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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.

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Notice under section 34AC of the Agricultural and Veterinary Chemicals Code: Procymidone reconsideration – final decisions on reconsideration

1) The Australian Pesticides and Veterinary Medicines Authority (APVMA) has made regulatory decisions in relation to the reconsideration of procymidone active constituent approvals, product registrations, and label approvals 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 relates to the procymidone active constituent approvals, product registrations and label approvals listed in Attachment A of this notice.

3) The APVMA has decided to:

   a. vary the conditions of procymidone active constituent approval listed in Attachment A under section 34(A)1 of the Agvet Code, to allow affirmation (as varied in the manner set out in paragraph 13 of the statement of reasons in Attachment B), under section 34(1) of the Agvet Code

   b. vary the relevant particulars and conditions of the procymidone product registrations, listed in Attachment A, under section 34A(1) of the Agvet Code to allow affirmation (as varied in the manner set out in paragraphs 30 and 43 of the *statement of reasons* in Attachment B), under section 34(1) of the Agvet Code

   c. vary the relevant particulars of the label approvals listed in Attachment A under section 34A(1) of the Agvet Code to allow affirmation (as varied in the manner set out in the paragraph 54 of the *statement of reasons* in Attachment B) under section 34(1) of the Agvet Code.

4) The APVMA has determined under section 81(3)(c) that section 81(3) of the Agvet Code will apply to the previously approved labels, allowing supply of products bearing those previously approved labels for a period of 2 years from the date of the final regulatory decision.

Statement of reasons for the final regulatory decisions

5) The statement of reasons for the regulatory decisions is provided at Attachment B of this notice.

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

Table 1: Active constituent approval(s), product registration(s) and approved label(s) placed under reconsideration, and new label approval numbers

Product number	Holder	Name	Previous label approval number(s)	New label approval number
50862	Sumitomo Chemical Australia Pty Ltd	Procymidone	N/A	N/A
50883	Sumitomo Chemical Australia Pty Ltd	Sumitomo Sumisclex 500 Fungicide	50883/109040	50883/RV22
53963	Sumitomo Chemical Australia Pty Ltd	Sumitomo Sumisclex Broadacre Fungicide	53963/109044	53963/RV22
54455	Adama Australia Pty Ltd	Spiral Aquaflo Fungicide	54455/113938	54455/RV22
59268	Nutrien Ag Solutions Limited	Genfarm Proflex 500 Fungicide	59268/121945	59268/RV22
63494	Accensi Pty Ltd	Accensi Procymidone 500 Fungicide	63494/114813	63494/RV22
65892	Titan Ag Pty Ltd	Titan Procymidone 500 Fungicide	65892/113868	65892/RV22
67183	4 Farmers Australia Pty Ltd	4Farmers Procymidone 500 FS Seed Dressing	67183/55408, 67183/131983	67183/RV22
67536	4 Farmers Australia Pty Ltd	4Farmers Procymidone 500 Fungicide	67536/102271, 67536/56322	67536/RV22
69208	Titan Ag Pty Ltd	Apparent Procymidone 500 Fungicide	69208/112969	69208/RV22
69322	Farmalinx Pty Ltd	Farmalinx Metapris 500 SC Fungicide	69322/62976	69322/RV22
70284	Imtrade Australia Pty Ltd	Imtrade Nosclex 800 WG Fungicide	70284/119054	70284/RV22
80001	Shandong Rainbow International Co Ltd	Proclex 500 Fungicide	80001/100003	80001/RV22
83139	Nutrien Ag Solutions Limited	Prodone 500sc Fungicide	83139/114367	83139/RV22
84082	Conquest Crop Protection Pty Ltd	Conquest Concydone 500 SC Fungicide	84082/116307	84082/RV22
84695	Imtrade Australia Pty Ltd	Imtrade Procymidone 800 WG Fungicide	84695/120106	84695/RV22

Product number	Holder	Name	Previous label approval number(s)	New label approval number
84896	Oz Crop Pty Ltd	Ozcrop Procymidone 500 SC Fungicide	84896/111711	84896/RV22
85344	Axichem Pty Ltd	AC Palatial 500 Fungicide	85344/112973	85344/RV22
85546	Sumitomo Chemical Australia Pty Ltd	Sporex Fungicide	85546/113595	85546/RV22
87227	Imtrade Australia Pty Ltd	IA Nosclex 800 WG fungicide	87227/133463*	87227/RV22
91364*	Kenso Corporation (M) Sdn. Bhd.	Kenso Agcare Kondone 500 SC Fungicide	91364/131991	91364/RV22

* Label 87227/133463 and product 91364 were approved and registered, respectively, after the proposed decision was prepared. The relevant holders have provided consent to vary these labels to be consistent with the outcomes of the review under s 29A of the Agvet Code.

Attachment B: Statement of reasons

1) The Australian Pesticides and Veterinary Medicines Authority (APVMA) has reconsidered the toxicology, health, environment, chemistry and trade aspects of the active constituent procymidone, registered products containing procymidone and associated label approvals under Part 2, Division 4 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) to determine whether the approved active constituents, registered products and approved labels meet the safety criteria (see section 5A of the Agvet Code), trade criteria (see section 5C of the Agvet Code) and labelling criteria (see section 5D of the Agvet Code).

2) The APVMA has decided to:

   a. vary the conditions of procymidone active constituent approval listed in Attachment A under section 34(A)1 of the Agvet Code, to allow affirmation (as varied in the manner set out in paragraph 13 of the statement of reasons in Attachment B), under section 34(1) of the Agvet Code

   b. vary the relevant particulars and conditions of the procymidone product registrations, listed in Attachment A, under section 34A(1) of the Agvet Code to allow affirmation (as varied in the manner set out in paragraphs 30 and 43 of this *statement of reasons*), under section 34(1) of the Agvet Code

   c. vary the relevant particulars of the previous label approvals listed in Attachment A under section 34A(1) of the Agvet Code to allow affirmation (as varied in the manner set out in paragraph 54 of this *statement of reasons*) under section 34(1) of the Agvet Code.

3) The APVMA has determined under section 81(3)(c) that section 81(3) of the Agvet Code will apply to the previously approved labels (that is, the labels in Attachment A before variation), allowing supply of products bearing those previously approved labels for a period of 2 years from the date of the final regulatory decision.

4) The reasons for the decisions are set out below as outlined in the table of contents.

