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The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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General information

The APVMA Gazette is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

Distribution and subscription

The APVMA Gazette is published in electronic format only and is available from the [APVMA website](http://apvma.gov.au).

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APVMA contacts

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Notice under section 34AB of the Agricultural and Veterinary Chemicals Code: Fenitrothion reconsideration – proposed decisions on reconsideration

- 1) The Australian Pesticides and Veterinary Medicines Authority (APVMA) is proposing to make regulatory decisions in relation to the reconsideration of fenitrothion active constituent approvals, product registrations, and label approvals being conducted under Part 2, Division 4 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).
- 2) This notice is issued under section 34AB of the Agvet Code and relates to the reconsideration of fenitrothion active constituent approvals, product registrations and label approvals listed in Attachment A of this notice. This reconsideration extends to compliance with requirements prescribed by the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Regulations) for those approvals and registrations listed in Attachment A.
- 3) The Draft Statement of Reasons for the proposed decision is set out in Attachment B of this notice.
- 4) The information on which the reasons are based is set out in Attachment C of this notice.
- 5) Pursuant to section 34A of the Agvet Code, the APVMA proposes to:
 - a. vary the relevant particulars and conditions of the fenitrothion active constituent approvals listed in Table 1 in Attachment A of this notice in the manner set out in paragraphs 9) and 13) of the draft statement of reasons in Attachment B, to allow affirmation under section 34A(1) of the Agvet Code; and
 - b. vary the relevant particulars and conditions of the product registrations listed in Table 1 in Attachment A of this notice in the manner set out in paragraphs 22), 28) and 35) of the draft statement of reasons in Attachment B, to allow affirmation under section 34A(1) of the Agvet Code; and
 - c. vary the relevant particulars of the label approvals listed in Table 1 in Attachment A of this notice in the manner set out in paragraph 56) of the draft statement of reasons in Attachment B, and as reflected in the proposed sample labels in Attachment D, to allow affirmation under section 34A(1) of the Agvet Code.
- 6) Pursuant to section 34AA(1) of the Agvet Code, the APVMA proposes to:
 - a. cancel the chemical product registration listed in Table 2 in Attachment A of this notice, as the APVMA is **not satisfied** that the relevant particulars or conditions of the registrations can be varied in such a way as to allow the registrations to be affirmed; and
 - b. cancel the label approval listed in Table 2 in Attachment A of this notice, as the APVMA is **not satisfied** that the relevant particulars or conditions of the approvals can be varied in such a way as to allow the approvals to be affirmed.

Written submissions are invited

- 7) The APVMA invites written submissions on the proposed decision. All submissions received will be considered by the APVMA before a final regulatory decision is made on this reconsideration.
- 8) Submissions or requests for further information can be sent to:

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2400

Email: chemicalreview@apvma.gov.au

Please note: Submissions will be published on the APVMA website, unless you have asked for the submission to remain confidential (see [public submission coversheet](#)).

- Please lodge your submission with a [public submission coversheet](#), which provides options for how your submission will be published.
- Note that all submissions received are subject to legislative requirements, including the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Code. In providing your submission to the APVMA, unless you have indicated that you want your submission to remain confidential, you agree to the APVMA publicly disclosing your submission in whole or summary form. The APVMA confirms that if your submission includes confidential commercial information or protected information as defined in the Agvet Code, such information will be subject to the relevant provisions of the Agvet Code including relevant limitations on use and disclosure by the APVMA.

9) The closing date for submissions is 8 July 2024.

Sheila Logan
Executive Director, Risk Assessment Capability

With the delegated authority under sections 11, 32 and 44 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*

Date: 9 April 2024

Attachments:

Note: The attachments below form part of this Notice

Attachment A: Active constituent approval(s), product registration(s) and approved label(s) placed under reconsideration.

Attachment B: Draft Statement of Reasons.

Attachment C: Information on which the reasons are based.

Attachment D: Proposed sample labels for fenitrothion chemical products.

Contact information

For any enquiries or further information about this matter, please contact:

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Attachment A: Active constituent approval, product registration(s) and label approval(s) under reconsideration

Table 1: Active constituent approval, product registration(s) and associated label approval(s) placed under reconsideration that the APVMA is proposing to vary to allow affirmation

Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Proposed varied sample label associated with the product
Active constituent	44499	Fenitrothion	Sumitomo Chemical Australia Pty Ltd	N/A	N/A
Product	46127	Methograin Fenitrothion 1000 Insecticide	Babolna Bioenvironmental Centre Private Limited Company	46127/129275	Sample Label 1
Product	50775	Sumithion 1000EC Insecticide	Sumitomo Chemical Australia Pty Ltd	50775/0800, 50775/0401, 50775/0110, 50775/118216, 50775/128296	Sample Label 2
Product	56170	Kendon Fenitrothion 1000EC Insecticide	Kendon Plant Care Pty Ltd	56170/0702, 56170/136950	Sample Label 2
Product	66520	Grain-Guard Duo Insecticide	Sumitomo Chemical Australia Pty Ltd	66520/53810	Sample Label 3
Product	67186	Freezone Fenitrothion Insecticide	Freezone Public Health Pty Ltd	67186/55411	Sample Label 2
Product	67567	Freezone Smart Grain Dual Insecticide	Freezone Public Health Pty Ltd	67567/56362	Sample Label 3
Product	91551	Titan Dual Grain Treatment	Freezone Public Health Pty Ltd	91551/132629	Sample Label 3

Table 2: Product registration(s) and associated label approval(s) under reconsideration that the APVMA is proposing to cancel

Type	Approval or registration number	Name	Label number(s) associated with the product
Product	50774	Sumitomo Sumithion ULV Premium Grade Insecticide	50774/0500

Attachment B: Statement of Reasons

- 1) The APVMA has reconsidered the chemistry, toxicology, worker exposure, residues, trade and environmental aspects of the fenitrothion active constituent approvals, chemical product registrations containing fenitrothion and associated label approvals under Part 2, Division 4 of the Agvet Code to determine whether the
 - a) active constituents meet the safety criteria (section 5A of the Agvet Code),
 - b) chemical products meet the safety criteria (section 5A of the Agvet Code), the trade criteria (section 5C of the Agvet Code), and the efficacy criteria (section 5B of the Agvet Code),
 - c) labels meet the labelling criteria (section 5D of the Agvet Code), and
 - d) active constituents, chemical products and labels comply with the requirements prescribed by the Agvet Regulations.

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Material findings of fact and reasons for the proposed decisions

Active constituents

- 2) Section 34(1) of the Agvet Code provides that the APVMA must affirm the approval of an active constituent if, and only if, it is satisfied that the constituent:
 - a) meets the safety criteria (section 5A), and
 - b) complies with any requirement prescribed by the Agvet Regulations.
- 3) Section 34(2) of the Agvet Code provides that subsection 34(1) applies only to the extent that the APVMA decides to reconsider matters covered by this subsection.
- 4) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of fenitrothion active constituent approvals.

Consideration of whether the active constituents meet the safety criteria

- 5) Section 5A(1) of the Agvet Code provides that an active constituent meets the safety criteria if use of the active constituent, in accordance with any instructions approved or to be approved by the APVMA for the constituent or contained in an established standard:
 - a) is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a))
 - b) is not, or would not be, likely to have an effect that is harmful to human beings (section 5A(1)(b))
 - c) is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).
- 6) For the purposes of being satisfied that the active constituents meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, the APVMA has had regard to the criteria set out in section 5A(2)(a) of the Agvet Code as follows:
 - a) Section 5A(2)(a)(i) of the Agvet Code – the toxicity of the constituent and its residues, including metabolites and degradation products in relation to relevant organisms and ecosystems, including human beings.
 - I. The APVMA has considered the following information in having regard to the toxicity of the constituent fenitrothion and its residues, as detailed in the *Fenitrothion interim review report: Toxicology assessment* and the *Fenitrothion Review Technical Report*.
 - acute toxicity, short-term repeat-dose, subchronic toxicity, chronic toxicity, reproductive toxicity, developmental toxicity, genotoxicity, neurotoxicity and human exposure studies
 - the impact of impurities of toxicological concern.
 - studies of the absorption, distribution, metabolism and excretion of fenitrothion in mammals.
 - environmental toxicity studies on the effects of fenitrothion and its residues on mammals, birds, aquatic species, adult bees, soil macro-organisms, soil micro-organisms and terrestrial plants.

- II. The APVMA has considered relevant toxicity studies and set health-based guidance values, as outlined in the *Fenitrothion Review Technical Report*.
- The acceptable daily intake (ADI¹) has been set at of 0.002 mg/kg bw/d based on a no observable adverse effect level (NOAEL) of 0.2 mg/kg bw/d and an uncertainty factor of 100, derived from a 1-year dietary study in dogs.
 - The acute reference dose (ARfD²) has been set at 0.03 mg/kg bw, based on a NOAEL of 0.33 mg/kg bw/d and an uncertainty factor of 10, derived from a single dose study using human volunteers.
- III. The APVMA is satisfied that the scheduling for fenitrothion in the Standard for Uniform Scheduling of Medicines and Poisons remains appropriate based on the fenitrothion toxicological database, as set out in the *Fenitrothion Review Technical Report*.
- IV. The APVMA has set the following regulatory acceptable levels for exposure of non-target species and consider them adequately protective, as set out in the *Fenitrothion Review Technical Report*:
- mammals – 33 mg ac/kg bw for acute exposure and 2.3 mg ac/kg bw/d for chronic exposure
 - birds – 4.5 mg ac/kg bw for acute exposure and 2.3 mg ac/kg bw/d for chronic exposure
 - aquatic species – 0.095 µg ac/L for acute exposure
 - adult bees – 0.064 µg ac/bee for acute contact exposure and 0.080 µg ac/bee for acute oral exposure
 - soil macro-organisms – 12 mg ac/kg ds for acute exposure
 - soil micro-organisms – 10 mg ac/kg ds for chronic exposure
 - terrestrial plants – 500 g ac/ha for post-emergent exposure.
- V. The APVMA is satisfied that there is sufficient information to assess the role of the toxicity of the constituent fenitrothion and its metabolites in relation to relevant organisms and ecosystems, including human beings.
- VI. The worker exposure assessment detailed in the *Fenitrothion Review Technical Report* has identified acceptable levels of exposure for occupational exposure to fenitrothion, applying a margin of exposure of 100 to a point of departure (dermal exposure) of 3 mg/kg bw/d.
- VII. The residues assessment detailed in the *Fenitrothion Review Technical Report* has confirmed that the acute and chronic dietary exposure calculated using the National Estimated Dietary Intake calculation, after variation of the instructions for use of fenitrothion chemical products as proposed in paragraphs 22), 28) and 35) below, are acceptable based on the ADI of 0.002 mg/kg bw/d and the ARfD of 0.03 mg/kg bw.
- VIII. The environmental exposures assessment detailed in the *Fenitrothion Review Technical Report* has identified acceptable levels of non-target species exposure to fenitrothion based on the regulatory

¹ ADI – acceptable daily intake (for humans): a level of intake of a chemical (expressed mg/kg bw/day; milligrams per kilogram of body weight per day) that can be ingested daily over an entire lifetime without any appreciable risk to health.

² ARfD – acute reference dose (for humans): the amount of a substance in food or drinking-water, (expressed as mg/kg of body weight), that can be ingested or absorbed over 24 hours or less, without appreciable health risk.

acceptable levels for mammals, birds, aquatic species, adult bees, soil macro-organisms, soil micro-organisms and terrestrial plants set out above.

- b) Section 5A(2)(a)(ii) of the Agvet Code – the method by which the constituent is, or is proposed to be, manufactured.
- I. The APVMA has considered the method of manufacture details submitted and assessed by the APVMA as part of the original approval, and manufacturing details supplied in response to a notice issued under section 33 of the Agvet Code, for the source of active constituent.
 - II. The APVMA is satisfied that the method by which the sole fenitrothion active constituent approval is manufactured remains appropriate.
- c) Section 5A(2)(a)(iii) of the Agvet Code – the extent to which the constituent will contain impurities.
- I. Having regard to the extent to which the constituent fenitrothion will contain impurities, the APVMA has considered:
 - the specifications for fenitrothion in the Food and Agriculture Organization of the United Nations Specifications for Pesticides established in 2010 and associated evaluations, and the *Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022* (Active Constituents Standard 2022) for fenitrothion, as detailed in the *Fenitrothion Review Technical Report*;
 - the minimum purity and maximum impurity level requirements for the active constituent, as set out in the Declaration of Composition submitted to the APVMA as part of the original approval; and
 - batch analyses, certificates of analysis, a Declaration of Composition and real time and accelerated stability information for the source of fenitrothion active constituent, supplied in response to notices issued under section 33 of the Agvet Code.
 - II. The APVMA is satisfied that the minimum purity and maximum impurity levels for fenitrothion set out in the *Active Constituents Standard 2022* remain appropriate, as detailed in the *Fenitrothion Review Technical Report*. Specifically, that a maximum level of less than or equal to 5 g/kg of the toxicologically significant impurity S-methyl fenitrothion and less than or equal to 3 g/kg of the toxicologically significant impurity Tetramethyl pyrophosphorothioate (TMPP) is adequately protective.
 - III. The APVMA is satisfied that the levels of impurities in the fenitrothion active constituent are appropriate and comply with the requirements of the Active Constituents Standard 2022.
- d) Section 5A(2)(a)(iv) of the Agvet Code – whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis.
- I. The APVMA has considered batch analyses, certificates of analysis, a Declaration of Composition and real time and accelerated stability information for each approved fenitrothion active constituent, which were supplied in response to notices issued under section 33 of the Agvet Code.
 - II. The APVMA is satisfied that the chemical composition of the fenitrothion active constituent has been analysed and that the results demonstrate that the chemical composition is appropriate, as further discussed in paragraph 6(c).
- e) Section 5A(2)(a)(v) of the Agvet Code – any conditions to which its approval is, or would be, subject.

