

## **EXPLANATORY STATEMENT**

Issued by Authority of the Minister for Agriculture, Fisheries and Forestry

*Agricultural and Veterinary Chemicals Code Act 1994*

*Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2025*

### **Legislative Authority**

The *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act), in part, sets out the regulatory framework for the evaluation, registration, control and manufacture of agricultural and veterinary (agvet) chemicals.

Subsection 6(1) of the Code Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Agricultural and Veterinary Chemicals Code set out in the Schedule to the Code Act (the Code) to be prescribed by regulations within the meaning of the Code, or that are necessary or convenient to be prescribed by such regulations for carrying out or giving effect to the Code.

Specifically, regulations can be made pursuant to, or for the purposes of, the following provisions:

- subsection 164(1) of the Code specifies, in part, that the regulations may prescribe, or prescribe a method of working out, the fees to be paid in respect of the making of an application to the Australian Pesticides and Veterinary Medicines Authority (APVMA) under the Code;
- section 3 of the Code provides that a “date-controlled chemical product” means a chemical product declared by the regulations to be a date-controlled chemical product.

The *Agricultural and Veterinary Chemicals Code Regulations 1995* (Code Regulations) is made under the Code Act and, in part, prescribes fees and charges for applications made to the APVMA and chemical products that are declared to be date-controlled chemical products.

### **Purpose**

The purpose of the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2025* (Amendment Regulations) is to amend the Code Regulations to give effect to changes in the 2025 Cost Recovery Implementation Statement (2025 CRIS) of the Australian Pesticides and Veterinary Medicines Authority (APVMA), to adjust fees for the renewal of registration of chemical products.

The Amendment Regulations also provide that agricultural chemical products containing malathion as an active constituent are “date-controlled chemical products” for the purposes of the Code.

## Background

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 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 Code as a law of their own jurisdiction, supported by an intergovernmental agreement.

The APVMA was established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. The APVMA is responsible for regulating agvet chemicals up to and including the point of supply, i.e., retail sale.

The operations of the APVMA are funded almost entirely through cost-recovery via fees and levies from industry. The 2025 CRIS for the period between 1 October 2025 and 30 June 2026 outlines how the APVMA will implement cost recovery arrangements relating to the agency fulfilling its statutory function to ensure that agvet chemicals sold within Australia are safe and effective and do not unduly prejudice trade. In particular, the 2025 CRIS informs that there will be stepped increases to chemical product registration renewal fees for the 2025-26, 2026-27 and 2027-28 financial years.

On occasion, credible new information may emerge after a product has been registered that suggests to the APVMA the existence of previously unknown risks to human health, animal or crop safety, the environment or trade, or that suggests product ineffectiveness. If this happens, the APVMA can initiate a reconsideration process under Division 4 of Part 2 of the Code to assess the identified risk and determine whether changes are needed to ensure that the product can continue to be used safely and effectively.

On 2 May 2024 the APVMA published the final decision for the reconsideration of malathion, an insecticide used for the control of pests in various broadacre and horticultural crops, vegetables and ornamental plants, and for veterinary and domestic uses. The APVMA decided to vary and affirm malathion active constituent approvals, chemical product registrations, and associated label approvals. These variations included, in part, conditions for all products containing malathion as an active constituent to have a shelf life and for the associated expiry date to be included on labels with associated requirements.

## Impact and Effect

The Amendment Regulations implement increases to chemical product registration renewal fees for the 2025-26, 2026-27 and 2027-28 financial years to align with the fee changes set out in the 2025 CRIS.

The effect of providing that agricultural chemical products containing malathion as an active constituent are “date-controlled chemical products” is that such products cannot be supplied in a container that does not have an approved label sufficiently identifying the date of manufacture and containing the relevant expiry date. This amendment imposes no new burden on registered product holders as this requirement reflects the obligation that the APVMA has imposed as a condition of the registration of chemical products containing

malathion as an active constituent under existing legislation following the APVMA's 2024 decisions from its reconsideration of malathion.

## **Consultation**

The Amendment Regulations were developed in consultation with the APVMA.