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Legislative framework

5) The following sections of legislation were relevant to the reconsideration of procymidone:

a. Agvet Code

Table 2: Sections of the Agvet Code relevant to the reconsideration of procymidone

Section	Provision
5A	Definition of meets the safety criteria
5B	Definition of meets the efficacy criteria
5C	Definition of meets the trade criteria
5D	Definition of meets the labelling criteria
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	The APVMA may reconsider an approval or registration
33	The APVMA may require information, reports, results or samples
34	The APVMA must affirm the approval or registration only if it is satisfied the active, product and label meet certain criteria. The APVMA must have regard to certain information and submissions in deciding if it is satisfied that the active, product and label meet those criteria
34A	The APVMA must vary the relevant particulars or conditions of the approval or registration if they can be varied in such a way as to allow the approval or registration to be affirmed
34AA	If the APVMA does not affirm the approval or registration, it must suspend or cancel the approval or registration
34AB	The APVMA must give notice of what it proposes to do before it varies the relevant particulars or conditions under section 34A or suspends or cancels the approval or registration under section 34AA
34AC	If the APVMA affirms the approval or registration it must give written notice to the holder and publish a notice of affirmation in the Gazette
81	Supply of registered chemical products with unapproved label

b. Agricultural and Veterinary Chemicals Code Regulations (Agvet Code Regs)

Table 3: Sections of the Agvet Code Regs relevant to the reconsideration of procymidone

Regulation	Provision
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

c. Agricultural and Veterinary Chemical Code (Efficacy Criteria) Determination 2014

d. Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021

Information on which the decision is based

6) The reasons for the APVMA's decisions are based on the following information:

a. The relevant provisions of the Agvet Code, in particular those set out above.

b. Information provided in response to notices issued under section 32(1) of the Agvet Code from:

i. Sumitomo Chemical Australia Pty Ltd, as indicated in the *Procymidone Review Technical Report*

ii. Crop Care Australasia Pty Ltd (Nufarm Australia Limited)

c. Information provided in response to notices issued under section 33 of the Agvet Code from:

i. Sumitomo Chemical Australia Pty Ltd, as indicated in the *Procymidone Review Technical Report*

d. APVMA records for approval of relevant active constituents and registration records of the relevant products

e. Submissions received in response to a notice published in the Gazette on 7 December 2004

f. 3 submissions received in response to the proposed regulatory decisions published in the Gazette on 9 May 2022, as indicated in the *Procymidone Review Technical Report*

g. Other information as detailed in the *Procymidone Review Technical Report*.

Material findings of fact and reasons for the decisions

Scope of the reconsideration of procymidone

7) The reconsideration of procymidone was initiated on the basis that information available showed that the APVMA might not be able to maintain its satisfaction that the continued approvals of the active constituent procymidone and registration of products containing procymidone based on the current use pattern:

a. would not be an undue hazard to the safety of people exposed to procymidone products during their handling or people using anything containing their residues

b. would not be likely to have an effect that is harmful to human beings

c. would not unduly prejudice trade or commerce between Australia and other places outside Australia.

8) It was also necessary to reassess whether product labels contain adequate instructions and warning statements.

9) The following aspects of the active constituent approvals, product registrations and label approvals were specifically included in the reconsideration of procymidone:

a. Toxicology, including:

i. the potential for birth defects or impairment of human fertility.

b. Work health and safety, including:

i. risks arising from exposure during handling and application

ii. re-entry exposure risks

iii. determination of appropriate personal protective clothing requirements.

c. Residues and trade, including:

i. residues in treated produce arising from application in accordance with label instructions

ii. establishment of appropriate Maximum Residue Levels (MRLs)

iii. determination of dietary exposure resulting from the consumption of produce treated with procymidone.

d. The adequacy of instructions and warnings on product labels.

Active constituent approvals

10) 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

b. complies with any requirement prescribed by the Agvet Code Regs.

Consideration of whether the active constituents meet the safety criteria

11) 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 is not, or would not be:

a. 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. likely to have an effect that is harmful to human beings (section 5A(1)(b))

c. likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).

12) In considering whether the active constituents meet the safety criteria, the APVMA has had regard to information related to the criteria set out in section 5A(2)(a) as follows.

a. Section 5A(2)(a)(i) – the toxicity of the constituent and its residues, including metabolites and degradation products in relation to relevant organisms and ecosystems, including human beings. In considering the toxicity of the constituent and its residues, the APVMA has had regard to:

i. The toxicity of procymidone in studies of acute, short-term, chronic, reproductive, developmental (including antiandrogenic), genotoxic and neurotoxic effects, which are detailed in the *Procymidone Review Technical Report*.

ii. Studies of the absorption, distribution, metabolism and excretion of procymidone in mammals.

iii. The use of the active in agricultural chemical products.

iv. The fate of the active in the environment and its toxicity to off-target species.

v. The chronic dietary exposure estimated by the National Estimated Daily Intake (NEDI) calculation for procymidone.

b. Section 5A(2)(a)(ii) – the method by which the constituent is manufactured.

i. In considering the method of manufacture, the APVMA has had regard to the existing approval records. Additionally, there have been no concerns raised as part of this reconsideration regarding the method of manufacture.

c. Section 5A(2)(a)(iii) – the extent to which the constituent will contain impurities.

i. In considering the extent to which the constituent will contain impurities, the APVMA has had regard to information, including 5 batch analyses completed within the last 5 years and a current “declaration of composition”, provided in response to section 33 notices issued to holders of active constituent approvals.

ii. 3,5-dichloroaniline was identified as an impurity of toxicological concern in procymidone active constituent, which is acceptable when present at levels below 1g/kg of procymidone active constituent, as described in the *Procymidone Review Technical Report*.

d. Section 5A(2)(a)(iv) – 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 had regard to recent 5 batch analyses and “declaration of composition” of the approved active constituent.

e. Section 5A(2)(a)(v) – any conditions to which its approval is subject.

i. The approval of an active constituent is subject to the conditions set out in the table in regulation 17C of the Agvet Code Regs). These are appropriate and apply to each source of active constituent.

ii. The approval of the only procymidone active constituent is also subject to the following conditions known as the “Active Constituent Quality Assurance Requirements” imposed by the APVMA in accordance with section 23(1) of the Agvet Code:

- 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
        - 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;
  - 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.

iii. The APVMA is not satisfied that the conditions referred to as the 'Active Constituent Quality Assurance Requirements' which refer to the "APVMA Standard" and indicate that this is published on the APVMA Website remain appropriate. 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 entered into the record for procymidone. These include the distinguishing number and the particulars prescribed by the Agvet Code Regs (see section 19 of the Agvet Code). The particulars prescribed by the Agvet Code Regs for the purposes of section 19(c) of the Agvet Code are set out in regulation 15 of the Agvet Code Regs. The APVMA is satisfied with the relevant particulars for the active constituent. The particulars on the record for the approved active procymidone have been reviewed 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. The entries are considered appropriate, and no concerns have been raised.

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 APVMA has established a standard for procymidone under section 6E as outlined in the *Procymidone Review Technical Report*.

ii. 3,5-dichloroaniline was identified as an impurity of toxicological concern and is limited to an acceptable level of less than 1g/kg of procymidone active constituent by the standard.

iii. The *Procymidone Review Technical Report* concludes that the source of procymidone listed in Attachment A, would conform to the standard.

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

i. Agvet Code Reg 8AA prescribes the method of analysis (if any) of the chemical composition of the active constituent concerned for the purposes of section 5A(2)(a)(vii) of the Agvet Code. Details of the method of analysis used to determine the chemical composition of the active constituent have been assessed and the APVMA is satisfied that the method is appropriate.

Consideration of whether the active constituents can be varied in such a way as to meet the safety criteria

13) Section 34A (1) 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 registration to be affirmed, the APVMA must vary the relevant particulars or conditions.

a. The APVMA is satisfied that the approvals can be varied in such a way as to meet the safety criteria as follows:

i. The conditions referred to as the 'Active constituent Quality Assurance Requirements' above can be varied to replace references to the "APVMA Standard" with "Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Active Constituent Standard 2022)" in the first instance, then "Active Constituent Standard 2022" in following instances, and by removing the previous definition for the "APVMA Standard" from the definitions in the conditions.

Conclusion on whether the active constituents meet the safety criteria

14) Having regard to the matters in section 5A(2)(a), the APVMA is satisfied that use of procymidone as an active constituent in agricultural chemical products, if varied as described in paragraph 13 above, would not be:

a. 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. likely to have an effect that is harmful to human beings: section 5A(1)(b))

c. likely to have an unintended effect that is harmful to animals, plants or things or to the environment: section 5A(1)(c).