-
- I. Section 23(1)(a) of the Agvet Code provides that the approval of an active constituent is subject to the conditions prescribed by the regulations (whether or not the conditions are prescribed at the time the constituent is approved).
- The table-items under Regulation 17C(1) of the Agvet Regulations prescribes the following:
 - The active constituent must be manufactured in accordance with the composition and purity entered for that source of active constituent in the Record in accordance with paragraph 15(1)(d) of the Agvet Regulations.
 - The active constituent must be manufactured by the manufacturer whose name is entered for the active constituent in the Record in accordance with paragraph 15(1)(e) of the Agvet Regulations.
 - The active constituent must be manufactured at the site of manufacture entered for the active constituent in the Record in accordance with paragraph 15(1)(f) of the Agvet Regulations.
 - The identifying information for the holder of the approval and the nominated agent (if any), of the active constituent must be the identifying information for the holder and nominated agent (if any) entered for the active constituent in the Record.
- II. Section 23(1)(b) of the Agvet Code provides that the approval of an active constituent is also subject to any conditions imposed on the approval as the APVMA thinks appropriate.
- III. In determining whether the active constituents meet the safety criteria, the APVMA has had regard to the following conditions imposed by the APVMA in accordance with section 23(1)(b) of the Agvet Code referred to as the Agricultural Active Constituents Quality Assurance Requirements.
- *“Agricultural Active Constituents must meet Quality Assurance Requirements*
 - *A person must not Supply the Active Constituent, or cause it to be supplied, unless the Active Constituent:*
 - *complies with the APVMA Standard for the Active Constituent; and*
 - *was manufactured at a site of manufacture listed in the Record of Approved Active Constituents.*
 - *A person must at the time of Supply of a Batch of the Active Constituent to another person also supply details of the Batch Number of the Active Constituent to the person to whom the active constituent was supplied.*
 - *For the purposes of these conditions a constituent complies with the APVMA Standard if the constituent, when measured using a validated analytical method:*
 - *does not contain less than the minimum purity and/or content of the constituent as set out in the APVMA Standard; and*
 - *does not contain more than the maximum level of any impurity as set out in the APVMA Standard*

- *Definitions and Interpretation – in these conditions the following words have the following meanings:*
 - ‘APVMA Standard’ means the standard determined by the APVMA to which a constituent must comply and which is published on the APVMA website;
 - ‘Batch’ means a defined quantity of material produced in a single series of operations;
 - ‘Batch Number’ means that a distinctive combination of numbers and/or letters that specifically identifies a Batch and from which the production history can be determined;
 - ‘Supply’ has the same meaning as given to it in Section 3 of the Agvet Codes and includes the doing of those things through, or pursuant to an arrangement with another person.”
 - IV. In determining whether the active constituents meet the safety criteria, the APVMA has also had regard to conditions imposed on active constituents by the *Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021* (Conditions of Approval or Registration Order).
 - V. The APVMA is satisfied that the holder of the fenitrothion active constituent can comply with the conditions prescribed by the Agvet Regulations and the conditions of approval imposed by the *Conditions of Approval or Registration Order*.
 - VI. The APVMA is **not satisfied** that the current condition referred to as the ‘Active Constituent Quality Assurance Requirement’ remains appropriate, as it references the ‘APVMA Standard’ and indicates that this is published on the APVMA Website. The APVMA Standard has been replaced by the legislative instrument *Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022*.
- f) Section 5A(2)(a)(vi) – any relevant particulars that are, or would be, entered in the Record for fenitrothion.
- I. The particulars on the record for each approved source of the active constituent fenitrothion have been reviewed. Section 3 and 19(c) of the Agvet Code provide that the relevant particulars are the distinguishing number, any instructions for use and any other particulars prescribed by the regulations. Regulation 15(1) prescribes the following particulars for the purposes of section 19(c) of the Agvet Code: the name of the active (including the IUPAC name), the composition and purity of the active, the name of the manufacturer, the address of each site at which the active constituent is manufactured, the holder of the approval and the date of entry of these particulars.
 - II. The APVMA is **not satisfied** that the information entered into the Record accurately reflects the composition of the fenitrothion active constituent, as shown in the recent Declaration of Composition and batch analyses supplied in response to a notice issued under section 33 of the Agvet Code, nor the requirements mandated by the *Active Constituents Standard 2022* for fenitrothion.
 - III. The APVMA is satisfied that the other relevant particulars entered into the record for fenitrothion active constituent approvals remain appropriate.
- g) Section 5A(2)(a)(via) – whether the constituent conforms, or would conform, to any standard made for the constituent under section 6E to the extent that the standard relates to matters covered by subsection 5A(1).
- I. The *Active Constituents Standard 2022* is made under section 6E(1) of the Agvet Code for active constituents used in agricultural chemical products, including fenitrothion.

II. The APVMA is satisfied that approved fenitrothion active constituent meets the Active Constituents Standard 2022, as further discussed in paragraph 6)c).

h) Section 5A(2)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.

I. Regulation 8AA – the method of analysis (if any) of the chemical composition of the active constituent concerned.

- Information on the method of analysis for the chemical composition of the fenitrothion active constituent was provided in response to a notice issued under section 33 of the Agvet Code. The APVMA has considered this information and is satisfied that these methods of analysis are sufficient to accurately determine the concentration of the active constituent and relevant impurities.

i) Section 5A(2)(b) of the Agvet Code – such other matters as the APVMA thinks relevant.

- There are no other matters that the APVMA thinks relevant regarding whether fenitrothion active constituents meet the safety criteria.

7) Having had regard to the matters and findings set out above, the APVMA is **not satisfied** that the use of the fenitrothion active constituent in Table 1 in Attachment A of this notice meets the safety criteria as defined in section 5A of the Agvet Code.

Consideration of whether the active constituents can be varied to meet the safety criteria

8) Section 34A(1) of the Agvet Code provides that if the APVMA is **not satisfied** under section 34(1) but is satisfied that the relevant particulars or conditions of the approval can be varied in such a way as to allow the approval to be affirmed, the APVMA must vary the relevant particulars or conditions.

9) The APVMA has considered whether the active constituent approvals can be varied in such a way as to meet the safety criteria as defined in section 5A of the Agvet Code as follows:

- a) To address concerns raised in paragraph 6)f), when considering the matters set out in section 5A(2)(a)(vi) of the Agvet Code, the APVMA proposes to vary the Record for the fenitrothion active constituent to be consistent with the current Declaration of Composition and the requirements set out in the *Active Constituents Standard 2022* for fenitrothion.
- b) To address concerns identified in paragraph 6)e), when considering the matters set out in section 5A(2)(a)(v) of the Agvet Code, the APVMA proposes to vary the conditions referred to as the 'Active Constituent Quality Assurance Requirements' so as to substitute the reference to the 'APVMA standard' with the Active Constituent Standard 2022) as follows:

I. *"Agricultural Active Constituents must meet Quality Assurance Requirements*

- *A person must not Supply the Active Constituent, or cause it to be supplied, unless the Active Constituent:*
 - *complies with the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Active Constituent Standard 2022); and*
 - *was manufactured at a site of manufacture listed in the Record of Approved Active Constituents.*

- *A person must at the time of Supply of a Batch of the Active Constituent to another person also supply details of the Batch Number of the Active Constituent to the person to whom the active constituent was supplied.*
- *A constituent complies with the Active Constituent Standard 2022; if the constituent, when measured using a validated analytical method:*
 - *does not contain less than the minimum purity and/or content of the constituent as set out in the Active Constituent Standard 2022; and*
 - *does not contain more than the maximum level of any impurity as set out in the Active Constituent Standard 2022.*
- *Definitions and interpretation: In these conditions the following words have the following meanings:*
 - *'Batch' means a defined quantity of material produced in a single series of operations;*
 - *'Batch Number' means that a distinctive combination of numbers and/or letters that specifically identifies a Batch and from which the production history can be determined;*
 - *'Supply' has the same meaning as given to it in section 3 of the Agvet Code."*

10) The APVMA is therefore satisfied that the relevant particulars or conditions of the active constituent approval in Table 1 in Attachment A of this notice can be varied in the ways set out in paragraph 9), so that the use of the fenitrothion active constituents, in accordance with instructions approved by the APVMA for the constituents, would meet the safety criteria as defined in section 5A of the Agvet Code.

Consideration on whether the active constituents comply with any requirement prescribed by the regulations

- 11) Section 34(1)(d) of the Agvet Code provides that the APVMA must affirm an active constituent approval only if it is satisfied that the constituent complies with any requirement prescribed by the regulations.
- a) There are no other requirements prescribed by the regulations for active constituents that have not already been considered above.

Conclusion of consideration of active constituents

- 12) Section 34A(1) of the Agvet Code provides that if the APVMA is **not satisfied** that the active constituent currently meets the safety criteria or complies with any requirement prescribed by the regulations, but is satisfied that the relevant particulars or conditions of the approval can be varied in such a way as to allow the approval to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 13) The APVMA is satisfied that the relevant particulars and conditions of the fenitrothion active constituent approval in Table 1 in Attachment A of this notice can be varied to meet the safety criteria and comply with the requirements prescribed by the regulations as follows:
- a) Vary the Record so that the composition of the fenitrothion active constituent is consistent with the recent Declaration of Composition and the requirements set out in the *Active Constituents Standard 2022* for fenitrothion, as set out in paragraphs 9)a) of this statement of reasons.

- b) Vary the condition of approval referred to as the 'Active Constituent Quality Assurance Requirements', as set out in paragraph 9)b) of this statement of reasons.

Agricultural chemical products

- 14) Section 34(1)(b) and (d) of the Agvet Code provides that the APVMA must affirm the registration for a chemical product if, and only if, it is satisfied that the product:
 - a) meets the safety criteria (section 5A),
 - b) meets the efficacy criteria (section 5B),
 - c) meets the trade criteria (section 5C), and
 - d) complies with any requirement prescribed by the Agvet Regulations.
- 15) Section 34(2) of the Agvet Code provides that subsection 34(1) applies only to the extent that the APVMA decides to reconsider matters covered by the subsection.
- 16) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of fenitrothion chemical product registrations.
 - a) For chemical products containing a combination of active constituents, the APVMA has decided to reconsider the matters covered by subsections 34(1)(b) and (d) only to the extent that the chemical product contains the active constituent fenitrothion. The impact of the second active constituent S-methoprene on relevant chemical product registrations (66520, 67567 and 91551) will be based on previous assessments of this active constituent.

Consideration of whether the registered agricultural products meet the safety criteria

- 17) Section 5A(1) of the Agvet Code provides that a chemical product meets the safety criteria if use of the product, in accordance with any instructions approved or to be approved by the APVMA for the product or contained in an established standard:
 - a) is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a)).
 - b) is not, or would not be, likely to have an effect that is harmful to human beings (section 5A(1)(b)).
 - c) is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).
- 18) For the purpose of being satisfied that the fenitrothion chemical products meet the safety criteria, the APVMA has had regard to the criteria set out in section 5A(3)(a) as follows:
 - a) Section 5A(3)(a)(i) – the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings:
 - I. The APVMA has considered the following information in having regard to the toxicity of fenitrothion chemical products and their residues, as detailed in the *Fenitrothion Review Technical Report*:

- Information on the toxicity of the constituent fenitrothion and its residues, as set out in paragraph 6)a) and the references therein, including the fenitrothion health-based guidance values and regulatory acceptable levels for exposure of non-target species.
 - The impact of impurities of toxicological concern in formulated chemical products.
 - The impact of any formulation excipients, and where relevant the active constituent S-methoprene, on the toxicity of the fenitrothion chemical products to relevant organisms and ecosystems, including human beings.
- II. The APVMA has assessed and considers the following health-based guidance values for the constituent fenitrothion to be adequately protective of human health, as set out in the *Fenitrothion Review Technical Report*.
- ADI of 0.002 mg/kg bw/d based on a NOAEL of 0.2 mg/kg bw/d and an uncertainty factor of 100, derived from a one-year dietary study in dogs; and
 - ARfD of 0.03 mg/kg bw based on a NOAEL of 0.33 mg/kg bw and an uncertainty factor of 10, derived from a single dose study using human volunteers.
- III. The APVMA is satisfied that applying a margin of exposure of 100 to a point of departure of 3 mg/kg bw/day for dermal exposure (based on the NOAEL for inhibition of blood cholinesterases from a 21-day rabbit dermal exposure study) is adequately protective for use of fenitrothion chemical products by occupational handlers, as set out in the *Fenitrothion Review Technical Report*.
- IV. The APVMA is satisfied that applying a margin of exposure of 100 to a point of departure of 0.2 mg/kg bw/d for oral and inhalation exposure (based on the NOAEL from a one-year dietary toxicity study in dogs) is adequately protective, though as set out in the *Fenitrothion Review Technical Report*, exposure to occupational handlers during mixing/loading/application and re-entry is principally via the dermal route.
- V. The APVMA is satisfied that exposure to fenitrothion below the regulatory acceptable levels set out in the *Fenitrothion Review Technical Report*, and paragraph 6)a)IV of this statement of reasons, is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment.
- VI. The APVMA is satisfied that there is sufficient information on the toxicity of the impurities of toxicological concern S-methyl fenitrothion and TMPP, and the origin of these impurities in both technical fenitrothion and formulated products, to establish appropriate specifications for chemical products containing fenitrothion, as set out in the *Fenitrothion Review Technical Report*.
- VII. The APVMA is satisfied that there is sufficient information to assess the impact of formulation excipients and, where relevant, the active constituent S-methoprene on the toxicity of fenitrothion chemical products and their residues in relation to relevant organisms and ecosystems, including human beings.
- VIII. The APVMA is therefore satisfied that the toxicity of fenitrothion chemical products and their residues, including metabolites and degradation products, are sufficiently defined to allow assessment of the risks to relevant organisms and ecosystems, including human beings, and the adequacy of the instructions for use for fenitrothion chemical products.
- b) Section 5A(3)(a)(ii) of the Agvet Code – the relevant poison classification of the product under the law in force in this jurisdiction.