The APVMA consulted widely about the 2025 CRIS through targeted consultation with key stakeholders and public consultation via the APVMA's website for a five-week period between 16 September and 18 October 2024. In response to stakeholder feedback the application fees have been maintained at the same rate as the 2023-25 CRIS, apart from chemical product registration renewal fees.

The APVMA publicly consulted on the proposal to ensure that agricultural chemical products containing malathion as an active constituent have an approved label with the expiry date for the product, before making its proposed reconsideration decision in May 2024 to apply a condition of registration to that effect to all chemical products containing malathion as an active constituent.

Relevant state and territory agencies were also provided with the opportunity to comment and make suggestions about all measures set out in the Amendment Regulations through the 2025 CRIS and reconsideration consultation processes.

The Office of Impact Analysis (OIA) was consulted in the preparation of the Amendment Regulations (ID OIA24-08184). The OIA advised that a detailed impact analysis was not required under the Australian Government's Policy Impact Analysis Framework.

## **Details/ Operation**

The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003* (Legislation Act).

Sunsetting does not apply to the Code Regulations due to subsection 54(1) of the Legislation Act. This is because the Code Regulations and its enabling legislation, the Code Act, are part of the legislative framework that facilitates the establishment or operation of an intergovernmental scheme (being the NRS) and authorises the Code Regulations to be made for the purposes of the NRS. The Code Regulations are therefore part of a multilateral agreement, with the states and territories applying the Code and the Code Regulations as a law of their own jurisdictions. It would be inappropriate for the Code Regulations to be subject to a unilateral sunseting process that would have repercussions for each jurisdiction that is a party to the intergovernmental agreement.

The Amendment Regulations commence on 1 October 2025.

Details of the Amendment Regulations are set out in Attachment A.

## **Other**

The Amendment Regulations are compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full Statement of Compatibility with Human Rights is set out in Attachment B.

**Details of the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2025***

**Section 1 – Name**

This section specifies that the name of the instrument is the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2025* (Amendment Regulations).

**Section 2 – Commencement**

This section has the effect that the whole of the Amendment Regulations commences on 1 October 2025.

**Section 3 – Authority**

This section specifies that the Amendment Regulations are made under the authority of the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act).

**Section 4 – Schedules**

This section is the formal enabling provision for the Schedule to the Amendment Regulations and specifies that each instrument that is specified in a Schedule is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in the Schedule has effect according to its terms.

## **Schedule 1 – Amendments**

Schedule 1 to the Amendment Regulations deals with two matters:

- changes to give effect to the 2025 Cost Recovery Implementation Statement (2025 CRIS) of the Australian Pesticides and Veterinary Medicines Authority (APVMA) to implement stepped increases to chemical product registration renewal fees for the 2025-26, 2026-27 and 2027-28 financial years; and
- a change to provide that agricultural chemical products containing malathion as an active constituent are “date-controlled chemical products” for the purposes of the Agricultural and Veterinary Chemicals Code set out in the Schedule to the Code Act (the Code).

### **Part 1 – Main amendments**

*Agricultural and Veterinary Chemicals Code Regulations 1995*

#### **Item [1] – Subregulation 71A(1) (table item 2, column 1)**

This item omits the words “and later financial years” and substitutes “1 July 2022, 1 July 2023 or 1 July 2024” in column 1 of table item 2 in subregulation 71A(1) of the Code Regulations.

Table item 2 currently refers to the financial year beginning on 1 July 2021 and later financial years. This amendment adds references to each financial year from 1 July 2022 until 1 July 2024, with the effect that the fees currently set out in columns 2 and 3 for a 12 month or a 5 year product registration renewal apply until the financial year beginning on 1 July 2025.

This item is consequential to item 2 of this Schedule, which provides for fees that apply from 1 July 2025. The amendment preserves the existing effect of table item 2 in relation to the fees for continued registration of a chemical product for past financial years.

#### **Item [2] – Subsection 78A(1) (at the end of the table)**

This item adds table items 3, 4 and 5 at the end of the table in subregulation 71A(1) of the Code Regulations.

Subregulation 71A(1) of the Code Regulations provides for fees payable for an application for the renewal, or further renewal, of the registration of a chemical product, for the purposes of section 164 of the Code. The table in subregulation 71A(1) sets out the fees payable for the financial year in which the application for the renewal, or further renewal, of the product registration is made. Regulation 23A of the Code Regulations provides that the registration of a chemical product can be renewed, or further renewed, for a period of either 12 months or 5 years. The registered product holder can choose whether to pay registration renewal fees for 12 months, or 5 years in advance. As such, subregulation 71A(1) of the Code Regulations provides for fees payable for a renewal, or further renewal, of the registration of a chemical product for a 12 month renewal and a 5 year renewal.

The 2025 CRIS provides for stepped increases to the product registration renewal fees for each financial year from 2025-26 to 2027-28 for both a 12-month renewal and a 5-year renewal. The amount payable for the 5-year renewal specified in the 2025 CRIS is calculated by summing the anticipated annual fee applicable each year over the 5-year period from the financial year in which the fee is paid.

Consistent with the 2025 CRIS, item [1] of the Amendment Regulations amends subsection 71A(1) to provide for the following increases to product registration renewal fees, which will take effect from commencement of this Schedule on 1 October 2025:

- Table item 3 specifies that the fee for an application for renewal made in the financial year beginning on 1 July 2025 is \$700 for a 12 month period or \$3,850 for a 5 year period;
- Table item 4 specifies that the fee for an application for renewal made in the financial year beginning on 1 July 2026 is \$750 for a 12 month period or \$3,950 for a 5 year period;
- Table item 5 specifies that the fee for an application for renewal made in the financial year beginning on 1 July 2027 and later financial years is \$800 for a 12 month period or \$4,000 for a 5 year period.

The effect of the application provision in item 4 of this Schedule is that the increased fees for a renewal application made in the financial year beginning on 1 July 2025 apply in relation to an application that is made on or after the commencement of this Schedule on 1 October 2025. The effect of the existing legislation is that an application for renewal of a registration for the following financial year cannot be made before 1 April 2026. Section 48 of the Code provides that an application for renewal of registration cannot be made earlier than three months before the registration ends, or later than one month (or such shorter period as the APVMA allows) before the registration ends. The registration of a chemical product and each renewal thereafter always ends on 30 June of a year (see subsections 20(3) and 50(3) of the Code). This means that an application for renewal of a registration for the next financial year must always be made during the period of 1 April to 31 May of a year, unless a shorter period is approved by the APVMA.

For example, the increased fee for an application for a 12-month registration renewal made in the 2025-26 financial year, will take effect from 1 October 2025 and before an application for renewal in that financial year can be made (which can only be made between 1 April and 31 May 2026). Such an application would cover a 12-month registration for the 2026-27 financial year.

The fees in this item are prescribed for the purposes of subsection 164(1) of the Code.

### **Item [3] – Schedule 1 (at the end of the table)**

This item adds table item 7 at the end of the table in Schedule 1 to the Code Regulations.

Schedule 1 to the Code Regulations specifies agricultural chemical products that are “date-controlled chemical products” for the purposes of regulation 4 of the Code Regulations and section 3 of the Code. Regulation 4 of the Code Regulations has the effect that a “date-controlled chemical product” is a veterinary chemical product, or an agricultural chemical product specified in Schedule 1 to the Code Regulations. As malathion is contained in both

agricultural chemical products and veterinary chemical products, veterinary chemical products containing malathion are already “date-controlled products”.

New table item 7 adds an agricultural chemical product containing malathion as an active constituent to Schedule 1, with the effect that such products are date-controlled chemical products for the purposes of the Code and the Code Regulations. This would not include products that contain malathion in trace quantities as a non-active constituent (such as an excipient), rather than as an active constituent.

Subsection 91(1) of the Code prohibits a person from supplying, or causing or permitting the supply of, a date-controlled chemical product in a container that does not have an approved label containing:

- matter that the APVMA has approved as sufficient to enable the APVMA to identify the date of manufacture of the product; and
- the expiry date required to be contained on the label as a condition of the registration of the product.