15) Reasons for satisfaction:

a. Section 5A(1)(a) – the APVMA is satisfied that the use of the active constituent is not an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues because:

i. the toxicology assessment detailed in the *Procymidone Review Technical Report* found no objections on toxicological grounds to the ongoing approval of the active constituent procymidone

ii. an acceptable daily intake (ADI) has been determined for procymidone of 0.05 mg/kg bw/d as a safe level of exposure for long term dietary exposure. The ADI is the level of intake of a chemical that can be ingested daily over an entire lifetime without appreciable risk to health. The ADI incorporates a 100-fold uncertainty factor to account for inter- and intra-species variation in sensitivity

iii. it has been determined that an acute reference dose (ARfD) for procymidone is not required for safe levels of exposure for short term dietary exposure. The ARfD is the estimate of the amount of a substance in food or drinking water, expressed on a milligram per kilogram body weight basis, that can be ingested over a short period of time, usually one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation

iv. as an ADI has been established, and it has been determined that an ARfD is not required for short term dietary exposure, the APVMA can consider whether use patterns for products containing procymidone will meet the safety criteria

v. the worker exposure assessment detailed in the *Procymidone Review Technical Report* has identified acceptable levels of exposure for occupational exposure to procymidone, applying a margin of exposure of 100 to a no observed adverse effect level of 20 mg/kg bw/day

vi. Procymidone will remain in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons

vii. the active constituent complies with the APVMA standard for procymidone active constituents made under section 6E including acceptable levels of 3,5- dichloroaniline, the impurity of toxicological concern identified in the *Procymidone Review Technical Report*

viii. to address Section 5A(2)(a)(v) - any conditions to which its approval is subject, the conditions of the approval referred to as the 'Active Constituent Quality Assurance Requirements' can be varied to refer to the "Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022" (Active Constituent Standard 2022), as set out in paragraph 13 above.

b. Section 5A(1)(b) – the APVMA is satisfied that the use of the active constituents is not, or would not be, likely to have an effect that is harmful to human beings because:

i. as noted above, the toxicology assessments detailed in the *Procymidone Review Technical Report* have established acceptable levels of exposure for both short and long-term exposure to procymidone

ii. the worker exposure assessment has identified safe levels of exposure for occupational exposure to procymidone

iii. an acceptable ADI has been established, while an ARfD is not required, indicating there is a level of dietary exposure to procymidone through consumption of foods containing residues of procymidone that is not likely to have an effect that is harmful to human beings

iv. the acute and chronic dietary exposure to procymidone calculated using the National Estimated Dietary Intake calculation after variation of the uses of procymidone chemical products as detailed in paragraphs 30(a) below, are acceptable.

c. Section 5A(1)(c) – the APVMA is satisfied that the use of the active constituent is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment because:

i. the mandatory no-spray buffer zones described in the *Procymidone Review Technical Report* can be applied to procymidone products and are adequate to protect non-target fauna and flora

ii. the addition of storage and disposal, and protection statements as outlined in the *Procymidone Review Technical Report* can be applied to procymidone products and are adequate to prevent unintended effects harmful to plants or animals or things or the environment

16) The APVMA is satisfied, for the purposes of section 34(1)(a), that the procymidone active constituent approval listed in Attachment A meets the safety criteria set out in section 5A(1) of the Agvet Code.

Consideration of whether the active constituents meet the prescribed regulations

17) Regulation 15 prescribes the particulars to be recorded for an active constituent. Based on the information provided, the APVMA is satisfied that the current entries in the record are correct and that no concerns have been raised as part of this reconsideration.

18) In accordance with section 23(1) of the Agvet Code, the conditions of approval for active constituents are:

a. those detailed in regulation 17C(1)

19) the conditions referred to as the 'Active Constituent Quality Assurance Requirements' conditions of approval for active constituents imposed by the APVMA under section 23(1)(b) of the Agvet Code as follows described in paragraph 12 above. The APVMA is not satisfied that these conditions remain appropriate, as described in paragraph 12, but is satisfied that the conditions could be varied as set out in paragraph 13 and once varied are appropriate for the current active constituent approval.

Conclusion of consideration of active constituents

20) As the APVMA is satisfied that the active constituent if varied, as described in paragraph 13 above, meets the safety criteria, including compliance with requirements prescribed by the Agvet Code Regs, section 34(1) of the Agvet Code provides that the APVMA must affirm the approval of the active constituent.

21) The APVMA has established a standard for procymidone which includes a limit of 3,5-dichloroaniline at levels below 1g/kg of procymidone.

22) As the APVMA is able to establish an ADI for safe levels of consumption for long-term dietary intake and has established that an ARfD is not required for safe levels of consumption and short-term dietary intake, the APVMA is satisfied that the use of the active constituent in products can be assessed as to whether it presents an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues. Both the ADI and ARfD are health-based guidance values which underpin the assessment of product use patterns. Although they indicate safe levels of exposure, they are not relevant particulars that are entered into the Record for the active constituent. Therefore, a change to these values does not change any relevant particulars in the Record for the active constituent.

Registered chemical products

23) Section 34(1) 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)

d. complies with any requirement prescribed by the regulations.

Consideration of whether the registered chemical products meet the safety criteria

24) The following considerations apply to all registered procymidone products, unless otherwise specified.

25) 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 constituent or 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)).

26) In determining whether the chemical products meet the safety criteria the APVMA has had regard to information relevant to the criteria set out in section 5A(3)(a) as follows.

a. In relation to the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings (Section 5A(3)(a)(i)), the APVMA had regard to:

i. The existing product registration records and the existing approval records for the active constituents.

ii. The findings in the *Procymidone Review Technical Report*, that there are no objections on toxicological grounds to the ongoing approval of procymidone as an active constituent.

iii. The finding in the *Procymidone Review Technical Report*, that the approved active constituent will contain acceptable levels of the impurity of toxicological concern 3,5-dichloroaniline.

iv. The toxicity of procymidone in studies of acute, short-term, chronic, reproductive, developmental (including antiandrogenic), genotoxic and neurotoxic effects, which are detailed in the *Procymidone Review Technical Report*.

v. Studies of the absorption, distribution, metabolism and excretion of procymidone in mammals.

vi. The establishment of an ADI at 0.05 mg/kg bw/day on the basis of a no observed adverse effect level of 4.5 mg/kg bw/day in an 18 month repeat dose dietary study in mice and application of an uncertainty factor of 100 to account for intra- and inter-species differences.

vii. The finding that an ARfD is not required, on the basis that that anti-androgenic effects on development are unlikely to occur following a single exposure incident, and the observed effects in the acute neurotoxicity study do not require the establishment of an ARfD.

viii. The finding in the *Procymidone Review Technical Report* that the current procymidone residue definition in the MRL standard remains appropriate as procymidone per se.

ix. The finding that MRLs for procymidone in certain commodities require revision, as outlined in the *Procymidone Review Technical Report*.

x. The finding in the *Procymidone Review Technical Report* that the use of procymidone according to the current instructions for use does not pose an unacceptable risk to human health through exposure during use of the registered products.

xi. The findings in the *Procymidone Review Technical Report* and existing product registration records, on the fate of the active in the environment and its toxicity to off target species.