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- I. Fenitrothion is listed in the Standard for the Uniform Scheduling of Medicines and Poisons for all preparations under Schedule 6 to the *Therapeutic Goods (Poisons Standard—February 2024) Instrument 2024*. The Poisons Standard is a Legislative Instrument for the purposes of the *Legislation Act 2003*. The Poisons Standard may also be cited as the Standard for the Uniform Scheduling of Medicines and Poisons.
- II. The APVMA is satisfied that the current fenitrothion scheduling remains appropriate based on the assessment of available toxicology data as outlined in the *Fenitrothion Review Technical Report*.
- c) Section 5A(3)(a)(iii) – how the product is formulated.
- I. The APVMA has considered the existing registration records in having regard to how the chemical products containing fenitrothion are formulated. Chemical products containing fenitrothion are formulated as follows:
- 1230 g/L fenitrothion as an ultra-low volume liquid,
 - 1000 g/L fenitrothion as an emulsifiable concentrate,
 - 600 g/L fenitrothion and 60 g/L of S-methoprene as an emulsifiable concentrate.
- II. The APVMA has also considered the levels of toxicological impurities that may be present in formulated fenitrothion products. As further discussed in the *Fenitrothion Review Technical Report*:
- S-methyl fenitrothion levels can increase during storage of both technical fenitrothion and formulated products, particularly when stored at elevated temperature or in the presence of other formulation excipients such as anionic surfactants. The level of water and pH of formulated products can also contribute to the degradation of fenitrothion.
 - Alternatively, TMPP can be formed during the manufacture of technical fenitrothion but is not likely to increase during storage of technical fenitrothion or formulated products.
- III. The APVMA is **not satisfied** that there is sufficient information to demonstrate that chemical products containing fenitrothion are formulated in a way that ensures impurities of toxicological concern will not exceed acceptable levels.
- d) Section 5A(3)(a)(iv) of the Agvet Code – the composition and form of the constituents of the product.
- I. The APVMA has considered the following in regard to the composition and form of the constituents of chemical products containing fenitrothion:
- batch analyses, certificates of analysis, a current Declaration of Composition and real time and accelerated stability information for the sole fenitrothion active constituent, supplied in response to notices issued under section 33 of the Agvet Code
 - existing registration records, including the manufacturer's specification of formulation excipients and, where relevant, Declarations of Composition for the active constituent S-methoprene.
- II. Based on the assessment of this information, the APVMA is satisfied that the composition and form of the constituents of fenitrothion chemical products are appropriate.
- e) Section 5A(3)(a)(v) of the Agvet Code – any conditions to which its registration is, or would be, subject.

- I. In accordance with section 23(1)(a) of the Agvet Code, the agricultural product registrations are currently subject to the conditions prescribed in items 1, 2, 5, 6 and 7 of the table in regulation 17C(2) of the Agvet Regulations.

Note: Items 3 and 4 of this do not apply to agricultural product registrations as these are prescribed under regulation 59(1) for the purposes of section 120A of the Agvet Code (see regulation 17C(3)).

- II. In accordance with section 23(1)(a) of the Agvet Code, products are also subject to the conditions of registration prescribed in section 6 of the *Conditions of Approval or Registration Order*. Section 6 of this Order prescribes the following conditions:
- The chemical product must not be supplied if the manufacture of the chemical product contravenes, or fails to comply with, any manufacturing law of the country, or part of the country, in which it is manufactured.
 - The holder of the registration must, on written request by the APVMA and within 28 days after the request is given, provide the APVMA with written evidence that the manufacture of the chemical product does not contravene, or fail to comply with, any manufacturing law of the country, or part of the country, in which it is manufactured.
- III. The APVMA is satisfied that holders of fenitrothion chemical products can comply with the conditions prescribed by the Agvet Regulations and the *Conditions of Approval or Registration Order*.
- IV. Agricultural product registrations are also subject to the additional conditions imposed by the APVMA under section 23(1)(b) of the Agvet Code referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements' as follows:
- *"Agricultural Products must meet the Agricultural Products Active Constituent Quality Assurance Requirements"*
 - *Manufacture of active constituent – the registrant must not supply the chemical product, or cause it to be supplied, unless the active constituent contained in the chemical product:*
 - *complies with the APVMA Standard for that active constituent; and*
 - *was manufactured at a site of manufacture listed in the Record of approved active constituents.*
 - *Analysis results – the registrant must not supply the chemical product or cause it to be supplied unless the registrant has in its possession prior to the supply of each batch of the chemical product, batch analysis results that show:*
 - *the active constituent contained in the chemical product complied with the APVMA Standard for that active constituent;*
 - *if there is an APVMA Standard for a constituent in the chemical product that is not an active constituent, the constituent complied with the APVMA Standard for that constituent; and*
 - *the batch number of the active constituent contained in the chemical product.*
 - *Records – the registrant must, at or prior to the supply of a batch of the chemical product by the registrant or by another person on behalf of the registrant, make or have in its possession, a record that contains the following information:*

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- *The name of the chemical product.*
 - *The APVMA product number of the chemical product.*
 - *If the chemical product was imported into Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.*
 - *If the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.*
 - *The date of importation into, or manufacture in, Australia as the case may be.*
 - *The batch number of the chemical product from which the supply was made.*
 - *The quantity of the chemical product that constitutes the batch*
 - *The batch number, and name and address of the manufacturer of the active constituent contained in the chemical product*
 - *The registrant must produce, or cause to be produced, to the APVMA any batch analysis results or record within 10 working days of the request having been made by the APVMA, or other such period as determined by the APVMA.*
 - *The registrant must keep, or cause to be kept, any batch analysis results or record for 2 years after any batch analysis results or record is made.*
 - *Possession of batch analysis results and records – for the purposes of these conditions, batch analysis results or records are in the possession of the registrant if batch analysis results or records are:*
 - *in the possession of the registrant; or*
 - *in the possession of another person pursuant to an arrangement with the registrant.*
 - *Compliance with the Standard – for the purposes of these conditions, a constituent complies with the APVMA Standard if the constituent, when measured using a validated analytical method does not contain:*
 - *less than the minimum purity and/or content of the constituent as set out in the APVMA Standard for the Constituent*
 - *more than the maximum level of any impurity as set out in the APVMA Standard.*
 - *Definitions and Interpretation – in these conditions the following words have the following meanings:*
 - *'APVMA Standard' means the standard determined by the APVMA to which a constituent contained in chemical products must comply and which is published on the APVMA website.*
 - *'Batch' means a defined quantity of material produced in a single series of operations.*

- *'Batch number' means that a distinctive combination of numbers and/or letters that specifically identifies a batch and from which the production history can be determined.*
 - *'Batch analysis results' means the results of analysis from each batch of the constituent that include:*
 - 1. *the name of the manufacturer and the manufacturing site address*
 - 2. *the date of the analysis*
 - 3. *the batch number and date of manufacture of the batch*
 - 4. *the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the APVMA Standard for the constituent*
 - 5. *full details and validation data for the analytical method(s) used for the determination of the constituent purity (linearity and precision) and/or the content and/or the isomer ratio and/or the specified impurities (linearity, precision, accuracy and limit of quantitation if relevant).*
 - 6. *If analytical methods and validation data have been previously provided to the APVMA, a reference to that submission will suffice.*
 - *'Record' means a document in written or electronic form that contains the particulars set out in paragraph (3) and which is readily accessible for the purposes of Part 9 of the Agvet Code (Enforcement).*
 - *'Supply' has the same meaning as given to it in section 3 of the Agvet Code and includes the doing of those things through, or pursuant to an arrangement with, another person."*
- V. The APVMA is **not satisfied** that the current condition referred to as 'Agricultural Products Quality Assurance Requirements', to which each agricultural product registration is subject, remains appropriate, as the condition references the 'APVMA Standard' available on the APVMA Website. The 'APVMA Standard' has been replaced by the legislative instrument *Active Constituents Standard 2022*. The condition also references a 'registrant' which is not defined within the Agvet Code or related legislation, rather than referring to the 'holder'.
- f) Section 5A(3)(a)(vi) of the Agvet Code – any relevant particulars that are, or would be, entered in the Register for the product:
- I. The relevant particulars required to be entered in the Register for a chemical product are set out by section 20(1)(c) of the Agvet Code and prescribed by Regulation 16 of the Agvet Regulations as: the distinguishing number, any instructions for the use, the distinguishing name, the constituents, the concentration of each constituent, the composition and purity of each active constituent (if possible), the formulation type, the net contents, the holder of the registration, the name of each manufacturer, the address of each site at which the chemical product is manufactured, the nominated agent (if relevant) and the date of entry of these particulars.
 - II. The APVMA is **not satisfied** that the instructions for use of fenitrothion chemical products would not pose an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues for the following reason:

- The instructions for the use of chemical products containing fenitrothion may result in exposure of occupational handlers at levels that exceed the margin considered adequately protective, excluding the instructions for use on bulk stored grains, as set out in the *Fenitrothion Review Technical Report*.
- III. The APVMA is **not satisfied** that when used according to the instructions for use, fenitrothion chemical products would not be likely to have an effect that is harmful to human beings for the following reasons:
- There is insufficient information to assess the level of fenitrothion residues that are expected from the use of chemical products containing fenitrothion in accordance with instructions in the following situations:
 - Use on pasture for control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub.
 - Use in soybeans (particularly forage) for control of locust and grasshopper pests (spur-throated locust, migratory locust, wingless grasshopper, Australian plague locust, yellow winged locust and small plague grasshopper).
 - Use in apples, cabbages, cherries, grapes, lettuce and tomatoes for control of locust and grasshopper pests.
 - The use of fenitrothion products according to the instructions for use, including the withholding periods and number of applications per season, for fenitrothion chemical products may result in unacceptable levels of finite residues in food crops and crops that may be fed to animals, as set out in the *Fenitrothion Review Technical Report*.
- IV. The APVMA is **not satisfied** that the use of fenitrothion chemical products in accordance with instructions would not be likely to have an unintended effect that is harmful to non-target species, based on the following findings set out in the *Fenitrothion Review Technical Report*:
- Fenitrothion is toxic to birds and use of chemical products on cereals, soybeans, forage crops, lucerne, pasture, pasture seed crops, apples, cherries, grapes, tomatoes, lettuce and cabbage in accordance with currently approved instructions posed an unacceptable risk to birds.
 - Fenitrothion is toxic to mammals and use of chemical products in the following situations in accordance with currently approved instructions pose an unacceptable risk to mammals:
 - use on pasture and pasture seeds crops,
 - use on soybeans, forage crops, lettuce and cabbage at BBCH 40-49,
 - use on tomatoes at BBCH 10-49 or during fruiting, and
 - use on apples, cherries and grapes up to BBCH 19.
 - Fenitrothion is toxic to bees and use of chemical products in accordance with currently approved instructions pose an unacceptable risk to foraging bees, excluding uses where exposure to bees is not likely to occur such as use in poultry houses or for stored grain protection.
 - Fenitrothion is toxic to birds and its use in accordance with currently approved instructions may result in unacceptable exposure. The use of fenitrothion products in poultry houses in accordance with

currently approved instructions poses an unacceptable risk to poultry. The instructions '*Remove birds from fowl houses before spraying. Avoid spraying drinking water and feed troughs,*' are required to mitigate the risks to birds, though it is noted that this use pattern also poses an unacceptable risk to occupational handlers as set out in paragraphs 18)f)II. and 22)a) of this statement of reasons.

- V. The APVMA is satisfied that use of fenitrothion chemical products in accordance with instructions would not have an unintended effect that is harmful to target crops, based on the history of use of fenitrothion chemical products and the fact that the Adverse Experience Reporting Program of the APVMA has not received any adverse experience reports in relation to in-crop damage or off target crop damage, as set out in the *Fenitrothion Review Technical Report*.
- VI. The APVMA is satisfied that, following variation to the instructions for use of fenitrothion chemical products as proposed in paragraphs 22), 28) and 35) below, no additional instructions for use are required to ensure that spray drift exposure for natural aquatic areas, pollinators, vegetation, bystander and livestock areas does not exceed the regulatory acceptable levels, as set out in the *Fenitrothion Review Technical Report*.
- VII. The APVMA is satisfied that all relevant particulars that are entered in the Register for fenitrothion chemical products, except for the instructions for use of the product, remain acceptable.
- g) Section 5A(3)(a)(via) of the Agvet Code – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1).
- I. The *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* prescribes the maximum allowable variation of the concentration of constituents in registered chemical products from the nominal quantities recorded in the Register for active constituents and non-active constituents. The APVMA is satisfied that agricultural chemical products containing fenitrothion conform to the requirements listed in this Standard.
- II. The APVMA is proposing to make a standard under section 6E for fenitrothion chemical products as an outcome of the reconsideration, which includes limits on fenitrothion content, S-methyl fenitrothion content, TMPP content, pH range and water content as set out in the *Fenitrothion Review Technical Report*. It is noted that the process for making a Standard made under section 6E(1) of the Agvet Code is set out in regulation 8AF of the Agvet Regulations and will be undertaken separately to this proposed regulatory decision.
- h) Section 5A(3)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.
- I. Regulation 8AB(1)(a) of the Agvet Regulations prescribes the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product.
- The APVMA has considered the existing registration records in having regard to the method of analysis of the chemical composition and form of the constituents of fenitrothion chemical products.
 - The APVMA is **not satisfied** that the method of analysis documented in existing registration records for fenitrothion chemical products include methods to determine the level of S-methyl fenitrothion, TMPP and water impurities, nor the pH range.
- II. Regulations 8AB(1)(b) and (c) of the Agvet Regulations prescribe, respectively, that for a product manufactured in Australia—whether each step in the manufacture of the product complies, or will comply, with the manufacturing principles and the Australian GMP Code, and for a product manufactured outside

Australia—whether each step in the manufacture of the product complies, or will comply, with a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code.

- In accordance with regulation 8AB(2), regulations 8AB(1)(b) and (c) of the Agvet Regulations does not apply to agricultural chemical products as these are prescribed under regulation 59(1) for the purposes of section 120A of the Agvet Code.

