments within the given response period. All comments on the proposed variations were considered and addressed.

A Sanitary and Phytosanitary notification to the World Trade Organization (WTO) was also made in relation to the proposed variations to MRLs in the Maximum Residue Limits Standard. The APVMA received a number of submissions from the notification. Every submission on the proposed variations was considered and addressed.

Disallowance and sunsetting

The Amending Instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act* 2003 (**Legislation Act**). Subsections 44(1) and 54(1) of the Legislation Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act) 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.

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 FSANZ to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and a related international agreement between Australia and New Zealand; it consists of New Zealand, 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, State and Territory and New Zealand food laws. The standards or instruments are then administered, applied and enforced by these

jurisdictions' regulators as part of those food laws. These standards include the Maximum Residue Limits Standard.

Statement of compatibility with human rights obligations

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the Legislation Act.

More information

A provision-by-provision explanation of the variation made by the Amending Instrument is provided in <u>Attachment A</u>.

NOTES ON ITEMS

Item 1 Name of Instrument

1. This item states that the full name of the Amending Instrument is the *Australia New Zealand Food Standards Code* — *Schedule 20* — *Maximum Residue Limits Variation Instrument No. APVMA 2, 2025.*

Item 2 Commencement

- 2. Subsection 82(8) of the FSANZ Act has the effect that, despite the provisions in the Legislation Act, a legislative instrument made by the APVMA varying the Maximum Residue Limits Standard commences on the day a copy of the instrument is published by the APVMA in the *Gazette*.
- 3. A Note to item 2 records that a copy of the variations made by the Amending 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 Amending Instrument is to vary the Maximum Residue Limits Standard (that is, the *Australia New Zealand Food Standards Code — Schedule 20 — Maximum Residue Limits)* 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 means the Australia New Zealand Food Standards Code Schedule 20 Maximum Residue Limits, with the Australia New Zealand Food Standards Code being defined in section 4 of the Food Standards Australia New Zealand Act 1991 as the Food Standards Code published in the 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 *Australia New Zealand Food Standards Code Schedule 20 Maximum Residue Limits* 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 Schedule 1 to this Amending Instrument sets out the variations made to the Maximum Residue Limits Standard (Schedule 20 Maximum Residue Limits of the Food Standards Code) by this Amending Instrument.
- 10. The variations to MRLs made by the Amending Instrument include variations made by the APVMA to the **MRL Standard for Residues of Chemical Products** for December 2024 comprising amendments numbered Agricultural and Veterinary Chemicals Code (MRL Standard for Residues of Chemical Products) Amendment Instrument (No. 5) 2024.