xii. The finding in the *Procymidone Review Technical Report* that mandatory no-spray buffer zones protective of sensitive areas are able to be established and are required to protect non-target flora and fauna, and human health.

xiii. The finding that storage and disposal, and protection statements as outlined in the *Procymidone Review Technical Report* can be applied to procymidone products and are adequate to prevent unintended effects harmful to plants or animals or things or the environment.

xiv. The history of use of the product and that no reports of crop damage from the use of procymidone products have been received by the Adverse Experience Reporting Program of the APVMA.

b. Section 5A(3)(a)(ii) − the relevant poison classification of the product under the law in force in this jurisdiction.

i. Procymidone is listed in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons.

c. Section 5A(3)(a)(iii) − how the product is formulated.

i. In considering how the products are formulated, the APVMA has had regard to the existing registration records. The currently registered products containing procymidone as an active constituent are formulated as 500 g/L of procymidone as a suspension concentrate (SC, 15 products) or 500 g/L of procymidone flowable concentrate for seed treatment (FS, 1 product), and as 800 g/kg of procymidone as a water dispersible granule products (WG, 3 products).

ii. There have been no concerns raised as part of this reconsideration regarding the formulation of the products.

d. Section 5A(3)(a)(iv) − the composition and form of the constituents of the product.

i. In considering the composition and form of the constituents of the product, the APVMA has had regard to the existing registration records.

ii. The APVMA has had regard to 5 batch-analyses of the approved active constituent conducted within the previous 5 years and a current “Declaration of Composition” of the approved active constituent.

iii. In addition, there have been no concerns raised as part of this reconsideration regarding the composition and form of the constituents of the product.

e. Section 5A(3)(a)(v) – any conditions to which its registration is, or would be, subject.

i. The products are currently subject to the conditions of registration detailed under regulation 17C(2) items 1,2, 5, 6 and 7 (items 3 and 4 do not apply to agricultural chemical products as prescribed under regulation 59).

ii. The products are currently subject to the following additional conditions referred to as the ‘Agricultural Products Active Constituent Quality Assurance Requirements’, which are routinely applied to all agricultural chemical products under section 23(1)(b), to assure quality of those products:

- 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
  - 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:
  - 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:
    - the name of the manufacturer and the manufacturing site address
    - the date of the analysis
    - the batch number and date of manufacture of the batch
    - 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
    - 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).
    - 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 [of the conditions] 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.

iii. The APVMA is not satisfied that the conditions referred to as the ‘‘Agricultural Products Active Constituent Quality Assurance Requirements’’ which refer to the “APVMA Standard” and indicate that this is published on the APVMA Website remain appropriate. The APVMA Standard has been replaced by the legislative instrument Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022.

f. Section 5A(3)(a)(vi) – any relevant particulars that are, or would be, entered in the Register for the product.

i. The distinguishing number remains appropriate.

ii. The instructions for use considered during the reconsideration were those previously applied to the product and detailed on the product labels.

iii. Other particulars prescribed by the Agvet Code Regs (see regulation 16) were considered confirmed by existing product registration records.

g. Section 5A(3)(a)(via) – 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 is no standard for these products made under section 6E.

h. Section 5A(3)(a)(vii) – any matters prescribed by the regulations.

i. Regulation 8AB(1)(a) of the Agvet Code Regs prescribes the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product. In considering method of analysis of the chemical composition and form of the constituents in the chemical products, the APVMA has had regard to the existing product records. Additionally, there have been no concerns raised as part of this reconsideration regarding analysis of the composition and form of the constituents in these chemical products.

ii. Regulations 8AB(1)(b) and (c) do not apply as the product is an agricultural product and is prescribed under regulation 59(1) for the purposes of section 120A of the Agvet Code.

iii. Regulations 8AB(1)(d) and (e) do not apply based on the use pattern of the product.

iv. Regulation 8AB(1)(f) prescribes, for an agricultural chemical product to be applied to seeds to be stored before planting or sowing—whether the product contains sufficient pigment or dye to colour the seed to enable the seed to be readily distinguished from seed to which the product has not been applied.

i. The APVMA has had regard to the existing product records including the formulation of registered of products that have instructions for use for seed treatment prior to sowing.

27) Under section 5A(3)(b) 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) – the acceptable daily intake of each constituent contained in the product

i. An ADI for procymidone has been determined at 0.05 mg/kg bw/day.

b. Section 5A(3)(b)(ii) – 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. The dietary exposure associated with the use of procymidone was considered and is detailed in the *Procymidone Review Technical Report*.

c. Section 5A(3)(b)(ii) – 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. In considering whether residues of procymidone resulting in food commodities from use of the product will not be greater than the limits that the APVMA has approved or will approve, the APVMA has had regard to existing product records and information submitted in response to notices under section 32 and section 33 of the Agvet Code, as outlined in the *Procymidone Review Technical Report*.

d. Section 5A(3)(b)(iv) – the stability of the product.

i. In considering the stability of the chemical products, the APVMA has had regard to the existing product records. Additionally, there have been no concerns raised as part of this reconsideration regarding analysis of the composition and form of the constituents in these chemical products.

e. Section 5A(3)(b)(v) – the specifications for containers for the product.

i. In considering specifications for containers, the APVMA has had regard to the existing product records regarding the stability of the product in the container and the integrity of the container during storage of the product. Additionally, there have been no concerns raised with the current specifications for containers for these products.

ii. The product is subject to the conditions of registration in relation to containers for chemical products prescribed under regulation 18(2), which are satisfied.

f. Section 5A(3)(b)(vi) – there are no other matters that the APVMA thinks relevant.

28) The APVMA is not satisfied that the registered procymidone chemical products currently meet the safety criteria for the reasons set out below:

a. The toxicology assessment detailed in the *Procymidone Review Technical Report* found that the current ADI and ARfD for procymidone should be amended/established as follows:

i. The ADI should be amended to be 0.05 mg/kg bw/d as a safe level of exposure for long-term dietary exposure.

ii. An ARfD is not required for safe levels of exposure for short-term dietary exposure.

b. The dietary exposure associated with the use of procymidone in accordance with the current use patterns was not acceptable for the following reasons:

i. The available information was insufficient to determine the likely residues of procymidone in faba beans or navy beans when used according to the current instructions for use.

ii. The available information was insufficient to determine the likely level of resides of procymidone on potatoes with the current harvest withholding period.

iii. The residues remaining on potatoes after more than 4 applications per season would likely exceed the established MRL.

c. The current use pattern does not ensure that the Regulatory Acceptable Level (RALs) of exposure resulting from spray drift that must not be exceeded for protection of relevant organisms and ecosystems, including human beings, will not be exceeded. The basis for the establishment of each RAL is detailed in the *Procymidone Review Technical Report.* They are:

i. bystander areas: 8364 g ac/ha

ii. natural aquatic areas: 120 μg ac/L

iii. pollinator areas: 16667 g ac/ha

iv. vegetation areas: not required

v. livestock areas: 1.2 mg ac/kg

d. The current storage and disposal statement and protection statement applied to procymidone products are not sufficient to prevent unintended effects harmful to plants or animals or things or the environment.

e. The current conditions of registration applied by the APVMA under section 23(1)(b) of the Agvet Code do not refer correctly to the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022, which replaced the APVMA Standard available on the APVMA Website.

Consideration of whether the registered chemical products can be varied in such a way as to meet the safety criteria

29) Section 34A (1) 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.