III. Regulations 8AB(1)(d), (e) and (f) of the Agvet Regulations do not apply based on the use patterns of fenitrothion products.

19) Under section 5A(3)(b) of the Agvet Code, the APVMA may have regard to one or more of the following matters in determining whether a chemical product meets the safety criteria:

- a) Section 5A(3)(b)(i) of the Agvet Code – the acceptable daily intake of each constituent contained in the product;
 - I. The APVMA considered the toxicity of fenitrothion, as set out in the *Fenitrothion Review Technical Report*, and is satisfied that the acceptable daily intake of 0.002 mg/kg bw/d remains appropriate.
- b) Section 5A(3)(b)(ii) of the Agvet Code – any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under section 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under section 82(4) of that Act.
 - I. There has not been a dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991*.
- c) Section 5A(3)(b)(iii) of the Agvet Code – whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves.
 - I. The APVMA is **not satisfied** that sufficient trials or laboratory experiments have been carried out to determine the residues of the fenitrothion chemical products expected from use in the following situations, as detailed in the *Fenitrothion Review Technical Report* and paragraph 18)f)III above.
 - Use on pasture for control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub.
 - Use in soybeans (particularly forage) for control of locust and grasshopper pests (Spur-throated locust, Migratory locust, Wingless grasshopper, Australian plague locust, yellow winged locust and Small plague grasshopper).
 - Use in apples, cabbages, cherries, grapes, lettuce and tomatoes for control of locust and grasshopper pests.
 - II. The APVMA is satisfied that sufficient trials or laboratory experiments have been carried out to determine an appropriate maximum residues limit (MRL) for the use of fenitrothion on remaining approved crops, and that these results show the residues of fenitrothion chemical products will not be greater than the maximum limits set, as detailed in the *Fenitrothion Review Technical Report*.
- d) Section 5A(3)(b)(iv) of the Agvet Code – the stability of the product.

- I. In considering the stability of the chemical products, the APVMA has had regard to the information submitted as part of the original registrations and in response to notices issued under section 33 of the Agvet Code, and the specifications and associated evaluations outlined in the FAO Specifications and Evaluations for Agricultural Pesticides for Fenitrothion. As further discussed in the *Fenitrothion Review Technical Report*:
 - The consideration of that information indicates that concentrations of impurities of toxicological concern, particularly S-methyl fenitrothion, have the potential to significantly increase during prolonged storage or storage at elevated temperatures.
 - Water is considered a relevant impurity in EC and ULV fenitrothion chemical products as it has the potential to reduce product stability, as does a pH of below 3 or greater than 6.
 - II. The APVMA does not have sufficient stability information to determine whether fenitrothion content, S-methyl fenitrothion content, TMPP content, pH range and water content will remain at acceptable levels, as set out in the proposed specifications in the *Fenitrothion Review Technical Report*.
 - III. The APVMA is therefore **not satisfied** of the stability of fenitrothion chemical products.
- e) Section 5A(3)(b)(v) of the Agvet Code – the specifications for containers for the product.
- I. There were no concerns identified in relation to the specifications for containers for fenitrothion chemical products. Fenitrothion chemical product registrations are also subject to the conditions of registration prescribed under regulation 18(2) related to specifications for containers for the product, which the APVMA is satisfied that the holders can comply with. Therefore, the APVMA is satisfied that specifications for containers of the product remain appropriate.
- f) Section 5A(3)(b)(vi) of the Agvet Code – such other matters as it thinks relevant.
- I. The APVMA has conducted a dietary exposure assessment for fenitrothion chemical products, following variation to the instructions for use of fenitrothion chemical products as proposed in paragraphs 22), 28) and 35) and as set out in the *Fenitrothion Review Technical Report*.
 - II. The APVMA is satisfied that, following variation to the instructions for use of fenitrothion chemical products as proposed in paragraphs 22), 28) and 35), acute and chronic dietary exposure to fenitrothion calculated using the National Estimated Dietary Intake calculation will not exceed the ADI and ARfD for fenitrothion and is not likely to have an effect that is harmful to human beings.

20) Having had regard to the matters and findings set out above, the APVMA is **not satisfied** that the use of chemical products containing fenitrothion meets the safety criteria as defined in section 5A of the Agvet Code.

Consideration of whether registered chemical products can be varied to meet the safety criteria

- 21) Section 34A(1) of the Agvet Code provides that if the APVMA is **not satisfied** under section 34(1) but is satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 22) The APVMA has considered whether registered chemical products can be varied in such a way as to meet the safety criteria set out in Section 5A(1) as follows:

- a) To address concerns identified in paragraph 18)f) and 19)c) when considering the criteria in sections 5A(3)(a)(vi) and 5A(3)(b)(iii) of the Agvet Code:

I. The APVMA proposes to vary the instructions for use of fenitrothion chemical products listed in Table 1 in Attachment A of this notice as follows, as detailed in the *Fenitrothion Review Technical Report*:

- Remove the following uses for which the risks to occupational handler exposure could not be adequately mitigated:
 - Use in grain storage structures for the control of stored grain pests, using various hand-held application methods including backpack sprayers and both manually and mechanically pressurised hand wands.
 - Use in broiler poultry houses for the control of lesser mealworm using mechanically pressurised handgun application.
 - Foliar application to corn at rates at or above 400 g ac/ha.
 - Foliar application to grapes at rates at or above 300g ac/ha.
- Remove the following uses for which the risks to human beings from exposure through residues in food could not be adequately assessed and/or mitigated:
 - Use on pasture for control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub.
 - Use in soybeans (particularly forage) for control of locust and grasshopper pests (spur-throated locust, migratory locust, wingless grasshopper, Australian plague locust, yellow winged locust and small plague grasshopper).
 - Use in apples, cabbages, cherries, grapes, lettuce and tomatoes for control of locust and grasshopper pests as above.
- Remove the following uses for which the risks to non-target species could not be adequately mitigated:
 - Use in cereals grains, fodder and forage for the control of locust and grasshopper pests.
 - Use in lucerne for the control of Sitona weevil.
 - Use on pasture for control of pasture cockchafer, corbie, winter corbie, underground grass grub and oxycanus grub.
 - Use in soybeans (particularly forage) for control of locust and grasshopper pests (spur-throated locust, migratory locust, wingless grasshopper, Australian plague locust, yellow winged locust and small plague grasshopper).
 - Use in apples, cabbages, cherries, grapes, lettuce and tomatoes for control of locust and grasshopper pests as above.
- Add the environmental protection statement 'Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.'

- II. The APVMA is satisfied that, following variation to the instructions for use of fenitrothion chemical products as proposed in paragraph 22)a)I. above, sufficient trials or laboratory experiments have been carried out to determine an appropriate maximum residues limit (MRL) for the remaining uses of fenitrothion chemical products, and that these results show the residues of fenitrothion chemical products will not be greater than the maximum limits set, as detailed in the *Fenitrothion Review Technical Report*.
- III. The APVMA proposes to remove all current uses approved for the product listed in Table 2 in Attachment A of this notice, due to safety risks that could not be adequately mitigated as set out in paragraphs 22)a)I. of this statement of reasons and the *Fenitrothion Review Technical Report*. Therefore, the APVMA is **not satisfied** that the instructions for use of the registered chemical product containing fenitrothion listed in Table 2 in Attachment A of this notice can be varied to mitigate risks associated with use of the product.
- b) To address concerns raised in paragraphs 18)c), 19)d) and 18)h)I. when considering criteria in sections 5A(3)(a)(iii) and 5A(3)(b)(iv) of the Agvet Code and Regulation 8AB(1)(a) of the Agvet Regulations:
- I. The APVMA does not have sufficient information to demonstrate that fenitrothion chemical products will contain acceptable levels of impurities as outlined out in the proposed specifications listed in the *Fenitrothion Review Technical Report*, that the stability of fenitrothion chemical products is such that the products contain acceptable levels of impurities when stored, nor that appropriate methods of analysis have been used to determine these.
- II. Therefore, the APVMA proposes to vary the conditions of registration to add the following condition:
- *'Within one year of publication of the section 34AC notice of the fenitrothion final regulatory decision, you are required to provide batch analysis data, product storage stability data and validation data to demonstrate compliance with product specifications. This data should include analysis of fenitrothion content, S-methyl fenitrothion content, tetramethyl phosphorothioate (TMPP) content, water content and pH range.'*
 - For the purposes of this condition, this information could be supplied to the APVMA confidentially from the manufacturer and the data required would include:
 - Batch analysis data from one batch of formulated fenitrothion chemical product.
 - Storage stability data that is generated in accordance with the APVMA guideline 'Generation of storage stability data for agricultural chemical products' available at <https://www.apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/chemistry-manufacture-part-2/storage-stability>.
 - Details of the validated analytical methods used to determine the content of fenitrothion, S-methyl fenitrothion and TMPP, and validation data generated in accordance with the APVMA guideline 'Validation of analytical methods for active constituents and agricultural products', available at <https://www.apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/chemistry-manufacture-part-2/validation>.
- c) To address concerns identified in paragraph 18)e)V when considering the criteria in section 5A(3)(a)(v) of the Agvet Code, the APVMA proposes to vary the conditions referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements' so as to substitute the reference to the 'APVMA standard' with the *Active Constituent Standard 2022* as follows:

- *“Agricultural Products must meet the Agricultural Products Active Constituent Quality Assurance Requirements*
 - *Manufacture of active constituent – the holder must not supply the chemical product, or cause it to be supplied, unless the active constituent contained in the chemical product:*
 - *complies with the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Active Constituent Standard 2022) for that active constituent; and*
 - *was manufactured at a site of manufacture listed in the Record of approved active constituents.*
 - *Analysis results – the holder must not supply the chemical product or cause it to be supplied unless the holder has in its possession prior to the supply of each batch of the chemical product, batch analysis results that show:*
 - *the active constituent contained in the chemical product complied with the Active Constituent Standard 2022 for that active constituent;*
 - *if there is a standard for a constituent in the chemical product that is listed in the Active Constituent Standard 2022, that the constituent complies with the Active Constituent Standard 2022 for that constituent; and*
 - *the batch number of the active constituent contained in the chemical product.*
 - *Records – the holder must, at or prior to the supply of a batch of the chemical product by the holder or by another person on behalf of the holder, make or have in its possession, a record that contains the following information:*
 - *The name of the chemical product.*
 - *The APVMA product number of the chemical product.*
 - *If the chemical product was imported into Australia by another person on behalf of, or pursuant to an arrangement with the holder, the name and address of that person.*
 - *If the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the holder, the name and address of that person.*
 - *The date of importation into, or manufacture in, Australia as the case may be.*
 - *The batch number of the chemical product from which the supply was made.*
 - *The quantity of the chemical product that constitutes the batch.*
 - *The batch number, and name and address of the manufacturer of the active constituent contained in the chemical product.*
 - *The holder must produce, or cause to be produced, to the APVMA any batch analysis results or record within 10 working days of the request having been made by the APVMA, or other such period as determined by the APVMA.*

- *The holder must keep, or cause to be kept, any batch analysis results or record for 2 years after any batch analysis results or record is made.*
- *Possession of batch analysis results and records – for the purposes of these conditions, batch analysis results or records are in the possession of the holder if batch analysis results or records are:*
 - *in the possession of the holder; or*
 - *in the possession of another person pursuant to an arrangement with the holder.*
- *Compliance with the Standard – for the purposes of these conditions, a constituent complies with the Active Constituent Standard 2022 if the constituent, when measured using a validated analytical method does not contain:*
 - *less than the minimum purity and/or content of the constituent as set out in the Active Constituent Standard 2022 for the Constituent; and*
 - *more than the maximum level of any impurity as set out in the Active Constituent Standard 2022.*
- *Definitions and Interpretation – in these conditions the following words have the following meanings:*
 - *‘Batch’ means a defined quantity of material produced in a single series of operations.*
 - *‘Batch number’ means that a distinctive combination of numbers and/or letters that specifically identifies a batch and from which the production history can be determined.*
 - *‘Batch analysis results’ means the results of analysis from each batch of the constituent that include:*
 1. *the name of the manufacturer and the manufacturing site address*
 2. *the date of the analysis*
 3. *the batch number and date of manufacture of the batch*
 4. *the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the Active Constituent Standard 2022 for the constituent*
 5. *full details and validation data for the analytical method(s) used for the determination of the constituent purity (linearity and precision) and/or the content and/or the isomer ratio and/or the specified impurities (linearity, precision, accuracy and limit of quantitation if relevant)*
 6. *if analytical methods and validation data have been previously provided to the APVMA, a reference to that submission will suffice.*
 - *‘Record’ means a document in written or electronic form that contains the particulars set out in paragraph (3) and which is readily accessible for the purposes of Part 9 of the Agvet Code (Enforcement).*

- *‘Supply’ has the same meaning as given to it in section 3 of the Agvet Code and includes the doing of those things through, or pursuant to an arrangement with, another person.*

23) Having had regard to the matters and findings set out above, the APVMA is:

- a) satisfied that the relevant particulars and conditions of the registered chemical products in Table 1 of Attachment A of this notice can be varied in the ways set out in paragraph 22) to meet the safety criteria.
- b) **not satisfied** that the relevant particulars or conditions of the registered chemical product in Table 2 of Attachment A of this notice can be varied to meet the safety criteria.

Consideration of whether registered chemical products meet the efficacy criteria

24) Section 5B(1) of the Agvet Code provides that a chemical product meets the efficacy criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA for the product or contained in an established standard, is, or would be, effective according to criteria determined by the APVMA by legislative instrument.

- a) Fenitrothion chemical products are not contained in an established standard.
- b) The criteria for agricultural chemical products are listed in Part 2 of the Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014, including:
 - I. criteria based on type of product, as set out in clause 3; and
 - II. criteria based on demonstrated effectiveness, as set out in clause 4.