Malathion is a synthetic organophosphorus chemical insecticide and acaricide used in domestic, agricultural and veterinary situations. The APVMA, after reconsidering malathion under the framework set out in Division 4 of Part 2 of the Code, recently applied conditions of registration to all chemical products containing malathion as an active constituent due to human health concerns that may arise after opening and during the storage of those products. Specifically, prolonged storage may increase the concentration of impurities of toxicological concerns to concentrations that the APVMA does not consider to be safe.

The APVMA currently applies these conditions of registration to all chemical products containing malathion as an active constituent. This amendment ensures certainty and clarity by ensuring that the requirement to have an approved label sufficiently identifying the date of manufacture and the expiry date is included in the Code Regulations. This amendment imposes no new burden on registered product holders as this requirement reflects the obligation that the APVMA has imposed as a condition of the registration of chemical products containing malathion as an active constituent.

## **Part 2 – Application provisions**

### *Agricultural and Veterinary Chemicals Code Regulations 1995*

#### **Item [4] – At the end of Part 10**

This item inserts Division 10.9 in the appropriate position in Part 10 of the Code Regulations.

Regulation 96 is the only provision in new Division 10.9 of the Code Regulations and provides for the application of amendments made by this Schedule.

Regulation 96 provides that the amendments of subregulation 71A(1) made by Part 1 of this Schedule apply in relation to an application that is made on or after commencement of this regulation. Section 2 of the Amendment Regulations provides that the whole of the instrument commences on 1 October 2025.



The effect of this amendment is that the increased fees applying for the financial year beginning on 1 July 2025 apply in relation to an application for renewal, or further renewal, of the registration of a chemical product that is made on or after 1 October 2025. As explained above in relation to item 2 of this Schedule, the Code Regulations currently have the effect that an application for renewal in the 2025-26 financial year cannot be made until 1 April 2026, so the amendments to subregulation 71A(1) will commence before an application for product registration renewal can be made.

## **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 Amendment (Cost Recovery and Other Measures) Regulations 2025*

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 Australian Pesticides and Veterinary Medicines Authority (APVMA), established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, assesses, registers, and approves agricultural and veterinary (agvet) chemicals for use in Australia.

The *Agricultural and Veterinary Chemicals Code Act 1994* sets out in its Schedule the Agricultural and Veterinary Chemicals Code (the Code), as it applies as a law for the government of the participating Territories. The object of the Code is to make provision for and in relation to:

- the evaluation, approval, and control of the supply, of active constituents for proposed or existing agricultural chemical products or veterinary chemical products; and
- the evaluation, registration, and control of the manufacture and supply, of agricultural chemical products and veterinary chemical products.

The APVMA is responsible for regulating agvet chemicals up to and including the point of supply, i.e., retail sale. The control of use of agvet chemicals after supply is the responsibility of individual states and territories.

The operations of the APVMA are funded almost entirely through cost-recovery via fees and levies from industry. The Cost Recovery Implementation Statement (2025 CRIS) outlines how the APVMA implements cost recovery arrangements relating to the agency fulfilling its statutory function to ensure that agvet chemicals sold within Australia are safe and effective and do not unduly prejudice trade. In particular, the 2025 CRIS informs that there will be stepped increases to chemical product registration renewal fees for the 2025-26, 2026-27 and 2027-28 financial years.

The amendments in Schedule 1 to the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery and Other Measures) Regulations 2025* (Legislative Instrument) amend the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Code Regulations) to give effect to the afore-mentioned changes specified in the 2025 CRIS.

The amendments in Schedule 1 to the Legislative Instrument also amend the Code Regulations to provide that agricultural chemical products containing malathion as an active constituent are “date-controlled chemical products” for the purposes of the Code, with the effect that such products cannot be supplied in a container that does not have an approved label sufficiently identifying the date of manufacture and containing the relevant expiry date.

This amendment imposes no new burden on registered product holders as this requirement reflects the obligation that the APVMA has imposed as a condition of the registration of chemical products containing malathion as an active constituent under existing legislation following the APVMA's 2024 decisions from its reconsideration of malathion.

### **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.

**The Hon Julie Collins MP**  
**Minister for Agriculture, Fisheries and Forestry**