30) The APVMA has considered whether the instructions for use, including spray drift restraints, can be varied in such a way as to meet the safety criteria as follows:

a. After determining that an appropriate ADI for procymidone is 0.05 mg/kg bw/day, the current instructions for use can be varied to remove the potential for unacceptable human dietary exposure as follows:

i. remove instructions for use on faba beans and navy beans

ii. change the harvest withholding period for potatoes to 21 days

iii. add the restraint “Do not apply more than 4 applications per crop” to uses on potatoes

iv. add the harvest withholding periods of “Not required when used as directed” to uses on garlic and lupins

v. add the grazing withholding period “DO NOT graze treated turf or lawn; or feed turf or lawn clippings from any treated area to poultry or livestock” to uses on turf.

b. The protection statement *“Toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.”* can be added to all products to protect sensitive areas from exposure to the product.

c. For products which include instructions for seed treatment, the protection statement should read as follows: "Toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product, used containers or bags which have held treated seed." The protection statement “DO NOT feed treated seed or otherwise expose to wild or domestic birds. Any spillages of treated seed must be cleaned up immediately, preferably by recovery and re-use. If disposal is required, ensure treated seed are thoroughly buried in compliance with relevant local, state or territory government regulations and not accessible to birds or other wildlife” can be added to all products to prevent birds or other wildlife from being able to eat treated seed.

d. The disposal statement “Dispose of spent dip in an authorised dip disposal facility. If an authorised dip disposal facility is not available, the spent dip should be evenly spread over flat land not exceeding 20,000 L/ha. The disposal site must be dedicated, limed and adequately bunded (soil at least 15 cm high). DO NOT dispose unwanted spent dip in the same place for at least 420 days, as repeated depositions in one location may, over time, create a contaminated site. Unused or spent dips should be disposed of carefully to avoid contamination of wetlands or watercourses” can be added to all products to prevent harm to the environment by spent dips.

e. There is no scientific or regulatory basis to restrict specific use patterns to various states or territories therefore the limitation of uses to specific states or territories can be removed.

f. The conditions referred to as the ‘Agricultural Products Quality Assurance Requirements’ above can be varied to replace references to the “APVMA Standard” with "Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Active Constituent Standard 2022)” in the first instance, then “Active Constituent Standard 2022” in following instances, and by removing the previous definition for the “APVMA Standard” from the definitions in the conditions. References to “Registrant” can be replaced with the term “Holder” which is defined in the Agvet code.

g. Spray drift restraints and buffer zones can be applied to protect sensitive areas from exceedance of RALs, as follows:

i. General spray drift restraints

DO NOT allow bystanders to come into contact with the spray cloud.

DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature inversion conditions exist most evenings one to 2 hours before sunset and persist until one to 2 hours after sunrise.

ii. Additional spray drift restraints for SC 500 g/L procymidone products

Boom sprayers

DO NOT apply by a boom sprayer unless the following requirements are met:

- spray droplets not smaller than a MEDIUM spray droplet size category
- minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.

Table 4: Buffer zones for boom sprayers (SC 500 g/L procymidone)

Buffer zones for boom sprayers (SC 500 g/L procymidone)						
Application rate	**Boom height above the target canopy**	**Mandatory buffer zones**				
		Bystander areas (metres)	**Natural aquatic areas (metres)**	**Pollinator areas (metres)**	**Vegetation areas (metres)**	**Livestock areas (metres)**
Up to 10,000 mL/ha (5000 g ac/ha)	0.5 m or lower	0	10	0	0	350
	1.0 m or lower	0	35	0	0	375
Up to 6500 mL/ha (3250 g ac/ha)	0.5 m or lower	0	0	0	0	210
	1.0 m or lower	0	25	0	0	350
Up to 6000 mL/ha (3000 g ac/ha)	0.5 m or lower	0	0	0	0	180
	1.0 m or lower	0	20	0	0	350

Up to 4000 mL/ha (2000 g ac/ha)	0.5 m or lower	0	0	0	0	85
	1.0 m or lower	0	15	0	0	325
Up to 2000 mL/ha (1000 g ac/ha)	0.5 m or lower	0	0	0	0	30
	1.0 m or lower	0	10	0	0	140
Up to 1000 mL/ha (500 g ac/ha)	0.5 m or lower	0	0	0	0	10
	1.0 m or lower	0	0	0	0	65
Up to 500 mL/ha (250 g ac/ha)	0.5 m or lower	0	0	0	0	0
	1.0 m or lower	0	0	0	0	30

Vertical sprayers

DO NOT apply by a vertical sprayer unless the following requirements are met:

- spray is not directed above the target canopy
- the outside of the sprayer is turned off when turning at the end of rows and when spraying the outer row on each side of the application site
- for dilute water rates up to the maximum listed for each type of canopy specified, minimum distances between the application site and downwind sensitive areas (see ‘Mandatory buffer zones’ section of the following table titled ‘Buffer zones for vertical sprayers’) are observed.

Table 5: Buffer zones for vertical sprayers (SC 500 g/L procymidone)

Buffer zones for vertical sprayers (SC 500 g/L procymidone)					
Type of target canopy and dilute water rate	**Mandatory buffer zones**				
	Bystander areas (metres)	**Natural aquatic areas (metres)**	**Pollinator areas**	**Vegetation areas (metres)**	**Livestock areas (metres)**
2 metres tall and shorter, maximum dilute water rate of 1000 L/ha	0	0	0	0	0
Taller than 2 metres (not fully foliated), maximum dilute water rate of 1500 L/ha	0	0	0	0	20
Taller than 2 metres (fully foliated), maximum dilute water rate of 1500 L/ha	0	0	0	0	10

Aircraft

DO NOT apply by aircraft unless the following requirements are met:

- spray droplets not smaller than a MEDIUM spray droplet size category for lentil application
- spray droplets not smaller than a COARSE spray droplet size category for canola application
- for maximum release height above the target canopy of 3 metres or 25% of wingspan or 25% of rotor diameter, whichever is the greatest, minimum distances between the application site and downwind sensitive areas (see ‘Mandatory buffer zones’ section of the following table titled ‘Buffer zones for aircraft’) are observed.

Table 6: Buffer zones for aircraft (MEDIUM spray droplet size SC 500 g/L procymidone)

Buffer zones for aircraft (MEDIUM spray droplet size, SC 500 g/L procymidone)						
Application rate	**Type of aircraft**	**Mandatory buffer zones**				
		Bystander areas (metres)	**Natural aquatic areas (metres)**	**Pollinator areas (metres)**	**Vegetation areas (metres)**	**Livestock areas (metres)**
Up to 500 mL/ha (250 g ac/ha)	Fixed wing	0	0	0	0	230
	Helicopter	0	10	0	0	140

Table 7: Buffer zones for aircraft (Coarse spray droplet size SC 500 g/L procymidone)

Buffer zones for aircraft (COARSE spray droplet size, SC 500 g/L procymidone)						
Application rate	**Type of aircraft**	**Mandatory buffer zones**				
		Bystander areas (metres)	**Natural aquatic areas (metres)**	**Pollinator areas (metres)**	**Vegetation areas (metres)**	**Livestock areas (metres)**
Up to 1000 mL/ha (500 g ac/ha)	Fixed wing	0	5	0	0	180
	Helicopter	0	15	0	0	110

iii. Additional spray drift restraints for WG 800 g/kg procymidone labels

Boom sprayers

DO NOT apply by a boom sprayer unless the following requirements are met:

- spray droplets not smaller than a MEDIUM spray droplet size category
- minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed

Table 8: Buffer zones for boom sprayers (WG 800 g/L procymidone)

Buffer zones for boom sprayers (WG 800 g/kg procymidone)						
	Mandatory buffer zones					
Application rate	**Boom height above the target canopy (metres)**	**Bystander areas (metres)**	**Natural aquatic areas (metres)**	**Pollinator areas (metres)**	**Vegetation areas (metres)**	**Livestock areas (metres)**
Up to 6000 g/ha (4800 g ac/ha)	0.5 m or lower	0	10	0	0	350
	1.0 m or lower	0	30	0	0	375
Up to 4000 g/ha (3200 g ac/ha)	0.5 m or lower	0	0	0	0	200
	1.0 m or lower	0	25	0	0	350
Up to 3500 g/ha (2800 g ac/ha)	0.5 m or lower	0	0	0	0	160
	1.0 m or lower	0	20	0	0	350

Buffer zones for boom sprayers (WG 800 g/kg procymidone)						
Up to 1250 g/ha (1000 g ac/ha)	0.5 m or lower	0	0	0	0	30
	1.0 m or lower	0	10	0	0	140
Up to 600 g/ha (480 g ac/ha)	0.5 m or lower	0	0	0	0	10
	1.0 m or lower	0	0	0	0	60
Up to 300 g/ha (240 g ac/ha)	0.5 m or lower	0	0	0	0	0
	1.0 m or lower	0	0	0	0	30

Vertical sprayers

DO NOT apply by a vertical sprayer unless the following requirements are met:

- spray is not directed above the target canopy
- the outside of the sprayer is turned off when turning at the end of rows and when spraying the outer row on each side of the application site
- for dilute water rates up to the maximum listed for each type of canopy specified, minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for vertical sprayers') are observed.

Table 9: Buffer zones for vertical sprayers (WG 800 g/L procymidone)

Buffer zones for vertical sprayers (WG 800 g/kg procymidone)					
Type of target canopy and dilute water rate	**Mandatory buffer zones**				
	Bystander areas (metres)	**Natural aquatic areas (metres)**	**Pollinator areas (metres)**	**Vegetation areas (metres)**	**Livestock areas (metres)**
2 metres tall and shorter, maximum dilute water rate of 1000 L/ha	0	0	0	0	0
Taller than 2 metres (not fully foliated), maximum dilute water rate of 1500 L/ha	0	0	0	0	20
Taller than 2 metres (fully foliated), maximum dilute water rate of 1500 L/ha	0	0	0	0	10

Aircraft

DO NOT apply by aircraft unless the following requirements are met:

- spray droplets not smaller than a MEDIUM spray droplet size category for lentil application
- spray droplets not smaller than a COARSE spray droplet size category for canola application
- for maximum release height above the target canopy of 3 metres or 25% of wingspan or 25% of rotor diameter, whichever is the greatest, minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for aircraft') are observed.

Table 10: Buffer zones for aircraft (MEDIUM spray droplet size, WG 800 g/L procymidone)

Buffer zones for aircraft (MEDIUM spray droplet size, WG 800 g/kg procymidone)						
Application rate	**Type of aircraft**	**Mandatory buffer zones**				
		Bystander areas (metres)	**Natural aquatic areas (metres)**	**Pollinator areas (metres)**	**Vegetation areas (metres)**	**Livestock areas (metres)**
Up to 300 g/ha (240 g ac/ha)	**Fixed wing**	0	0	0	0	220
	Helicopter	0	10	0	0	140

Table 11: Buffer zones for aircraft (Coarse spray droplet size, WG 800 g/L procymidone)

Buffer zones for aircraft (COARSE spray droplet size, WG 800 g/kg procymidone)						
Application rate	**Type of aircraft**	**Mandatory buffer zones**				
		Bystander areas (metres)	**Natural aquatic areas (metres)**	**Pollinator areas (metres)**	**Bystander areas (metres)**	**Livestock areas (metres)**
Up to 600 g/ha (480 g ac/ha)	**Fixed wing**	0	5	Fixed wing	0	180
	Helicopter	0	15	Helicopter	0	110

Consideration of whether the registered chemical products meet the efficacy criteria

31) 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.

32) 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. 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

b. any conditions to which its registration is, or would be, subject

c. any relevant particulars that are, or would be, entered in the Register for the product

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)

d. any matters prescribed by the regulations.

33) Section 5B(3) of the Agvet Code provides that for the purposes of the operation of the Agvet 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:

a. to the extent prescribed by the regulations

b. if there are no such regulations – to the extent that the APVMA thinks the matters are relevant.

34) Having had regard to the matters in sections 5B(1) and 5B(2)(a – d)1, and clause 4 of the Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014, the APVMA is satisfied that use of procymidone products is effective as a fungicide for control of various fungal diseases in the following: canola, faba beans, lentils, lupins, navy beans, stone fruit (including cherries), wine grapes, garlic, onions, potatoes, ornamentals and turfgrass.

35) The APVMA is satisfied that the use of procymidone products would, to a reasonable degree, achieve one of the effects, listed in paragraphs 4(2)(a) of the Agvet Code, of destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place or a thing, namely destroying fungal pests on plants.

a. The reasons for the APVMA's satisfaction in this respect are:

i. the results of efficacy trials or experiments, considered as part of the existing product registrations

ii. that there is a demonstrated history of sale and effective use in equivalent uses as outlined in the *Procymidone Review Technical Report*.

Consideration of whether the registered chemical products meet the trade criteria

36) Section 5C(1) of the Agvet Code provides that a 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.

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

a. any conditions to which its registration is, or would be, subject

b. any relevant particulars that are, or would be, entered in the Register for the product

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)

c. any matters prescribed by the regulations.

38) Section 5C(3) of the Agvet Code provides that for the purposes of the operation of the Agvet Code in relation to a particular chemical product, the APVMA is required to have regard to the matters set out in subsections 5C(1) and 5C(2) only:

a. to the extent prescribed by the regulations; or

b. if there are no such regulations – to the extent that the APVMA thinks the matters are relevant.

39) Regulation 8AD of the Agvet Code Regs provides that for the purpose of determining whether a chemical product meets the trade criteria, the APVMA must have full regard to the matters set out in subsections 5C(1) and 5C(2) of the Agvet Code, if it can reasonably be expected that the product will be used in relation to:

a. a crop or animal, a product of which might be provided to a place outside Australia; or

b. a crop that will be fed to an animal mentioned in paragraph (a).

40) In determining whether the products meet the trade criteria, the APVMA has had regard to the following:

a. the conditions of registration to which the currently registered products are subject;

[1] The Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014 enacted under s 5B(1) contains efficacy criteria determined by the APVMA by legislative instrument. The APVMA considers this instrument to contain relevant matters for the purposes of s 5B(3).

b. the relevant particulars, including the instructions for use approved for the currently registered procymidone products currently entered in the register for the products, including;

i. the crops and situations where procymidone is used

ii. the harvest withholding periods currently required for each use

iii. the extent to which each use is expected to result in residues of procymidone or its degradation products remaining on the treated crop, as outlined in the *Procymidone Review Technical Report*

iv. the current Australian MRLs and international MRLs for procymidone in crops treated according to the current instructions for use

v. the history of use according to the current instructions without known residue detection or known trade incidents, as outlined in the *Procymidone Review Technical Report*

a. that there are no standards made under section 6E of the Agvet Code for the products; and

b. that it can be reasonably expected that the products will be used in relation to:

i. a crop or animal, a product of which might be provided to a place outside Australia, or

ii. a crop fed to an animal, where a product of the animal might be provided to a place outside Australia.

41) The APVMA is not satisfied that the registered procymidone chemical products currently meet the trade criteria for the reasons set out below:

a. the available residue data for potatoes, faba beans, and navy beans is inadequate to calculate the residues that will remain in those crops, or fodder or forage consisting of those crops, following treatment with procymidone according to the current instructions for use;

b. the current instructions for use for procymidone on garlic and lupin (seed dressing) uses do not include harvest and grazing withholding period statements;

c. the current instructions for use of procymidone on turf (non-food) do not include a grazing withholding period statement;

d. the instructions for use for procymidone products do not contain adequate spray-drift restraints to prevent exceedance of the livestock RAL which is required to ensure that exposure of livestock to residues of procymidone resulting from spray drift does not exceed 1.2 mg ac/kg.

Consideration of whether the registered chemical products can be varied in such a way as to meet the trade criteria

42) Section 34A (1) 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 has considered whether the instructions for use for registered procymidone products can be varied in such a way as to meet the trade criteria as follows:

a. the instructions for use of procymidone on potatoes can be varied to include a harvest withholding period of 21 days and the restraint “DO NOT apply more than 4 applications per crop”, which would result in acceptable procymidone residues;

b. the instructions for use of procymidone products can be varied to remove the uses on faba beans and navy beans, which are not acceptable on the basis that the level of residue expected to remain in those crops cannot be determined;

c. the current instructions for use for procymidone on garlic and lupin (seed dressing) can be varied to include the harvest and grazing withholding period statements indicating “Not required when used as directed”;

d. the current instructions for use of procymidone on turf (non-food) can be varied to include the grazing withholding period statement “*DO NOT graze treated turf or lawn; or feed turf or lawn clippings from any treated area to poultry or livestock*”;

e. the instructions for use for procymidone products can be varied to include spray-drift restraints, as set out in paragraph 30)e. above, to prevent exceedance of the livestock RAL which is required to ensure that exposure of livestock to residues of procymidone resulting from spray drift does not exceed 1.2 mg ac/kg.

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

44) The particulars to be recorded for a chemical product are listed under regulation 16. Based on the information submitted with the application for registration of the product the current entries have been confirmed and no concerns have been raised as part of this reconsideration.

45) The conditions of registration for chemical products are detailed in regulation 17C. Additional conditions apply to the current product registrations as outlined in paragraph 26)e. above. The conditions that currently apply to these products remain appropriate.

46) The conditions of registration relating to the product containers are detailed in regulation 18. Based on the information submitted with the application for registration of the product, these remain appropriate and no additional container conditions are required.

Conclusion of considerations of chemical products

47) The APVMA is satisfied that the registered procymidone chemical products listed in Attachment A meet the efficacy criteria. The APVMA is not satisfied that those same products meet the safety or trade criteria, however, the APVMA is satisfied that the relevant particulars of those product can be varied to allow affirmation (as varied) under section 34(1) of the Agvet Code.

Label approvals

48) Section 34(1) 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

b. complies 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 such of the following as are appropriate:

a. The circumstances in which the product should be used

b. How the product should be used

c. The times when the product should be used

d. The frequency of the use of the product

e. The withholding period after the use of the product

f. The re-entry period after the use of the product

g. The disposal of the product when it is no longer required

h. The disposal of containers of the product

i. The safe handling of the product and first aid in the event of an accident caused by the handling of the product

j. Any matters prescribed by the regulations. Regulation 8AE(1) of the Agvet Code Regs 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) Section 5D(2) of the Agvet Code outlines the matters the APVMA must have regard to in determining whether a label meets the labelling criteria. These are:

a. any conditions to which its approval is, or would be, subject (section 5D(2)(a))

b. any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label (section 5D(2)(b))

c. 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) (section 5D(2)(c)).

Consideration of whether the approved labels meet the labelling criteria

51) In considering whether the current approved labels for containers for procymidone chemical products meet the labelling criteria the APVMA has had regard to the following matters:

a. any conditions to which a label's approval is, or would be, subject (section 5D(2)(a))

i. the prescribed conditions for label approval (regulations 18B to 18J) currently apply to the label. These conditions remain appropriate.

b. the APVMA has considered the current labels to determine whether relevant particulars and instructions that are, or would be, entered into the relevant APVMA file for the label are adequate, as follows:

i. The circumstances in which the product should be used

a. the crop/situation and pest statements in the instructions for use contained on the approved labels

b. the crop/situation and pest statements remain appropriate, with the exception of uses in faba beans and navy beans, as outlined in the consideration of the product ability to meet the safety and trade criteria in paragraphs 30 and 43 above

c. the instructions limiting use of procymidone to particular States or Territories are no longer required, as these reflect the historical State and Territory based registration of Agvet products. Current APVMA policy is to register products for use in all Australian jurisdictions unless there is a reason why a product is not suitable for use in a specific geographical region.

ii. How the product should be used

a. the rate, application method and spray quality statements in the instructions for use contained on the approved labels

b. the finding in the *Procymidone Review Technical Report* mandatory no-spray buffer zones are required to prevent exceedance of the relevant RALs in sensitive areas as described at paragraph 30)e., above.

c. the recommendation in the *Procymidone Review Technical Report* to include the following additional instructions to assist in reducing the likelihood of fungicide resistance development "Specific resistance management strategies for dicarboximide fungicides can be found on the Croplife Australia website".

iii. The times when the product should be used

a. the application timing statements in the instructions for use contained on the approved labels were considered

b. the critical comment "DO NOT apply after shuck fall" applied to use on stone fruit is no longer required as recommended in the *Procymidone Review Technical Report*

c. all other application timing statements remain appropriate

iv. The frequency of the use of the product

a. the directions indicating multiple applications (where applicable) in the instructions for use contained on the approved labels

b. the finding in the *Procymidone Review Technical Report* that use on potatoes should not exceed 4 applications per year to prevent exceedance of the relevant MRL

v. The withholding period after the use of the product

a. the withholding period statements in the instructions for use contained on the approved labels

b. the findings in the *Procymidone Review Technical Report* that potatoes require a harvest withholding period of 21 days and that turf requires a grazing withholding statement "*DO NOT graze treated turf or lawn; or feed turf or lawn clippings from any treated area to poultry or livestock*"

vi. The re-entry period after the use of the product

a. the re-entry period statements in the instructions for use contained on the approved labels were considered

b. the finding in the *Procymidone Review Technical Report* that labels require inclusion of a re-entry statement as follows, "RE-ENTRY: Do not enter treated areas until spray has dried. If prior entry is necessary, wear cotton overalls buttoned to the neck and wrist, elbow-length chemical resistant gloves and goggles."

vii. The disposal of the product when it is no longer required and in the disposal of containers for the product

a. the finding in the *Procymidone Review Technical Report* that the following disposal statement is required to prevent harm to the environment with procymidone "Dispose of spent dip in an authorised dip disposal facility. If an authorised dip disposal facility is not available, the spent dip should be evenly spread over flat land not exceeding 20,000 L/ha. The disposal site must be dedicated, limed and adequately bunded (soil at least 15 cm high). DO NOT dispose unwanted spent dip in the same place for at least 420 days, as repeated depositions in one location may, over time, create a contaminated site. Unused or spent dips should be disposed of carefully to avoid contamination of wetlands or watercourses"

b. the finding in the *Procymidone Review Technical Report* that the following additional storage and disposal statement is required for products that include instructions for use as seed treatments "Treated Seed and Containers of Treated Seed: When treated seed is stored it should be kept apart from other grain and the bags or containers should be clearly marked to indicate the contents have been treated with this product. DO NOT use treated seed for human consumption. Bags which have held treated seed are not to be used for any other purpose"

c. the finding in the *Procymidone Review Technical Report* that the precaution statements "Toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers" or for products with instructions for use as seed treatment, "Toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product, used containers or bags which have held treated seed" and "DO NOT feed treated seed or otherwise expose to wild or domestic birds. Any spillages of treated seed must be cleaned up immediately,

preferably by recovery and re-use. If disposal is required, ensure treated seed are thoroughly buried in compliance with relevant local, state or territory government regulations and not accessible to birds or other wildlife" are required

viii. The safe handling of the product and first aid in the event of an accident caused by the handling of the product

a. the APVMA has had regard to the current instructions for safe handling of the product, the "Safety Directions", and for first aid in the event of an accident, the "First Aid Directions"

b. the finding in the *Procymidone Review Technical Report* that the Safety Directions should read "May irritate the eyes and skin. Avoid contact with eyes and skin. When opening the container and preparing the product for use, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow length chemical resistant gloves. When using the product, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing). Wash hands after use. After each day's use, wash gloves and contaminated clothing."

c. the finding in the *Procymidone Review Technical Report* that the First Aid directions should read "If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766"

ix. Any matters prescribed by the regulations. Regulation 8AE(1) of the Agvet Regs relevantly prescribes the following:

1) Regulation 8AE(1)(a) – for a chemical product that is a veterinary chemical product, the duration of the treatment.

a. Procymidone is not used as a veterinary chemical product, thus this regulation is not relevant

2) Regulation 8AE(1)(b) – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.

a. The current instructions for use, together with changes to the relevant harvest and grazing withholding periods outlined at paragraph 43 above were considered

3) Regulation 8AE(1)(c) – the appropriate signal words (if any) required by the current Poisons Standard.

a. As a Schedule 7 poison, the appropriate signal heading is "DANGEROUS POISON" and the label requires the cautionary phrase "KEEP OUT OF REACH OF CHILDREN". As safety directions are required, the signal heading must also include the statement "READ SAFETY DIRECTIONS BEFORE OPENING OR USING".

b. The current labels meet these requirements.

4) Regulation 8AE(1)(d) – for a chemical product that is a date-controlled product, the storage of containers for the product.

a. procymidone products are not date controlled

5) Regulation 8AE(1)(e) – any other matter determined by the APVMA CEO under regulation 8AE(2).

a. no other matters have been determined by the APVMA CEO

b. 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) (section 5D(2)(c));

i. this section does not apply, as there is no standard made for procymidone labels under section 6E.

52) The APVMA is not satisfied that the approved labels for containers for registered procymidone chemical products meet the labelling criteria for the reasons set out in paragraph 51 above.

Consideration of whether the approved labels for containers for registered procymidone chemical products can be varied in such a way as to meet the labelling criteria

53) 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.

54) The APVMA has considered whether the labels approved for containers for procymidone chemical products can be varied in such a way as to meet the labelling criteria as follows:

a. the instructions on the circumstances in which the product should be used can be varied to remove uses on faba beans and navy beans

b. the instructions for the times when the product should be used can be varied to remove the critical comment "DO NOT remove after shuck fall" from the instructions for use on stone fruit

c. the instructions for use can be varied to remove the restriction on use patterns to specific States or Territories

d. the instructions for how the product should be used can be varied to include spray drift restraints as described at paragraph 30)e

e. the instructions for use can be varied to include the additional instructions to reduce likelihood of fungicide resistance development "Specific resistance management strategies for dicarboximide fungicides can be found on the Croplife Australia website"

f. the instructions for the frequency of the use of the product can be varied to include the restraint "DO NOT apply more than 4 applications per seasons" to uses on potatoes

g. the instructions for the withholding periods after the use of the product can be varied to include:

i. for uses on potatoes, "DO NOT harvest for 21 days after application"

ii. for uses on turf, "DO NOT graze treated turf or lawn; or feed turf or lawn clippings from any treated area to poultry or livestock"

1) the instructions for the re-entry period after the use of the product can be varied to "RE-ENTRY: Do not enter treated areas until spray has dried. If prior entry is necessary, wear cotton overalls buttoned to the neck and wrist, elbow-length chemical resistant gloves and goggles."

2) the instructions for disposal of the product when it is no longer required and in the disposal of containers for the product can be varied to include the restraint "Toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers" is required

3) the instructions for storage and disposal of the product when it is no longer required and the disposal of containers for the product, for products that have instructions for seed treatments can be varied to include the instructions "Treated Seed and Containers of Treated Seed: When treated seed is stored it should be kept apart from other grain and the bags or containers should be clearly marked to indicate the contents have been treated with this product. DO NOT use treated seed for human consumption. Bags which have held treated seed are not to be used for any other purpose."

4) the labels of products that have instructions for pre-planting dip of onion and garlic can be varied to include instructions for the disposal of spent dip as follows "Dispose of spent dip in an authorised dip disposal facility. If an authorised dip disposal facility is not available, the spent dip should be evenly spread over flat land not exceeding 20,000 L/ha. The disposal site must be dedicated, limed and adequately bunded (soil at least 15 cm high). DO NOT dispose unwanted spent dip in the same place for at least 420 days, as repeated depositions in

one location may, over time, create a contaminated site. Unused or spent dips should be disposed of carefully to avoid contamination of wetlands or watercourses."

5) The instructions for the safe handling of the product and first aid in the event of an accident caused by the handling of the product can be varied to include:

i. Safety Directions: May irritate the eyes and skin. Avoid contact with eyes and skin. When opening the container and preparing the product for use, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow length chemical resistant gloves. When using the product, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing). Wash hands after use. After each day's use, wash gloves and contaminated clothing.

ii. First Aid Directions: "If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766"

55) Section 34A (3) 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.

i. the coordinators for each jurisdiction were invited to comment during the statutory 3 months of consultation on the proposed regulatory decision

ii. no comments were received.

Conclusion on consideration of the approved labels

56) The APVMA is not satisfied that the approved labels listed in Attachment A meet the labelling criteria but is satisfied that the labels can be varied in such a way as to allow affirmation (as varied) under section 34(1).

Conclusion

57) For the purposes of sections 34(1) and 34A(1) of the Agvet Code, and having regard to the matters set out above, the APVMA is:

a. not satisfied that the active constituent approval listed in Attachment A meet the safety criteria

b. not satisfied the registered procymidone products listed in Attachment A meet the safety criteria or trade criteria

c. not satisfied the approved labels for containers for procymidone chemical products listed in Attachment A meet the labelling criteria

d. satisfied that the particulars and conditions of the active constituent approvals, product registrations and label approvals listed in Attachment A can be varied as detailed above to allow the active constituent and label approvals, and the chemical product registrations to be affirmed.

58) Consequently, the APVMA has:

a. VARIED the active constituent approval, chemical product registrations and the label approvals listed in Attachment A, as set out above; and then

b. AFFIRMED the active constituent approval, chemical product registrations and the label approvals (as varied) listed in Attachment A.