25) Section 5B(2) of the Agvet Code provides that for the purposes of being satisfied as to whether a chemical product meets the efficacy criteria, the APVMA must have regard to the following:

- a) Section 5B(2)(a) – whether any trials or laboratory experiments have been carried out to determine the efficacy of the product and, if so, the results of those trials or experiments.
 - I. The APVMA has considered the assessments of previously submitted information for the registration and variation of chemical products containing fenitrothion. The APVMA is satisfied that this information continues to support the efficacy of these chemical products.
- b) Section 5B(2)(b) – any conditions to which its registration is, or would be, subject;
 - I. The APVMA has considered the conditions of registration which apply to chemical products containing fenitrothion. The APVMA is satisfied that no additional conditions of registration are required to satisfy the efficacy criteria.
- c) Section 5B(2)(c) – any relevant particulars that are, or would be, entered in the Register for the product;
 - I. The APVMA has considered the relevant particulars that are entered in the Register for chemical products containing fenitrothion.
 - II. The variations to the instructions for use proposed to satisfy the safety criteria (as set out in paragraph 22)) are within existing use patterns. The APVMA is satisfied that these variations will not impact the efficacy of these products.

- III. The fenitrothion chemical products (56170 and 67186) include instructions for grain protection from stored product insect pests (including lesser grain borer) using a compulsory tank mix with Sumithrin Synergised Grain Protectant (50 g/L phenothrin 20:80 and 425 g/L piperonyl butoxide). This product is no longer registered by the APVMA, nor is any product with equivalent active ingredients. Therefore, the APVMA is **not satisfied** that the use of the fenitrothion chemical products (56170 and 67186) for protection from stored product insect pests (including lesser grain borer) remains efficacious.
 - IV. The fenitrothion/S-methoprene chemical products (66520, 67567 and 91551) lack adequate instructions as they do not define a period for which cereal grains are protected from infestation by stored product insect pests. The, APVMA is **not satisfied** that the use of the fenitrothion chemical products (66520, 67567 and 91551) for protection against stored product insect pests (including lesser grain borer) remain efficacious indefinitely as indicated by the current instructions for use.
 - V. The APVMA is satisfied that all remaining relevant particulars entered in the Register remain appropriate with regards to the efficacy of the products.
- d) Section 5B(2)(ca) – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);
- I. There are no standards made under section 6E which are relevant to the efficacy of chemical products containing fenitrothion.
- e) Section 5B(2)(d) any matters prescribed by the regulations.
- I. There are no regulations which are relevant to the efficacy of chemical products containing fenitrothion.

26) Having considered the above relevant matters in relation to whether registered chemical products meet the efficacy criteria, the APVMA is:

- a) **not satisfied** that the use of fenitrothion chemical products (56170 and 67186) for grain protection from stored product insect pests (including lesser grain borer), which requires a compulsory tank mix with a type of product no longer registered by the APVMA, meets the efficacy criteria as defined in section 5B of the Agvet Code.
- b) **not satisfied** that the use of fenitrothion/S-methoprene chemical products (66520, 67567 and 91551), which lack a defined protection period, meet the efficacy criteria as defined in section 5B of the Agvet Code.
- c) satisfied that the use of fenitrothion chemical products, except for the situation outlined in paragraph 26)a) and b) above, meets the efficacy criteria as set out in section 5B of the Agvet Code, based on the criteria for demonstrated effectiveness for agricultural chemical products determined by the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014*.

Consideration of whether registered chemical products can be varied to meet the efficacy criteria

- 27) Section 34A(1) of Agvet Code provides that if the APVMA is **not satisfied** under section 34(1) but is satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 28) The APVMA has considered whether the instructions for use for registered fenitrothion products can be varied in such a way as to meet the efficacy criteria set out in Section 5B(2) as follows:
- a) To address concerns identified in paragraph 26)a), when considering the criteria in section 5B(2)(b) of the Agvet Code, the APVMA proposes to remove the use for grain protection from stored product insect pests (including lesser grain borer), which requires a compulsory tank mix with a type of product no longer registered by the APVMA, from relevant fenitrothion chemical products (56170 and 67186).
 - b) To address concerns identified in paragraph 26)b), when considering the criteria in section 5B(2)(b) of the Agvet Code, the APVMA proposes to add a protection period of 'up to 9 months' to the instructions for use for grain protection from stored product insect pests (including lesser grain borer), based on previous assessments of fenitrothion products where tank mixes with S-methoprene are recommended, to the relevant fenitrothion/S-methoprene products (66520, 67567 and 91551)
- 29) Having had regard to the matters and findings set out above, the APVMA is satisfied that the relevant particulars or conditions of the fenitrothion chemical products (56170 and 67186) in the situation outlined in paragraph 26)a) and the fenitrothion chemical products (66520, 67567 and 91551) in the situation outlined in paragraph 26)b) can be varied in the ways set out in paragraph 28) to meet the efficacy criteria as set out in section 5B of the Agvet Code.

Consideration of whether registered chemical products meet the trade criteria

- 30) Section 5C(1) of the Agvet Code provides that a chemical product meets the trade criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA or contained in an established standard, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.
- 31) Section 5C(3) of the Agvet Code provides that for the purposes of the operation of this Code in relation to a particular chemical product, the APVMA is required to have regard to the matters set out in subsections (1) and (2) only to the extent prescribed by the regulations; or if there are no such regulations—to the extent that the APVMA thinks the matters are relevant.
- a) Regulation 8AD(2) of the Agvet Regulations provides that if it can be reasonably expected that a chemical product will be used in relation to a crop or animal, a product of which might be provided to a place outside Australia; or a crop that will be fed to animals a product of which might be provided to a place outside Australia then the APVMA must have full regard to the matters set out in section 5C(1) and (2) of the Agvet Code.
 - I. Chemical products containing fenitrothion are approved for use on crops that are considered a major export commodity including cereal grains, oaten hay (i.e. forage crops), grapes, pome fruit (i.e. apples) and stone fruit (i.e. cherries). It is therefore reasonably expected that a product of these crops might be provided to a place outside of Australia.
 - II. Chemical products containing fenitrothion are approved for use on bulk stored cereal grain, including uses as a structural or surface treatment, which are considered a major export commodity. It is further expected that fenitrothion contamination of stored oilseeds and pulses, also considered a major export commodity, could occur as grain storage is not segregated. It is reasonably expected that a product of these bulk stored cereal grains, oilseeds or pulses might be provided to a place outside of Australia.

- III. Chemical products containing fenitrothion are approved for use on pastures and crops that can be used as stockfeed for mammalian and poultry animals. Mammalian and poultry animals and their products (including cattle, cattle dairy products, pigs, sheep, goats, poultry and eggs) are considered major export commodities. It is therefore reasonably expected that a product of these animals might be provided to a place outside of Australia.

32) For the purposes of being satisfied whether fenitrothion chemical products meet the trade criteria as described in section 5C(1) of the Agvet Code, the APVMA has considered the criteria set out in section 5C(2) for the use patterns listed in paragraph 38) and has determined as follows:

- a) Section 5C(2)(a) – any conditions to which its registration is, or would be, subject.
- I. The APVMA has considered the conditions of registration which apply to chemical products containing fenitrothion. The APVMA is satisfied that no additional conditions of registration are required to satisfy the trade criteria.
- b) Section 5C(2)(b) – any relevant particulars that are, or would be, entered in the Register for the product.
- I. The relevant particulars entered in the Register for each registered product containing fenitrothion have been reviewed, including the instructions for use for the chemical products.
- The APVMA does not have sufficient information to assess the level of fenitrothion residues that are expected from the use of chemical products containing fenitrothion on apples, cherries or grapes, as set out in the *Fenitrothion Review Technical Report*. Therefore, the instructions for use may result in finite residues of fenitrothion that exceed residues tolerance requirements for importing countries.
 - The instructions for use of chemical products containing fenitrothion on cereal grains crops or as a post-harvest treatment on stored cereal grains may result in finite residues of fenitrothion that exceed residues tolerance requirements for importing countries, as set out in the *Fenitrothion Review Technical Report*.
 - The instructions for use of chemical products containing fenitrothion on bulk stored cereal grain may result in contamination of oilseeds and pulses and finite residues that exceed residues tolerance requirements for importing countries, as set out in the *Fenitrothion Review Technical Report*.
 - The instructions for use of chemical products containing fenitrothion on crops that may be grazed or fed to animals, are not expected to result in finite residues in mammalian or poultry animal products that exceed residues tolerance requirements for importing countries.
- II. The APVMA is **not satisfied** that the instructions for use entered into the Register for fenitrothion chemical products will not unduly prejudice trade or commerce between Australia and places outside Australia.
- c) Section 5C(2)(ba), whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);
- I. There are no standards made under section 6E that are relevant to the risk to trade or commerce between Australia and places outside Australia.
- d) Section 5C(2)(c), any matters prescribed by the regulations.

- I. The APVMA has had regard to Regulation 8AD, as outlined in paragraph 31)a) above, in considering the risk to trade or commerce between Australia and places outside Australia, posed by the use of chemical products containing fenitrothion.

33) Having considered the above relevant matters in relation to whether registered chemical products meet the trade criteria, the APVMA is **not satisfied that** the use of chemical products containing fenitrothion, in accordance with instructions approved for major export commodities, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.

Consideration of whether registered chemical products can be varied to meet the trade criteria

34) Section 34A(1) of Agvet Code provides that if the APVMA is **not satisfied** under section 34(1) but is satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.

35) The APVMA has considered whether the instructions for use for registered fenitrothion products can be varied in such a way as to meet the trade criteria set out in Section 5C(1) as follows:

- a) To address concerns identified in paragraph 32)b), when considering the criteria in section 5C(2)(b) of the Agvet Code, the APVMA proposes to vary the instructions for use of chemical products containing fenitrothion as follows, as detailed in the *Fenitrothion Review Technical Report*:

- I. Remove the uses on apples, cherries and grapes, for which the risk to trade or commerce between Australia and places outside Australia could not be adequately mitigated. It is noted that the APVMA has also proposed to remove uses on oaten hay (i.e. forage crops) due to environmental safety risks that could not be adequately mitigated, as set out in paragraph 22)a)I of this statement of reasons.
- II. Add the following trade advice statement for chemical products approved for use in bulk stored cereal grain, noting the risks to international trade have been managed effectively by the grains industry for many years, with well-established practices in place and that consultation with the grains industry will be undertaken on this proposed regulatory decision.
 - *'EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain or using this product.'*

36) Having had regard to the matters and findings set out above, the APVMA is satisfied that the relevant particulars or conditions of chemical products containing fenitrothion can be varied in the ways set out in paragraph 35) above, so that so that the chemical products containing fenitrothion meet the trade criteria.

Consideration of whether registered chemical products comply with any requirement prescribed by the regulations

37) Regulation 16 of the Agvet Regulations prescribes the particulars of a chemical product which must be recorded in the Register pursuant to section 20(1)(c) of the Agvet Code.

- a) The APVMA has had regard to the particulars recorded in the Register for each chemical product containing fenitrothion and is satisfied that the particulars prescribed by regulation 16 of the Agvet Regulations and recorded in the Register for fenitrothion products remain appropriate.

- 38) Regulation 17C of the Agvet Regulations prescribes conditions to which the registration of a chemical product is subject:
- a) The APVMA is satisfied that holders of fenitrothion chemical products can comply with the conditions prescribed by regulation 17C of the Agvet Regulations.
- 39) Regulation 18 of the Agvet Regulations prescribes conditions of registration relating to the containers for chemical products:
- a) The APVMA is satisfied that fenitrothion chemical products comply with the conditions prescribed by regulation 18 of the Agvet Regulations.
- 40) Regulation 42(3) of the Agvet Regulations prescribes standards for chemical products to which chemical products must conform in accordance with section 87(1)(a) of the Agvet Code. In accordance with Regulation 42(3)(b):
- a) The APVMA has made the *Active Constituents Standard 2022* under section 6E(1) of the Agvet Code. The APVMA is satisfied that the fenitrothion active constituent in Table 1 in Attachment A conforms to the fenitrothion entry in the Active Constituents Standard 2022, as outlined in the *Fenitrothion Review Technical Report*.
 - b) The APVMA has made the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* under section 6E of the Agvet Code. The APVMA is satisfied that agricultural chemical products containing fenitrothion conform to the requirements listed in the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022*.
- 41) Having had regard to the matters and findings set out above, the APVMA is satisfied that fenitrothion chemical products meet the requirements prescribed by the regulations.

Conclusion of consideration of registered chemical products

- 42) Section 34A(1) of the Agvet Code provides that if the APVMA is **not satisfied** under section 34(1) but is satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 43) The APVMA is satisfied that fenitrothion chemical product registrations listed in Table 1 in Attachment A of this notice comply with any requirements prescribed by the regulations, and that the relevant particulars or conditions can be varied so that they meet the safety criteria, efficacy criteria and trade criteria. Therefore, APVMA proposes to vary the relevant particulars and conditions as follows:
- a) Vary the instructions for use as set out in paragraphs 22), 28) and 35) of this statement of reasons and the *Fenitrothion Review Technical Report*.
 - b) Add the condition of registration set out in paragraph 22)b)II on each fenitrothion product registration.
 - c) Vary the condition of registration referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements', previously imposed on each fenitrothion chemical product registration, as set out in paragraph 22)c) above.
- 44) The APVMA is **not satisfied** that the relevant particulars or conditions of the fenitrothion chemical product registration listed in Table 2 in Attachment A of this notice can be varied in such a way as to allow the registration to be affirmed for the following reasons:
- a) The APVMA is **not satisfied** that the safety risks associated with all current approved uses of this chemical product can be adequately mitigated, as set out in the *Fenitrothion Review Technical Report* and paragraph 22)a)III of this statement of reasons.
 - b) The APVMA is therefore **not satisfied** that the relevant particulars or conditions of this chemical product can be varied meet the safety criteria.
- 45) Section 34AA(1) of the Agvet Code provides that if the APVMA does not affirm the registration, it must suspend or cancel the registration.

Labels for chemical products

- 46) Section 34(1)(c) and (d) of the Agvet Code provides that the APVMA must affirm the approval of a product label if, and only if, it is satisfied that the label:
- a) meets the labelling criteria and
 - b) complies with any requirement prescribed by the regulations.
- 47) Subsection 34(2) of the Agvet Code provides that subsection 34(1) applies only to the extent that the APVMA decides to reconsider matters covered by this subsection.
- 48) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of fenitrothion label approvals.
- a) For chemical products containing a combination of active constituents, the APVMA has decided to reconsider the matters covered by subsections 34(1)(c) and (d) only to the extent that they relate to the fact that the

chemical product contains the active constituent fenitrothion. The impact of the second active constituent S-methoprene on relevant chemical product registrations (66520, 67567 and 91551) will be considered based on previous assessments of this active constituent.

Consideration of whether approved labels for chemical products meet the labelling criteria and comply with any requirement prescribed by the regulations

49) Section 5D(1) of the Agvet Code provides that a label for containers for a chemical product 'meets the labelling criteria' if the label contains adequate instructions relating to the following as are appropriate:

- a) the circumstances in which the product should be used (section 5D(1)(a));
- b) how the product should be used (section 5D(1)(b));
- c) the times when the product should be used (section 5D(1)(c));
- d) the frequency of the use of the product (section 5D(1)(d));
- e) the withholding period after the use of the product (section 5D(1)(e));
- f) the re-entry period after the use of the product (section 5D(1)(f));
- g) the disposal of the product when it is no longer required (section 5D(1)(g));
- h) the disposal of containers of the product (section 5D(1)(h));
- i) the safe handling of the product and first aid in the event of an accident caused by the handling of the product (section 5D(1)(i));
- j) any matters prescribed by the regulations (section 5D(1)(j)). In this regard, regulation 8AE(1) of the Agvet Regulations prescribes the following:
 - I. Regulation 8AE(1)(a) – for a chemical product that is a veterinary chemical product, the duration of the treatment.
 - II. Regulation 8AE(1)(b) – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.
 - III. Regulation 8AE(1)(c) – the appropriate signal words (if any) required by the current Poisons Standard.
 - IV. Regulation 8AE(1)(d) – for a chemical product that is a date-controlled product, the storage of containers for the product.
 - V. Regulation 8AE(1)(e) – any other matter determined by the APVMA CEO under regulation 8AE(2).

50) Regulation 17 of the Agvet Regulations prescribes the particulars of a label approval which must be recorded in the relevant APVMA file pursuant to sections 21(a), 6(2)(c) and 21(c)(iva) of the Agvet Code

51) Subdivision 2.1.6 of the Agvet Regulations (incorporating regulations 18B to 18J) prescribe the conditions of approval to which labels approvals are subject.

52) Section 5D(2) of the Agvet Code provides that for the purposes of being satisfied as to whether the current approved labels for containers for fenitrothion chemical products meet the labelling criteria, the APVMA must have regard to the criteria set out in section 5D(2). The APVMA has considered these criteria as follows:

- a) Section 5D(2)(a) of the Agvet Code – any conditions to which its approval is, or would be, subject.
 - I. The condition of approval prescribed by regulation 18E requires that if a labelling standard has not been made by the APVMA, then the label must comply with the requirements of either the *Veterinary Labelling Code*, if the product is a veterinary chemical product, or the *Agricultural Labelling Code*, if the product is an agricultural chemical product.
 - The APVMA has reviewed the current label approvals for fenitrothion agricultural chemical products and is **not satisfied** that the approved labels have adequate instruction to comply with the current *Agricultural Labelling Code*.
 - II. The APVMA is satisfied that fenitrothion labels approvals are compliant with all remaining conditions to which they are subject, including those prescribed by regulations 18B to 18D and 18F to 18J of the Agvet Regulations, and that no further conditions of approval are required.
- b) Section 5D(2)(b) of the Agvet Code – any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label.
 - I. In relation to the circumstances in which the product should be used (section s5D(1)(a)):
 - The APVMA is satisfied that the crop/situation and pest statements contained on approved labels remain appropriate for products formulated as combination S-methoprene/fenitrothion grain protectants (66520, 67567 and 91551).
 - The APVMA is **not satisfied** that the crop/situation and pest statements contained on the approved labels of all other products (44499, 46127, 50775, 56170 and 67186) are appropriate, as detailed in the *Fenitrothion Review Technical Report* and paragraphs 18)f), 25)c) and 32)b) of this statement of reasons.
 - II. In relation to how the product should be used (section s5D(1)(b)):
 - The APVMA is satisfied that the instructions for how products should be used, in relation to application rate and method, contained on approved labels remain adequate for combination S-methoprene/fenitrothion products approved only for use only as grain protectants (66520, 67567 and 91551).
 - The APVMA is **not satisfied** that the instructions for how products should be used, in relation to application rate and method of application, contained on approved labels for all other products (44499, 46127, 50775, 56170 and 67186) are adequate, as detailed in the *Fenitrothion Review Technical Report*. If the variations proposed in paragraphs 22), 28) and 35) to mitigate unacceptable safety, efficacy and trade risks are implemented, the APVMA is satisfied that the instructions related to application rate and method of application would be adequate for the remaining grain protectant uses on relevant products (44499, 46127, 50775, 56170, 66520, 67186, 67567 and 91551).
 - The APVMA is **not satisfied** that the instructions on how products should be used contained on all label approvals (44499, 46127, 50775, 56170, 66520, 67186, 67567 and 91551) are adequate to mitigate the environmental safety risks, as detailed in the *Fenitrothion Review Technical Report*.

III. In relation to the times when the product should be used (section s5D(1)(c)):

- The APVMA is satisfied that the instructions on the times where products should be used contained on approved labels remain adequate for combination S-methoprene/fenitrothion products approved only for use as grain protectants (66520, 67567 and 91551).
- The APVMA is **not satisfied** that the instructions on the times when products should be used contained on approved labels are adequate for all other fenitrothion products (44499, 46127, 50775, 56170 and 67186), as detailed in the *Fenitrothion Review Technical Report*. If the variations proposed in paragraphs 22), 28) and 35) to mitigate unacceptable safety, efficacy and trade risks are implemented, the APVMA is satisfied that the instructions on times when the product should be used would be adequate for the remaining grain protectant uses on relevant products (44499, 46127, 50775, 56170, 66520, 67186, 67567 and 91551).

IV. In relation to the frequency of the use of the product (section s5D(1)(d)).

- The APVMA is satisfied that the instructions for the frequency of use of the product contained on approved labels remain adequate for combination S-methoprene/fenitrothion approved only for use as grain protectants (66520, 67567 and 91551).
- The APVMA is **not satisfied** that the instructions for the frequency of use of the product contained on approved labels are adequate for all other fenitrothion products (44499, 46127, 50775, 56170 and 67186), as detailed in the *Fenitrothion Review Technical Report*. If the variations proposed in paragraphs 22), 28) and 35) to mitigate unacceptable safety, efficacy and trade risks are implemented, the APVMA is satisfied that the instructions for the frequency of use of the product are adequate for the remaining grain protectant uses on relevant products (44499, 46127, 50775, 56170, 66520, 67186, 67567 and 91551).

V. In relation to the withholding period after the use of the product (section s 5D(1)(e):

- The APVMA is **not satisfied** that that withholding periods contained on approved labels are adequate for fenitrothion products (44499, 46127, 50774, 50775, 56170, 66520, 67186, 67567 and 91551), as detailed in the *Fenitrothion Review Technical Report*. If the variations proposed in paragraphs 22), 28) and 35) to mitigate unacceptable safety, efficacy and trade risks are implemented, the post-harvest treatment of cereal grains is the only remaining supported use for which the APVMA is **not satisfied** that the withholding period is adequate.

VI. The re-entry period after the use of the product (section s5D(1)(f)):

- Re-entry period instructions are not required for combination S-methoprene/fenitrothion products that are approved only for use as grain protectants (66520, 67567 and 91551).
- The APVMA is **not satisfied** that the re-entry period instructions contained on approved labels for all other products (44499, 46127, 50775, 56170 and 67186) are adequate, as detailed in the *Fenitrothion Review Technical Report*. If the variations proposed in paragraphs 22), 28) and 35) to mitigate unacceptable safety, efficacy and trade risks are implemented, the label approvals do not require re-entry period instructions as the grain protection uses are the only remaining supported use.

VII. The disposal of the product when it is no longer required (section s5D(1)(g):

- The APVMA is **not satisfied** that disposal instructions for product when it is no longer required contained on approved labels are adequate, noting the best practice guide in the *Agricultural Labelling* and that it may be an offence to bury fenitrothion chemical products in some jurisdictions.
- VIII. The disposal of containers for the product (section s5D(1)(h):
- The APVMA is **not satisfied** that disposal instructions for containers of product when they are no longer required contained on approved labels are adequate, noting the best practice guide in the *Agricultural Labelling Code* and that it may be an offence to bury fenitrothion chemical products in some jurisdictions.
- IX. The safe handling of the product and first aid in the event of an accident caused by the handling of the product (section s5D(1)(i).
- The APVMA is satisfied that the first aid instructions contained on the approved label for all fenitrothion products remain appropriate.
 - The APVMA is **not satisfied** that the safety directions contained on the approved label for the fenitrothion product listed in Table 2 of Appendix A are adequate, as they are not consistent with the requirements set out in the *Fenitrothion Review Technical Report*. However, as outlined in paragraph 44), no uses of this product are supported and the APVMA is **not satisfied** that the relevant particulars or conditions of this product can be varied in such a way to allow the registration to be affirmed.
 - The APVMA is satisfied that the safety directions contained on the approved labels for the fenitrothion products listed in Table 1 of Attachment A of this notice remain appropriate.
- X. Any matters prescribed by the regulations (section s5D(1)(j).
- Regulation 8AE(1)(a) of the Agvet Regulations – for a chemical product that is a veterinary chemical product, the duration of the treatment.
 - Chemical products containing fenitrothion are not veterinary chemical products.
 - Regulation 8AE(1)(b) of the Agvet Regulations – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.
 - The APVMA is **not satisfied** that there are appropriate instructions on current label approvals to prevent undue prejudice to trade or commerce between Australia and places outside of Australia, as detailed in the *Fenitrothion Review Technical Report* and paragraph 32)b) of this Statement of Reasons.
 - Regulation 8AE(1)(c) of the Agvet Regulations – the appropriate signal words (if any) required by the current Poisons Standard.
 - Fenitrothion preparations are listed in the current Poison Standard which is specified in Schedule 6 to the *Therapeutic Goods (Poisons Standard—February 2024) Instrument 2024*. The Poisons Standard is a Legislative Instrument for the purposes of the *Legislation Act 2003*. The Poisons Standard may also be cited as the Standard for the Uniform Scheduling of Medicines and Poisons. The required signal word is 'POISON' and the label also requires the cautionary phrase 'KEEP OUT OF REACH OF CHILDREN'.

- The APVMA is satisfied that the appropriate signal words required by the current Poisons Standard are included on current approved labels.
 - Regulation 8AE(1)(d) of the Agvet Regulations – for a chemical product that is a date-controlled product, the storage of containers for the product.
 - In regulation 4 of the Agvet Regulations, a date-controlled chemical product is defined as each veterinary chemical product and an agricultural chemical product specified in Schedule 1 of the Agvet Regulations.
 - Chemical products containing fenitrothion are not date-controlled chemical products, as they are not veterinary chemical products and are not agricultural chemical products listed in Schedule 1 of the Agvet Regulations.
 - Regulation 8AE(1)(e) of the Agvet Regulations – any other matter determined by the APVMA CEO under regulation 8AE(2).
 - There are no other matters determined by the APVMA CEO under regulation 8AE(2) in relation to fenitrothion label approvals.
- c) Section 5D(2)(c) of the Agvet Code – whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1).
- I. There is no standard made for fenitrothion label approvals under section 6E.
- d) Section 5D(2)(d) of the Agvet Code – any matters prescribed by the regulations.
- I. Regulation 17 of the Agvet Regulations prescribes particulars for labels.
- The APVMA has reviewed the prescribed particulars for labels as defined by regulation 17 of the Agvet Regulations and is satisfied that the relevant particulars recorded in the APVMA file remain appropriate.
- II. Regulation 18E requires that if a labelling standard has not been made by the APVMA, then the label must comply with the requirements of either the *Veterinary Labelling Code*, if the product is a veterinary chemical product, or the *Agricultural Labelling Code*, if the product is an agricultural chemical product.
- The APVMA has reviewed the current label approvals for fenitrothion agricultural chemical products and is **not satisfied** that the approved labels have adequate instruction to comply with the current *Agricultural Labelling Code*.
- III. The APVMA is satisfied that fenitrothion labels approvals are compliant with all other matters prescribed by the regulations; specifically, the conditions to which label approvals are subject as prescribed by regulations 18B to 18J (inclusive).
- 53) The APVMA is **not satisfied** that current approved labels for containers for fenitrothion chemical products contain adequate instructions relating to the components set out in paragraph 49) above.
- 54) The APVMA is satisfied that, excluding the instructions contained on the label, all other particulars that are recorded in the relevant APVMA file remain appropriate.

Consideration of whether approved labels for chemical products can be varied as to meet the labelling criteria and comply with any requirement prescribed by the regulations

- 55) Section 34A(1) of the Agvet Code provides that if the APVMA is **not satisfied** under section 34(1) but is satisfied that the relevant particulars or conditions of the approval can be varied in such a way as to allow the approval to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 56) The APVMA has considered whether the labels approved for containers for fenitrothion chemical products can be varied in such a way as to meet the labelling criteria and comply with any requirement prescribed by the regulations as follows:
- a) To address concerns identified in paragraph 52)b), when considering the criteria in section 5D(2)(b) of the Agvet Code, the APVMA finds as follows:
- I. In relation to the concerns identified in paragraph 52)b)I regarding the instructions for the circumstances in which a product should be used section s5D(1)(a):
- The APVMA is satisfied that the label approvals listed in Table 1 of Attachment A of this notice can be varied to remove the crop/situation and pest statements, and all other associated instructions, for uses where the safety, efficacy and trade risks could not be adequately mitigated, as set out in the *Fenitrothion Review Technical Report* and paragraphs 22), 28) and 35) of this statement of reasons.
 - The APVMA is **not satisfied** that label approvals listed in Table 2 of Attachment A can be varied in such a way that there will be adequate instructions in relation to the circumstances in which the products should be used, as the APVMA is **not satisfied** that the safety risks can be adequately mitigated for any uses of these products, as set out in the *Fenitrothion Review Technical Report* and paragraph 44) of this statement of reasons.
- II. In relation to the concerns identified in paragraphs 52)b)II regarding the instructions for how the product should be used (section s5D(1)(b)), the APVMA proposes to vary the approved labels listed in Table 1 of Attachment A of this notice to include the following environmental protection statement, as set out in the *Fenitrothion Review Technical Report* and reflected in the proposed labels in Attachment D of this notice:
- *'Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.'*
- III. In relation to the concerns identified in paragraph 52)b)V regarding the instructions for the withholding period after the use of the product (section s5D(1)(e)), the APVMA proposes to vary the relevant label approvals listed in Table 1 of Attachment A of this notice to include the following withholding periods, as set out in the *Fenitrothion Review Technical Report* and reflected in the proposed labels in Attachment D of this notice:
- For cereal grain treated with 6ppm fenitrothion (including combination S-methoprene/fenitrothion products) *'Not required when used as directed.'*
 - For cereal grain treated with 12 ppm fenitrothion – *DO NOT use for processing into food for human consumption or stock food within 13 weeks of treatment.'*
- IV. In relation to the concerns identified in paragraphs 52)b)VII and 52)b)VIII regarding the disposal of the product when it is no longer required (section s5D(1)(g) and disposal of containers for the product

(s5D(1)(h), respectively, the APVMA proposes to vary the relevant label approvals listed in Table 1 to include the following disposal instructions:

- *'Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty packaging or unused product to an approved waste management facility. If an approved waste management facility is not available, dispose of empty container or unused product in compliance with relevant local, state or territory government regulations. DO NOT burn empty containers or product.'*

V. In relation to concerns identified in paragraph 52)b)X regarding the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia, the APVMA proposes to vary the approved labels listed in Table 1 of Attachment A of this notice to include the following trade advice statement, as set out in *Fenitrothion Review Technical Report* and reflected in the proposed labels in Attachment D of this notice:

- *'EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain or using this product.'* can be added to all remaining product labels.

VI. For the label approvals listed in Table 1 in Attachment A of this notice, the APVMA is proposing to make the variations outlined above so that it can be satisfied that the instructions regarding the matters listed in section 5D(1) of the Agvet Code, as appropriate, are adequate.

b) In relation to the concerns identified when considering the criteria in sections 5D(2)(a) and 5D(2)(d) of the Agvet Code related to compliance with the *Agricultural Labelling Code*, the APVMA is satisfied that label approvals listed in Table 1 in Attachment A will comply with the *Agricultural Labelling Code* if they are varied in the ways set out in paragraph 56)a) above, and in the additional ways set out below, as reflected in the proposed labels in Attachment D of this notice.

I. The required statement *'an anticholinesterase compound'* can be added to labels, when required.

II. The instructions for storage agricultural chemical products, where the container is impermeable to water, can be varied when required to *'Store in the closed, original container in a cool, well-ventilated area. DO NOT store for prolonged periods in direct sunlight.'*

III. The instructions for spillage, where present, can be varied to the general instruction *'For spill management, refer to instructions listed in the Safety Data Sheet.'*

57) Section 34A(3) of the Agvet Code provides that if the variation would affect instructions for use on a label, the APVMA must not make the variation until it has consulted each co-ordinator designated for a jurisdiction and taken into account any recommendations made by the co-ordinators.

a) The APVMA will consult with each co-ordinator designated for a jurisdiction and take into account any recommendations made by the co-ordinators prior to making any variations that would affect instructions for use on a label, noting the proposals set out in this statement of reasons may be amended after consideration of all consultation submissions.

- 58) The APVMA is satisfied that the relevant particulars of the label approvals listed in Table 1 in Attachment A can be varied in the ways set out in paragraph 56), so that the labels contain adequate instructions so as to meet the labelling criteria relating to the components set out in paragraph 49) and comply with any requirement prescribed by the regulations.
- 59) The APVMA is **not satisfied** that the relevant particulars or conditions of the label approvals in Table 2 in Attachment A can be varied so that labels contain adequate instructions so as to meet the labelling criteria relating to the components set out in paragraph 49).

Conclusion on consideration of approved labels for chemical products

- 60) Section 34A(1) of the Agvet Code provides that if the APVMA is **not satisfied** under section 34(1) but is satisfied that the relevant particulars or conditions of the approval can be varied in such a way as to allow the approval to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 61) The APVMA is satisfied that the relevant particulars of the label approvals listed in Table 1 in Attachment A can be varied to meet the labelling criteria and comply with any requirement prescribed by the regulations, as set out in paragraph 56) of this statement of reasons and as reflected in the proposed labels in Attachment D of this notice.
- 62) The APVMA is **not satisfied** that the relevant particulars or conditions of the fenitrothion chemical products registrations listed in Table 2 can be varied in such a way as to allow the registration to be affirmed for the following reasons:
- a) The APVMA is **not satisfied** that the label approvals can be varied in such a way that there will be adequate instructions in relation to the circumstances in which these products should be used, as set out in paragraph 56)a) of this statement of reasons.
- 63) Section 34AA(1) of the Agvet Code provides that if the APVMA does not affirm the approval, it must suspend or cancel the approval.

Overall conclusions

- 64) For the purposes of sections 34(1), 34A(1) and 34AA(1) of the Agvet Code, and having regard to the matters set out above, the APVMA has determined that:
- a) regarding fenitrothion active constituent approvals, the APVMA is:
- I. **not satisfied** that the fenitrothion active constituent approvals meet the safety criteria or comply with any requirement prescribed by the regulations; and
 - II. satisfied that the particulars or conditions of the fenitrothion active constituent approval listed in Table 1 in Attachment A can be varied in such a way (as set out in paragraphs 9) and 13) of the statement of reasons) to allow the active constituent approvals to be affirmed.
- b) Regarding fenitrothion chemical product registrations, the APVMA is:
- I. **not satisfied** that the fenitrothion chemical product registrations meet the safety criteria, trade criteria or efficacy criteria
 - II. satisfied that fenitrothion chemical product registrations meet any requirements prescribed by the regulations

- III. satisfied that the particulars and conditions of fenitrothion chemical product registrations listed in Table 1 in Attachment A can be varied in such a way (as set out in paragraphs 22), 28) and 35) of the statement of reasons) to allow the chemical product registrations to be affirmed
- IV. **not satisfied** that the particulars of fenitrothion chemical product registrations listed in Table 2 in Attachment A can be varied in such a way to allow the chemical product registrations to be affirmed, for the reasons set out in paragraph 23)b) of the statement of reasons.

c) Regarding fenitrothion label approvals, the APVMA is:

- I. **not satisfied** that the label approvals for containers of fenitrothion chemical products meet the labelling criteria and comply with any requirement prescribed by the regulations
- II. satisfied that the particulars of fenitrothion label approvals listed Table 1 in Attachment A can be varied in such a way (as set out in paragraph 56) of the statement of reasons and as reflected in the proposed labels in Attachment D) to allow the label approvals to be affirmed
- III. **not satisfied** that the particulars or conditions of fenitrothion label approvals listed in Table 2 in Attachment A can be varied in such a way to allow the label approvals to be affirmed, for the reasons as set out in paragraph 62) of the statement of reasons.

65) Consequently, pursuant to section 34A(1) of the Agvet Code, the APVMA proposes to:

- a) vary the relevant particulars and conditions of fenitrothion active constituent approvals listed in Table 1 in Attachment A of this notice, in a manner set out in paragraphs 9) and 13) of the statement of reasons, to allow affirmation under section 34(1) of the Agvet Code
- b) vary the relevant particulars and conditions of the chemical product registrations listed in Table 1 in Attachment A in a manner set out in paragraphs 22), 28) and 35) of the statement of reasons, to allow affirmation under section 34(1) of the Agvet Code
- c) vary the relevant particulars of the label approvals listed in Table 1 in Attachment A in the manner set out in paragraph 56) of the statement of reasons, and as reflected in the proposed labels in Attachment D of this notice, to allow affirmation under section 34(1) of the Agvet Code.

66) Further, pursuant to section 34AA(1) of the Agvet Code, the APVMA proposes to:

- a) cancel the fenitrothion chemical product registration listed in Table 2 in Attachment A, as the APVMA is **not satisfied** that the relevant particulars or conditions of the registrations can be varied in such a way as to allow the registrations to be affirmed
- b) cancel the label approval listed in Table 2 in Attachment A, as the APVMA is **not satisfied** that the relevant particulars or conditions of the approvals can be varied in such a way as to allow the approvals to be affirmed.

Preliminary consideration of a phase-out period

67) The APVMA has considered whether a phase-out period could be applied to existing fenitrothion approvals and registrations in the event of any final decision to suspend, cancel or vary any fenitrothion approvals or registrations.

68) If, having considered all submissions received in response to this section 34AB notice, the APVMA proceeds to suspend or cancel any fenitrothion active constituent approvals, chemical product registrations or label approvals,

this will be done in accordance with the Agvet Code and in particular Division 5 of Part 2 of that Code. Division 5 of Part 2 includes requirements regarding the giving of notice of suspensions and cancellations and the inclusion of instructions relating to possession, custody or use of the constituent or product (section 45A). This Division also includes provision in relation to the issuing of a permit to possess, have custody of or use the constituent or product, or product as labelled (section 45B).

- 69) If, having considered all submissions received in response to this section 34AB notice, the APVMA proceeds to vary any fenitrothion label approvals, a determination can be made under section 81(3)(c) of the Agvet Code to permit the supply of registered chemical products with labels that were approved at an earlier time for a period allowed by the APVMA.
- 70) While the APVMA has not yet made any final decision to suspend, cancel or vary any fenitrothion approvals or registrations, the preliminary view of the APVMA is that, in the event that a decision to cancel, suspend or vary is made, any section 45B permit could have the maximum duration of 12 months and any determination under section 81(3)(c) of the Agvet Code may allow supply of relevant chemical products with the earlier approved label also for a 12 month period.

Attachment C: Information on which the reasons are based

The information on which the reasons in the draft statement of reasons is based is set out below:

- 1) Information provided in response to notices issued under section 32(1) of the Agvet Code, including notices issued on 5 July 1996 and 1 July 2015.
- 2) Information provided in response to notices issued under section 33 of the Agvet Code on 31 August 2023 and 22 January 2024.
- 3) Submissions received in response to notices published in the Gazette on 2 May 1995, 19 July 1996, 2 January 2001 and 6 April 2004.
- 4) APVMA records for approval of relevant active constituents and registration of the relevant products, including information submitted at the time of approval and registration.
- 5) Other information as detailed in the following assessment reports:
 - a) Fenitrothion Review Technical Report (APVMA 2024, available at <https://www.apvma.gov.au/chemicals-and-products/chemical-review/listing/fenitrothion/fenitrothion-review-technical-report>).
 - b) Residues of fenitrothion in exported canola (APVMA 2007, available at www.apvma.gov.au/node/15251)
 - c) Fenitrothion Draft Review Report (APVMA 2004, available at www.apvma.gov.au/node/15286)
 - d) Fenitrothion Interim Review Report: Summary (APVMA 1999, available at www.apvma.gov.au/node/15281)
 - e) Fenitrothion interim review report: Chemical and agricultural assessment (APVMA 1999, available at www.apvma.gov.au/node/15256).
 - f) Fenitrothion interim review report: Toxicology assessment (APVMA 1999, available at www.apvma.gov.au/node/15261).
 - g) Fenitrothion interim review report: OHS assessment (APVMA 1999, available at www.apvma.gov.au/node/15266).
 - h) Fenitrothion interim review report: Environmental assessment (APVMA 1999, available at www.apvma.gov.au/node/15271).
 - i) Fenitrothion interim review report: Residues (APVMA 1999, available at www.apvma.gov.au/node/15276).
- 6) The relevant provisions of the Agvet Code, particularly those set out below.

Table A1: Agricultural and Veterinary Chemicals Code Act 1994

Section	Section heading
3	Definitions
5A	Definition of <i>meets the safety criteria</i>
5B	Definition of <i>meets the efficacy criteria</i>

Section	Section heading
5C	Definition of <i>meets the trade criteria</i>
5D	Definition of <i>meets the labelling criteria</i>
6E	The APVMA may make standards
19	How approval of active constituent takes place
20	How registration of chemical product takes place
21	How approval of label takes place
23	Conditions of approval or registration
31	APVMA may reconsider an approval or registration
33	APVMA may require information, reports, results or samples
34	Reconsideration by APVMA
34A	Varying relevant particulars or conditions to allow affirmation
34AA	Suspension or cancellation
34AB	Notice of proposed decision

Table A2: Agricultural and Veterinary Chemicals Code Regulations 1995

Regulation	Regulation heading
8AA	Safety criteria – active constituents
8AB	Safety criteria – chemical products
8AD	Trade criteria
8AE	Labelling criteria
15	Particulars of approved active constituents to be recorded
16	Particulars of registered chemical products to be recorded
17	Particulars for label
17C	Conditions of approval or registration – active constituents and chemical products
18	Conditions of registration of chemical products – containers
18E	Labelling standards and requirements

Table A3: Other legislative instruments under the *Agricultural and Veterinary Chemicals Code Act 1994*

Legislative instruments
<u>Agricultural and Veterinary Chemical Code (Efficacy Criteria) Determination 2014</u>
<u>Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021</u>
<u>Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022</u>

- 10) *Therapeutic Goods (Poisons Standard – February 2024)* (i.e. the Standard for the Uniform Scheduling of Medicines and Poisons)
- 11) The Agricultural Labelling Code as published on the APVMA website
- 12) Health based guidance values as published on the APVMA website
- 13) The fenitrothion specifications and associated evaluations included in the Food and Agriculture Organization of the United Nations Specifications for Pesticides

Attachment D: Proposed labels for fenitrothion chemical products

Fenitrothion 1000 g/L emulsifiable concentrate

Sample Label 1

Signal heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING														
Product name:	METHOGRAIN FENITROTHION 1000 INSECTICIDE														
Constituent statement:	ACTIVE CONSTITUENT: 1000 g/L FENITROTHION (an anticholinesterase compound)														
Mode of action:	Group	1B	Insecticide												
Statement of claims:	For control of grain pests (except Lesser Grain Borer) in stored cereal grain as per the Directions for Use table.														
Net contents:	300 mL – 1 L														
Restraints:															
Directions for use:	[This section contains an attachment below]														
Other limitations:	IN WA FOR USE BY BULK HANDLING AUTHORITIES ONLY.														
Withholding period:	Stored Cereal Grains 6PPM TREATED: NOT REQUIRED WHEN USED AS DIRECTED 12 PPM TREATED. DO NOT USE FOR PROCESSING INTO FOOD FOR HUMAN CONSUMPTION OR STOCK FOOD WITHIN 13 WEEKS OF TREATMENT.														
Trade advice:	EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of METHOGRAIN Fenitrothion 1000 Insecticide. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain using this product.														
General instructions:	APPLICATION TO STORED GRAIN: To check application rate, refer to the following table: <table><tr><td>Elevator delivery rate, tonnes per hour</td><td>10</td><td>30</td><td>40</td><td>50</td></tr><tr><td>Dilute spray collected from nozzles; litres in 3 minutes</td><td>0.5</td><td>1.5</td><td>2.0</td><td>2.5</td></tr></table> MIXING: Mix the required amount of spray for immediate use only. Slowly add the required amount to the bulk of the water in the tank and agitate well before commencing to spray. Store in original container tightly sealed in a safe place.					Elevator delivery rate, tonnes per hour	10	30	40	50	Dilute spray collected from nozzles; litres in 3 minutes	0.5	1.5	2.0	2.5
Elevator delivery rate, tonnes per hour	10	30	40	50											
Dilute spray collected from nozzles; litres in 3 minutes	0.5	1.5	2.0	2.5											
Resistance warning:	GROUP 1B INSECTICIDE INSECTICIDE RESISTANCE WARNING For insect resistance management METHOGRAIN Fenitrothion 1000 Insecticide is a Group 1B insecticide. Some naturally occurring insect biotypes resistant to METHOGRAIN Fenitrothion 1000 Insecticide and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if METHOGRAIN Fenitrothion 1000 Insecticide or other Group 1B insecticides are used repeatedly. The effectiveness of METHOGRAIN Fenitrothion 1000 Insecticide on resistant individuals could be significantly reduced. Since occurrence of resistant individuals is difficult to detect prior to use, Babolna Bioenvironmental Centre Ltd accepts no liability for any losses that may result from the failure of METHOGRAIN Fenitrothion 1000 Insecticide to control resistant insects. METHOGRAIN Fenitrothion 1000 Insecticide may be subject to specific resistance management strategies. For further information contact your local supplier, Babolna Bioenvironmental Centre Ltd representative, or local agricultural department agronomist.														
Precautions:															
Protection statements:	PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.														

Storage and disposal:	<p>Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight.</p> <p>Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty packaging or unused product to an approved waste management facility. If an approved waste management facility is not available, dispose of empty container or unused product in compliance with relevant local, state or territory government regulations. DO NOT burn empty containers or product.</p>
Safety directions:	<p>Product is poisonous if absorbed by skin contact, inhaled or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and preparing spray and using the prepared spray, wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves and face shield. When using in enclosed areas, wear goggles and half facepiece respirator with combined dust and gas cartridge. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash contaminated clothing, gloves, face shield, goggles and respirator and if rubber wash with detergent and warm water.</p>
First aid instructions:	<p>If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone e.g. Australia 131126; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.</p>
First aid warnings:	N/A

Directions for use**All states**

Crop	Pest	Protection period	Rate	Critical comments
Stored cereal (uninfested wheat, barley, oats, rice, sorghum and millet)	Stored grain insect pests (except lesser grain Borer and sawtoothed grain beetle) including rust red flour beetle, confused flour beetle, rice weevil, Indian meal moth, tropical warehouse moth	Up to 3 months	6 mL/L water (1 L of dilute spray per tonne of grain) (6 ppm)	Apply during transfer into storage. Suitable equipment should be installed which will give an even coverage to the grain and is capable of adjustment with the flow of the grain. Refer to application rate table.
		Up to 6 months	12 mL/L water (12 ppm)	Apply as above. Observe withholding period as indicated below.
Stored cereal	Stored grain insect pests including lesser grain borer and rust red flour beetle (including organophosphorus resistant strains), excluding <i>Sitophilus spp.</i>	Up to 9 months	Mix 300 mL with 50 L water and 1 L METHOGRain IGR Grain Protectant OR 100 mL METHOGRain IGR 300 Grain Protectant (6 ppm)	Apply 1 L diluted spray per tonne grain. Observe withholding period as indicated below.

**NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS
AUTHORISED UNDER APPROPRIATE LEGISLATION.**

Sample Label 2

Signal heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING										
Product name:	[Chemical product name]										
Constituent statement:	ACTIVE CONSTITUENT: 1000 g/L FENITROTHION (an anticholinesterase compound)										
Mode of action:	Group 1B Insecticide										
Statement of claims:	For the protection of cereal grain against stored product insect pests as per Directions for Use table.										
Net contents:	[Insert net contents]										
Restraints:											
Directions for use:	[This section contains an attachment below]										
Other limitations:	IN WA FOR USE BY BULK HANDLING AUTHORITIES ONLY.										
Withholding period:	Stored Cereal Grains 6PPM TREATED: NOT REQUIRED WHEN USED AS DIRECTED 12 PPM TREATED: DO NOT USE FOR PROCESSING INTO FOOD FOR HUMAN CONSUMPTION OR STOCK FOOD WITHIN 13 WEEKS OF TREATMENT.										
Trade advice:	EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain using this product.										
General instructions:	<p>APPLICATION TO STORED GRAIN: To check application rate, refer to the following table:</p> <table border="1"> <tr> <td>Elevator delivery rate, tonnes per hour</td><td>10</td><td>30</td><td>40</td><td>50</td></tr> <tr> <td>Dilute spray collected from nozzles; litres in 3 minutes</td><td>0.5</td><td>1.5</td><td>2.0</td><td>2.5</td></tr> </table> <p>MIXING: Mix the required amount of spray for immediate use only. Slowly add the required amount to the bulk of the water in the tank and agitate well before commencing to spray. Store in original container tightly sealed in a safe place.</p> <p>For spill management, refer to instructions listed in the Safety Data Sheet.</p>	Elevator delivery rate, tonnes per hour	10	30	40	50	Dilute spray collected from nozzles; litres in 3 minutes	0.5	1.5	2.0	2.5
Elevator delivery rate, tonnes per hour	10	30	40	50							
Dilute spray collected from nozzles; litres in 3 minutes	0.5	1.5	2.0	2.5							
Resistance warning:	<p>GROUP 1B INSECTICIDE INSECTICIDE RESISTANCE WARNING</p> <p>For insect resistance management [chemical product name] is a Group 1B insecticide.</p> <p>Some naturally occurring insect biotypes resistant to [chemical product name] and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if [chemical product name] or other Group 1B insecticides are used repeatedly. The effectiveness of [chemical product name] on resistant individuals could be significantly reduced. Since occurrence of resistant individuals is difficult to detect prior to use, [company name] accepts no liability for any losses that may result from the failure of [chemical product name] to control resistant insects.</p> <p>[Chemical product name] may be subject to specific resistance management strategies. For further information contact your local supplier, [company name] representative, or local agricultural department agronomist.</p>										
Precautions:											
Protection statements:	PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.										
Storage and disposal:	<p>Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight.</p> <p>Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty packaging or unused product to an approved waste management facility. If an approved waste management facility is not available, dispose of empty container or unused product in compliance with relevant local, state or territory government regulations. DO NOT burn empty containers or product.</p>										

Safety directions:	Product is poisonous if absorbed by skin contact, inhaled or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and preparing spray and using the prepared spray, wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves and face shield. When using in enclosed areas, wear goggles and half facepiece respirator with combined dust and gas cartridge. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash contaminated clothing, gloves, face shield, goggles and respirator and if rubber wash with detergent and warm water.
First aid instructions:	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone e.g. Australia 131126; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.
First aid warnings:	N/A

Directions for use

All states

Crop	Pest	Protection period	Rate	Critical comments
Grain protection. All cereal grains stored in bulk for periods	Stored grain insect pests (except lesser grain borer) including susceptible and malathion-resistant grain weevils, flour beetles, saw-toothed grain beetle, tropical warehouse moth and Indian meal moth.	Up to 3 months	0.6 L in 100 L water (6 ppm)	Apply 1 L diluted spray per tonne to the grain flow. The spray rate measured in litres per hour must equal the auger or elevator uptake in tonnes per hour, e.g. for an uptake of 20 tonnes per hour the nozzle(s) must deliver 20 L per hour.
Grain protection. All cereal grains stored in bulk		Up to 6 months	1.2 L in 100 L water (12 ppm)	

**NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS
AUTHORISED UNDER APPROPRIATE LEGISLATION.**

Fenitrothion 600g/L and S-methoprene 60 g/L, emulsifiable concentrate.**Sample label 3**

Signal heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING										
Product name:	[Chemical product name]										
Constituent statement:	ACTIVE CONSTITUENT: 600 g/L FENITROTHION (an anticholinesterase compound) 60 g/L S-methoprene										
Mode of action:	Group 1B 7A Insecticide										
Statement of claims:	For the control of insect pests in stored cereal grains including malting barley as specified in the Directions for Use table										
Net contents:	[Insert net contents]										
Restraints:	DO NOT move treated grain within 24 hours after treatment.										
Directions for use:	[This section contains an attachment below]										
Other limitations:	IN WA FOR USE BY BULK HANDLING AUTHORITIES ONLY.										
Withholding period:	Stored Cereal Grains: NOT REQUIRED WHEN USED AS DIRECTED										
Trade advice:	EXPORT OF TREATED PRODUCE: Users should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cereal grains, oilseeds or pulses which may be exposed to fenitrothion following the use of [chemical product name]. If necessary, details of overseas MRL's or tolerances should be obtained prior to treating cereal grain using this product.										
General instructions:	<p>MIXING</p> <p>Use clean water only to dilute the product. Shake concentrate well before adding water and use bypass agitation. Diluted spray should be used within 48 hours.</p> <p>EQUIPMENT</p> <p>The diluted spray should be applied via special grain spraying equipment. Throughput of spray must be regulated according to the flow of grain.</p> <p>APPLICATION</p> <p>Spray rate must be predetermined so that litres delivered per hour equal the auger or elevator throughput in tonnes per hour.</p> <table border="1"> <tr> <td>Elevator delivery rate, tonnes per hour</td><td>10</td><td>30</td><td>40</td><td>50</td></tr> <tr> <td>Dilute spray collected from nozzles; litres in 3 minutes</td><td>0.5</td><td>1.5</td><td>2.0</td><td>2.5</td></tr> </table> <p>CLEAN UP</p> <p>On completion, wash out spray equipment, mixing and measuring vessels with clean water. For spill management, refer to instructions listed in the Safety Data Sheet.</p>	Elevator delivery rate, tonnes per hour	10	30	40	50	Dilute spray collected from nozzles; litres in 3 minutes	0.5	1.5	2.0	2.5
Elevator delivery rate, tonnes per hour	10	30	40	50							
Dilute spray collected from nozzles; litres in 3 minutes	0.5	1.5	2.0	2.5							
Resistance warning:	<p>INSECTICIDE RESISTANCE WARNING</p> <p>GROUP 1B and 7A INSECTICIDE</p> <p>For insecticide resistance management [chemical product name] is both a Group 1B and 7A insecticide. Some naturally occurring insect biotypes resistant to [chemical product name] and other Group 1B and 7A insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if [chemical product name] or other Group 1B and 7A insecticides are used repeatedly. The effectiveness of [chemical product name] on resistant individuals could be significantly reduced.</p> <p>Since occurrence of resistant individuals is difficult to detect prior to use, [company name] accepts no liability for any losses that may result from the failure of [chemical product name] to control resistant insects. [Chemical product name] may be subject to specific resistance management strategies. For further information contact your local supplier, [company name] representative or local Department of Agriculture agronomist.</p>										
Precautions:											
Protection statements:	<p>PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT</p> <p>Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.</p>										

Storage and disposal:	<p>Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight.</p> <p>Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty packaging or unused product to an approved waste management facility. If an approved waste management facility is not available, dispose of empty container or unused product in compliance with relevant local, state or territory government regulations. DO NOT burn empty containers or product.</p>
Safety directions:	<p>Product is poisonous if absorbed by skin contact, inhaled or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and preparing spray and using the prepared spray, wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves and face shield. When using in enclosed areas, wear goggles and half facepiece respirator with combined dust and gas cartridge. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash contaminated clothing, gloves, face shield, goggles and respirator and if rubber wash with detergent and warm water.</p>
First aid instructions:	<p>If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone e.g. Australia 131126; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.</p>
First aid warnings:	N/A

Directions for use:

Crop	Pest	Protection period	Rate	Critical comments
Stored cereal grain, including malting barley	Stored grain insect pests including organophosphorus resistant strains, lesser grain borer, rust-red flour beetle, confused flour beetle, sawtoothed grain beetle, tropical warehouse moth (excluding <i>Sitophilus</i> spp.)	Up to 9 months	500 mL per 50 L	Apply at the rate of 1L diluted spray per tonne of grain. Apply through standard grain machinery. The output of spray through the nozzle must be regulated according to the flow of grain.

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION