



**Australian Pesticides &  
Veterinary Medicines Authority**

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**The Reconsideration of Approvals and Registrations  
Relating to Procymidone**

**PROCYMIDONE  
SCOPE DOCUMENT**

**NOVEMBER 2004**

**Australian Pesticides &  
Veterinary Medicines Authority**

**Canberra  
Australia**

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Manager Pesticides Review  
Australian Pesticides and Veterinary Medicines Authority  
PO Box E240  
KINGSTON ACT 2604  
Australia

Telephone: 61 2 6272 3213  
Facsimile: 61 2 6272 3218  
Email: [chemrev@apvma.gov.au](mailto:chemrev@apvma.gov.au)  
APVMA web site: <http://www.apvma.gov.au>

# Procymidone Review

## Scope Document

### SUMMARY

The APVMA has initiated its reconsideration of the approvals of the active constituent procymidone, the registrations of products containing procymidone and the approvals of associated labels. This document defines the scope of the matters of concern to the APVMA and outlines the kinds of information the APVMA requires to conduct a comprehensive scientific assessment of procymidone.

Procymidone is a fungicide used widely in horticulture as both a pre- and post-harvest chemical as well as for use in turf, ornamentals and pulse crops. Procymidone is being reconsidered because of toxicological, occupational health and safety, residue, and trade concerns.

The reconsiderations will be made after the APVMA assesses all the data and other information provided to it for this purpose – the assessment process is hereafter referred to in this document as the ‘review’

The APVMA will review the following aspects of active constituent approvals, product registrations and label approvals for procymidone:

- Toxicology, including:
  - the potential for birth defects or impairment of human fertility.
  
- Occupational health and safety, including:
  - risks arising from exposure during handling and application;
  - re-entry exposure risks; and
  - determination of appropriate personal protective clothing requirements.
  
- Residues and trade, including:
  - residues in treated produce arising from application in accordance with label instructions;
  - establishment of appropriate MRLs for all commodities on which procymidone is to be used (including those uses which have been removed from labels during the period of suspension); and
  - determination of dietary exposure resulting from the consumption of produce treated with procymidone.
  
- The APVMA will also consider whether product labels carry adequate instructions and warning statements.

A decision on the reconsideration will be made after the APVMA has reviewed all the data and other information provided to it for this purpose.

The public is invited to make submissions to the APVMA regarding any of the matters raised in the scope document (see Section 9).

## **1. INTRODUCTION**

Section 31 of the Agvet Codes, authorises the APVMA to reconsider:

- (a) the approval of an active constituent for a proposed or existing chemical product;
- (b) the registration of a chemical product; and
- (c) the approval of a label for containers for a chemical product.

The APVMA has decided to reconsider the approvals of the active constituent procymidone, the registrations of products containing procymidone and the approvals of associated labels, based on toxicological, occupational health and safety, residues and trade concerns.

## **2 REGULATORY STATUS AND USE OF PROCYMIDONE IN AUSTRALIA**

### **2.1 Current use patterns**

Procymidone is a systemic fungicide registered for use on lupins, grapes, stone fruit, strawberries, and some vegetables. It is widely used in horticulture either as a seed dressing, pre-harvest spray or post-harvest dip for the control of various fungal diseases in certain fruit and vegetables.

Procymidone has been registered in Australia since 1968. No previous regulatory activity has been taken by the APVMA in relation to procymidone.

### **2.2 Active constituent and products**

At the commencement of the review, there were five active constituent approvals for procymidone (Attachment 1, Table 1) and sixteen registered products containing the active constituent procymidone (Attachment 1, Table 2). All of these products are formulated as soluble concentrates containing 500g/L or less procymidone. These active constituent approvals and product registrations are subject to this review. It should be noted that any active constituent approvals and product registrations that occur after the commencement of the review would be subject to the outcomes of the review.

### **2.3 Suspension and recall action November 2004**

The APVMA has recently been made aware of human health effects associated with procymidone. Current label instructions were not adequate to ensure the continued safety of procymidone products to users in an occupational setting or those consuming fruits or vegetables that had been treated with procymidone. On the basis of these concerns it was considered necessary to ensure that product in the marketplace contained adequate instructions to protect against these concerns.

To achieve this the APVMA initiated suspension and recall action for those products listed in Attachment 1. This was required to enable new instructions to be placed on product containers and ensure that users were made aware of the changes in handling and use requirements for procymidone products. The new instructions issued for the use of procymidone products will remain in effect during the suspension, or until the review has been completed. These instructions can be found at Attachment 2.

### 3 REASONS FOR REVIEW

Procymidone was nominated for review because of concerns relating to human health, worker exposure and residues. These were identified following assessment of new information by The Office of Chemical Safety (OCS). A detailed discussion of the concerns can be found in Sections 5 to 7 of this scope document and are summarised below.

Current labels do not contain safety directions and warning statements as specified in the Handbook of First Aid Instructions and Safety Directions (FAISD). In the absence of this information, users of these products would not be aware of the necessary precautions to be taken to protect their health and safety particularly those female employees involved in the production enterprise.

In addition, procymidone has recently been recommended for inclusion into schedule 7 of the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP). This has implications for the handling of the product at the retail level. There are stricter controls on the supply of the chemical as opposed to unscheduled products. As a schedule 7 chemical certain levels of training must be attained before a product can be purchased.

Dietary intake calculations indicate that use in accordance with current label directions may result in exposure that exceeds the recently established Acute Reference Dose (ARfD). In addition the withholding periods on labels may mean that current MRLs may be exceeded.

As a result of the above, the APVMA cannot be satisfied that use of the product in accordance with the instructions for use would not be likely to have an effect that is harmful to human beings, as a result of dietary intake.

The review would provide information to enable the APVMA to determine whether the continued use of procymidone in accordance with instructions for use:

- (a) would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing their residue;
- (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 places outside Australia; and
- (d) whether product labels contain adequate instructions.

### 4 SCOPE OF THE REVIEW

The scope of the review has been defined taking into consideration the reasons for the nomination of procymidone, the information already available on this chemical and the way in which it is approved for use in Australia.

In light of concerns raised, the APVMA might not be able to remain satisfied that continued use of or any other dealing with, the active constituent procymidone or products containing procymidone in accordance with the approved instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and/or
- would not be likely to have an effect that is harmful to human beings; and/or
- would not unduly prejudice trade or commerce between Australia and other places outside Australia.

It also appears that the labels for products containing procymidone may not contain adequate instructions and warning statements.

On the basis of these concerns, it is appropriate that the registrations and approvals of procymidone be subject to reconsideration under Part 2, Division 4, of the Agvet Codes.

The APVMA will therefore review the following aspects of active constituent approvals, product registrations and label approvals for procymidone:

- Toxicology, including:
  - the potential for birth defects or impairment of human fertility;
- Occupational health and safety, including:
  - risks arising from exposure during handling and application; and
  - re-entry exposure risks; and
  - determination of appropriate personal protective clothing requirements.
- Residues and trade, including:
  - residues in treated produce arising from application in accordance with label instructions;
  - establishment of appropriate MRLs for all commodities on which procymidone is to be used (including those uses which have been removed from labels during the period of suspension); and
  - determination of dietary exposure resulting from the consumption of produce treated with procymidone.

The APVMA will also consider whether product labels carry adequate instructions and warning statements.

Registrants and approval holders will be required to undertake certain actions aimed at securing relevant data that might address these matters. The public is also invited to make submissions to the APVMA regarding any of the matters raised in the scope document (see Section 9).

## 5 TOXICOLOGICAL ISSUES

### *Toxicological assessment*

OCS has conducted an assessment of published studies on the developmental toxicity and mode of action of procymidone *in vivo* and *in vitro*, as part of a product application.

This assessment resulted in the following recommendations :

- The following warning statement (26), “*WARNING: contains procymidone which causes birth defects in laboratory animals. Women of child bearing age should avoid contact with procymidone*” be included into the FAISD;
- New safety directions and PPE be included into the FAISD; and

The OCS assessment also made recommendations that:

- the current ADI of 0.05 mg/kg bw/d be reduced to 0.03 mg/kg bw/d;
- an ARfD of 0.03mg/kg bw be established; and
- procymidone be placed into schedule 7 of the SUSDP.

### *Scheduling decision*

Procymidone had previously been listed in Appendix B of the SUSDP meaning that it was exempt from scheduling. This decision had been made on the basis of an evaluation in 1981 that indicated low acute toxicity for procymidone. Further studies considered in the late 1980s and early 1990s did not raise any concerns over its teratogenic potential.

The recommendation for a schedule 7 classification was on the grounds that the chemical is a reproductive and developmental toxin in laboratory animals, in the absence of maternal toxicity, and that this mechanism of toxicity is likely to be relevant to human beings.

## 6 OCCUPATIONAL HEALTH AND SAFETY ISSUES

Workers can be exposed to procymidone when opening containers, mixing, loading, applying the chemical product and cleaning up spills and equipment. Exposure to procymidone can also occur when handling treated vines and crops. The main routes of exposure are dermal, ocular and inhalation. The toxicology assessment identified that a single exposure event in humans may be associated with reproductive effects and therefore it will be necessary to investigate whether the occupational exposure is likely to pose an unacceptable risk, especially for pregnant females.

No occupational risk assessment has been performed in Australia for activities prior to, during and clean up following application of procymidone products. However, OCS recently considered post-application exposure for two products containing procymidone at 500 g/L and applied at a rate of up to 1 L per hectare. The assessment was undertaken to consider the occupational post-application risk for those involved in necessary activities, such as grape girdling and hand weeding, for a number of crops and turf grass.

The occupational risk for workers who are required to undertake activities likely to involve some exposure to procymidone residues post application was found to be acceptable from day 9 onwards except for grape girdling and hand weeding in turf. For these two activities the risk was only acceptable 24 days after application. If re-entry to treated crops or treated turf is necessary to perform an activity likely to result in exposure to residues such as grape girdling, before the

specified times (ie. 9 and 24 days) then appropriate PPE will need to be worn to reduce the exposure to an acceptable level.

Risks to workers handling procymidone products other than the two assessed in the above OCS assessment, have not been examined. The appropriate personal protective equipment and re-entry periods for all products and use situations will need to be determined.

## 7. RESIDUE ISSUES

The outcomes of the toxicology assessment, in particular the establishment of an acute reference dose, have implications for the exposure of people in their diets to produce containing procymidone. The residue data reviewed in the following discussion can be found at Attachment 3.

### Labels And Maximum Treatment Regimes

The following registered uses (food crops only) appear on procymidone product labels. Seed dressing products are not considered in this report, as the likely impact on dietary exposure is minimal.

**Table 1: Current Label Use Patterns**

Crop/Situation	Application Rate (g ai/ha) or Spray Conc. (g ai/100L)	Timing	WHP
<b>Green beans</b> (pre-harvest) Post-harvest dip	75 g ai/100L or 750 g ai/ha	Spray when 75% of plants first show open blossom and again 7 days later.	Nil
	50 g ai/100L (500 ppm)		Nil
<b>Navy beans</b>	75 g ai/100L or 750 g ai/ha	Spray when 75% of plants first show open blossom and again 7 days later.	Nil
<b>Faba beans</b>	250 g ai/ha	Apply spray in the early season of attack, i.e. 1 – 2 spots per leaflet and when weather conditions favour the disease. Repeat applications at intervals of 2 – 3 weeks to protect new growth.	Nil
<b>Grapes</b>	37.5 g ai/100L	Apply at the following stages: 80% cap fall just prior to bunch closure at veraison (when sugar content rises) and 2 – 3 weeks pre-harvest	5 days
<b>Stone fruit</b> (pre-harvest)  Post-harvest dip	37.5 g ai/100L	Apply at 10% blossom, full bloom, late petal and shuck fall. Where <i>Monilinia laxa</i> is known to occur apply an early spray at pink bud. In addition to earlier sprays above, apply 3 weeks and 1 week prior to harvest. If harvest is prolonged a further spray may be necessary after the first pick.	1 day
	50 g ai/100L (500 ppm)		Nil
<b>Strawberries</b>	75 g ai/100L	Apply to run-off at early flowering and full bloom, then at intervals of 7 to 10 days. Do not apply more than 4 dicarboximide sprays per season.	1 day
<b>Onions</b> Seed treatment	10 g ai/kg of seed	Add 20 ml of Sumitomo Sumisclex 500 Fungicide to the seed and mix thoroughly. Sow within 14 days of treatment.	4 weeks



Crop/Situation	Application Rate (g ai/ha) or Spray Conc. (g ai/100L)	Timing	WHP
In-furrow application	2 kg ai/ha	Thoroughly mix 4L of Sumitomo Sumisclex 500 Fungicide with required quantity of fertilizer for 1 hectare. Apply fertilizer in a band no more than 2 cm directly below the seed.	4 weeks
Soil spray	1 kg ai/ha	Apply to soil surface immediately after sowing and repeat application at 10 weeks after sowing. A further soil spray of 1 kg ai/ha may be necessary if frequent or extended periods of cool moist conditions occur later in the season.	4 weeks
Transplant dip	500 g ai/100L	Dip seedlings for up to 4 hours in fungicide suspension before transplanting.	4 weeks
<b>Garlic</b>	5 g ai/kg garlic	Pre-plant clove treatment	Nil
<b>Lettuce</b>			
Foliar spray	50 g ai/100L	Use 750 to 1200L water/ha depending on plant size	2 days
Drench	25 g ai/10L per 800 seedlings grown in modular trays	Apply to seedlings immediately before transplanting	2 days
Soil surface spray	100 g ai/100L	Use 1000L of water/ha. Apply soil surface spray immediately after transplanting and repeat applications at 1 and 2 weeks. Final application may be omitted if seedlings are drenched.	2 days
<b>Tomatoes</b>	50 g ai/100L	Use 750 to 1200L water/ha depending on plant size. Apply 2 to 3 weeks after thinning or transplanting and then at 10 – 14 day intervals while conditions favour disease. Do not apply more than 4 dicarboximide sprays per season.	2 days
<b>Potato</b>	500 g ai/ha	Apply first spray at hilling up. Apply a second spray just after hilling. Direct the sprays towards the stem bases and soil surface. Supplementary applications of 500 g ai/ha to foliage at 14 – 21 day intervals may be necessary if conditions favour further development of disease.	7 days

## Current MRLs

The MRLs for procymidone (current to October 2004) are as follows:

**Table 1 of the MRL Standard**

Code	Food Commodity	MRL (mg/kg)
VD 0560	Adzuki beans (dry)	0.2
VP 0061	Beans, except broad bean and soya bean	10
	Bergamot	T3
VB 0040	Brassica (cole or cabbage) vegetables,	T5
	Head cabbages, Flowerhead brassicas	T5
VP 0522	Broad bean (green pods and immature seeds)	10
VR 0577	Carrot	T1
VL 0465	Chervil	T2
	Coriander (leaves, stems, roots)	T3
HS 0779	Coriander seed	T3
HS 0730	Dill seed	T3

Code	Food Commodity	MRL (mg/kg)
MO 0105	Edible offal (mammalian)	0.05
PE 0112	Eggs	*0.01
VA 0380	Fennel, bulb	T1
HS 0731	Fennel seed	T3
VC 0045	Fruiting vegetables, Cucurbits	T2
VR 0581	Galangal, Greater	T0.5
VA 0381	Garlic	5
FB 0269	Grapes	2
HH 0092	Herbs	T3
VL 0478	Indian mustard	T2
	Kaffir lime leaves	T3
	Lemon grass	T3
DT 1111	Lemon verbena (fresh weight)	T3
VD 0533	Lentil (dry)	T0.5
VL 0482	Lettuce, Head	2
VL 0483	Lettuce, Leaf	2
VD 0545	Lupin (dry)	*0.01
MM 0095	Meat (mammalian)[in the fat]	0.2
ML 0106	Milks	0.02
	Mizuna	T2
VL 0485	Mustard greens	T2
VA 0385	Onion, Bulb	0.2
FP 0009	Pome fruits*	1
VR 0589	Potato	0.1
PO 0111	Poultry, Edible offal of	*0.01
PM 0110	Poultry meat [in the fat]	0.1
SO 0495	Rape seed	T1
OC 0495	Rape seed oil, crude	T2
	Rose and dianthus (edible flowers)	T3
VL 0496	Rucola (rocket)	T2
HH 4731	Salad burnett	T3
	Snow-peas	5
VL 0502	Spinach	T2
FS 0012	Stone fruits	10
FB 0275	Strawberry	5
VO 0448	Tomato	2
HS 0794	Turmeric, root (fresh)	T0.5

\* There are no label uses associated with the pome fruit MRL.

**Table 4 of the MRL Standard**

Code	Animal Feed Commodity	MRL (mg/kg)
	Canola forage	T5
	Canola fodder, dry	T5
	Lentil forage	T5
	Lentil straw and fodder, dry	T5
AL 0545	Lupin forage	0.1

## **Residues Data**

The only contemporary residues assessments conducted at the APVMA were for uses on strawberries, peanuts, potatoes and recently broadacre crops such as pulses and canola.

A review to date of limited data, available on APVMA files and published in JMPR reports, suggests that a number of the current MRLs may not be appropriate and are very close to levels that would be expected from actual treatment. Therefore a contemporary review may reveal that a number of the MRLs require revision.

### ***Strawberries***

The MRL for strawberries, may require amendment in association with the short 1 day withholding period, as available data suggest that the MRL of 5 mg/kg may be exceeded on occasion. The current MRL is not acceptable on the grounds of short-term dietary exposure, as shown in Table 2. Therefore, it is recommended that the use on strawberries be deleted.

### ***Stone fruit***

The available data for stone fruit suggest that only the pre-harvest use pattern may be accommodated by the existing MRL, without taking into account the post-harvest dip use. Current labels have uses for control of blossom blight and brown rot. The recommended spray program for blossom blight allows spraying up to the stage of shuck fall, whereas for brown rot sprays may be applied as late as 3 weeks and 1 week before harvest. As the existing MRL does not appear to adequately accommodate residues resulting from both pre-harvest sprays and post-harvest dipping, it is recommended that the post-harvest dip and the brown rot use patterns are deleted. As the blossom blight use pattern is linked to a final application at shuck fall, this will intrinsically lead to a longer withholding period than that which appears on current labels. Therefore the new instructions for use will indicate a restriction on application by inclusion of the following statement: *Do Not Apply After Shuck Fall*

### ***Green beans***

Registered uses on green beans include a pre-harvest spray for control of Sclerotinia rot with a nil withholding period and post-harvest dipping for control of Sclerotinia post-harvest rot, also with a nil withholding period. As there are no available data to consider the post-harvest dip use separately from the pre-harvest sprays, both use patterns are deleted, pending the provision of appropriate residues data in support of the uses. In addition, there are short-term dietary concerns in relation to the existing MRL of 10 mg/kg for green beans.

### ***Grapes***

The registered use patterns for control of grey mould in grapes allow application from 80% cap fall up to 2 to 3 weeks before harvest, although the withholding period is 5 days after application. On the basis of limited data from JMPR reports, it appears that the current MRL of 2 mg/kg may not be appropriate with a withholding period of 5 days. On the basis of the existing MRL, there is an exceedance of the short-term exposure for children from 2 to 6 years, therefore the use pattern for grapes must be deleted. This use pattern may be permitted for wine-grapes only, but not for table grapes that are consumed as fresh fruit or any fruit used to produce dried fruit.

### ***Lettuce***

In September 2004, the APVMA Adverse Experience Reporting Program made recommendations on a preliminary report regarding violative residue levels detected in lettuce grown in hydroponic situations. Initial investigations of data obtained in residue monitoring programs indicated that residue violations of procymidone in leafy varieties of lettuce had been

reported. The information suggests that the existing MRL for lettuce leaf does not adequately represent levels present from use on leafy varieties.

While the short-term dietary exposure on the basis of the existing MRLs does not indicate a concern, violative levels found in leafy lettuce can cause exposures above the acute RfD. Data for leafy varieties of lettuce have not been assessed by APVMA, and the current MRLs are not adequate to cover uses in different situations. On the basis of the preliminary AERP activity and limited monitoring information available to the APVMA, it is recommended that the use on lettuce be deleted. In addition, a restriction on use of procymidone in covered or protected situations such as glasshouses, greenhouses plastic tunnels, is recommended as part of the new instructions for use.

### ***Tomatoes***

Australian residues data could not be located for use of procymidone on tomatoes. Based on available data in JMPR reports, it appears that the existing MRL of 2 mg/kg associated with a withholding period of 2 days may not be appropriate. Therefore, the use pattern for tomatoes should be deleted. In addition, there are short-term dietary concerns associated with the registered use.

### **Withholding Periods And Re-Entry Intervals**

The Office of Chemical Safety has recommended a re-entry interval of 9 days in relation to occupational health and safety concerns. For a number of uses, the label withholding periods are shorter than 9 days, i.e. nil for faba beans and navy beans, 5 days for grapes, 7 days for potatoes. It is proposed that withholding periods for certain uses that are currently shorter than 9 days should be amended to 9 days to coincide with the proposed re-entry interval. The following changes to existing withholding period statements are therefore required:

Faba beans, Navy beans, Stonefruit (blossom blight control), Wine-grapes, Potatoes: Do Not Harvest For 9 Days After Application

### **Dietary Exposure Assessments**

Using the recommended ADI and acute RfD and using the MRLs (and HRs/STMRs were possible), the National Estimated Daily Intake (NEDI) and National Estimated Short-Term Intake (NESTI) were determined.

#### ***NEDI or Chronic Dietary Intake Calculation***

The recalculated NEDI using the revised ADI of 0.03 mg/kg bodyweight/day is equivalent to 40% of the ADI. From a chronic dietary intake perspective, the long-term exposure to procymidone residues is acceptable.

As the ADI is now the same as the acute RfD, and both figures are based on the same toxicological endpoint, there can be no excursions over the ADI, as would be accepted in situations where there are differences between the values of the ADI and the acute RfD. In essence this means that there can be no exceedance of the ADI or violations of existing MRLs.

#### ***NESTI or Acute Dietary Intake Calculation***

The calculated short-term exposures for 2 to 6 year old children and the general population (2 years and above) indicated that the acute RfD is exceeded for a number of registered uses for both age groups as shown in Table 2. No refinements have been included in these preliminary

calculations, as a contemporary assessment of residues data for many uses has not been conducted at the APVMA.

Table 2: Estimated Short-Term Exposures for Procymidone

Crop	% acute RfD	
	2 to 6 years	2 years and above
Apricot	1453	359
Cherry	439	124
Nectarine	941	417
Peach	1074	410
Plum	586	318
Beans	212	82
Strawberry	158	49
Grapes	120	51
Tomatoes	149	51

The exceedances for stone fruit are common to both children and the general population. The differences in estimated exposures are due to consumption patterns for children being different to the rest of the population, primarily on the basis of bodyweight.

As discussed in reference to the ADI, any violation of the existing MRLs can lead to an exceedance of the acute RfD in a number of situations, and in some cases, the existing MRLs may not be appropriate relative to the registered uses.

### Assessment findings

On the basis of the assessment of available residues data and use of the revised ADI and acute RfD, the APVMA has taken action to remove the following uses from labels on the basis of short-term dietary exposure and the MRL for such uses being inappropriate:

- Green Beans: All uses, i.e. uses for control of Sclerotonia rot and Sclerotinia post-harvest rot
- Grapes: Use for control for grey mould for table grapes and grapes used for dried fruit production
- Stone fruit: Use for control of brown rot and post-harvest use for control of brown rot and transit rot
- Strawberries: All uses
- Tomatoes: All uses
- Lettuce: All uses

The following restriction has been included in the new directions for use for stone fruit:

**Stone fruit for control of blossom blight only: DO NOT APPLY AFTER SHUCK FALL**

The following restriction has been included in the new directions for use for grapes:

**Do Not Use On Table Grapes or Grapes Used For the Production of Dried Fruit  
Use on Wine-grapes only**

The following withholding period statements are to be included in the new directions for use:

**Faba beans, Navy beans, Stonefruit (blossom blight control), Wine-grapes, Potatoes:  
Do Not Harvest For 9 Days After Application**

## 8 INTERNATIONAL REGULATORY STATUS OF PROCYMIDONE

Procymidone is not widely used internationally. It is registered for use in Europe and import tolerances for produce treated with procymidone have been established in the United States and Canada.

Australia is the only country to allow the use as a post-harvest application.

JMPR has considered procymidone in 1981 and again in 1989 where an ADI of 0.2 mg/kg bw/d was established.

Whilst not registered in the United States, the USEPA is scheduled to release a tolerance reassessment decision (TRED) for procymidone in 2006. A TRED is issued for pesticides that do not require a re-registration eligibility decision because, as in the case of procymidone, the pesticide is not registered for use in the US. However tolerances are established that allow treated crops to be imported from other countries

Similarly, whilst not registered in Canada there are MRLs established for procymidone in raisins (25 mg/kg), grapes (5 mg/kg) and wine (1 mg/kg). This enables the import of produce that has been treated with procymidone.

Procymidone is used in Europe and is included in a coordinated program of residue testing. Residues above the MRL have been detected in lettuce, apples and table grapes. The EU is currently undertaking a re-evaluation of procymidone as part of their program for a gradual reassessment of active substances available on the market (under directive 91/414/EEC). Procymidone is priority 51 on this list. The rapporteur member State for this review is France. No reports are yet available and the outcome is pending.

Poland has previously reviewed procymidone (1997) for "reclassification" and has documents available for toxicology, human exposure, chemistry and ecotoxicity. Korea reviewed procymidone for carcinogenesis and has reports for human exposure and residues. The APVMA have requested these reports but no responses have been received to date.

## 9 SUBMISSIONS FROM THE PUBLIC INVITED

Interested parties are invited to provide information or data relevant to the issues raised in this scope document. These must reach the APVMA by no later than **25 February 2005**. Submissions can be sent either by email to [chemrev@apvma.gov.au](mailto:chemrev@apvma.gov.au) or by mail to:

Manager Pesticides Review  
Australian Pesticides and Veterinary Medicines Authority  
PO Box E240  
KINGSTON ACT 2604  
Telephone: (02) 62723213  
Facsimile: (02) 6272 3218

## **10 DATA ASSESSMENT AND POSSIBLE OUTCOMES**

The APVMA will assess the data submitted for the review of procymidone in relation to the concerns raised in Sections 5, 6, and 7.

Depending on the findings of the technical assessment, a review can result in one of three broad outcomes:

- The APVMA is satisfied that active constituents and products containing procymidone continue to meet the conditions to which registration or approval are currently subject and affirms the registration and approvals; or
- The APVMA is satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration or approval will be complied with, and varies the conditions of approval or registration; or
- The APVMA is not satisfied that the conditions continue to be met and suspends or cancels the registration or approvals.

The data might lead the relevant government agencies that provide expert advice to the APVMA to consider revising appropriate public health standards, which in this case might involve:

- the Acceptable Daily Intake (ADI);
- the acute reference dose (ARfD);
- the poisons schedule; or
- the APVMA revising or establishing Maximum Residue Limits (MRL).

The APVMA will have regard to the appropriate public health standards in its reconsideration of approvals and registrations.

## **11 CONSULTATION THROUGHOUT THE REVIEW PROCESS**

From initiation of the review through to the implementation of the review outcomes, the APVMA will consult with relevant stakeholders and interested parties. Prior to finalisation of any report, comments from key stakeholders and the public will be sought.

The draft of the review report along with proposed recommendations is intended to be made available to the stakeholders and public through the APVMA website or direct communication. A period will then be allowed for the stakeholders and the public to comment on the draft.

## ATTACHMENT 1: Procymidone active constituents and products

**Table 1:** Active constituent approvals for procymidone.

<b>NCRIS no.</b>	<b>Active constituent</b>	<b>Approval holder</b>
50862	Procymidone	Sumitomo Chemical Australia Pty Limited
51725	Procymidone	Crop Care Australasia Pty Ltd
52193	Procymidone	Nufarm Australia Limited
53483	Procymidone	Lances Link Australia Pty Ltd
53652	Procymidone	Farmoz Pty Limited

**Table 2:** Registered products containing procymidone.

<b>NCRIS no.</b>	<b>Product</b>	<b>Registrant</b>	<b>Label approval no.</b>
50883	Sumitomo Sumisclex 500 Fungicide	Sumitomo Chemical Australia Pty Limited	50883/0199 50883/0399 50883/0400 50883/0698 50883/1002
50898	Sumitomo Sumisclex 500 Liquid Seed Dressing Fungicide	Sumitomo Chemical Australia Pty Limited	50898/0698 50898/0998
50899	Sumitomo Sumiturf Fungicide	Sumitomo Chemical Australia Pty Limited	50899/0698
52095	Fortress 500 Fungicide	Crop Care Australasia Pty Ltd	52095/0100 52095/0801 52095/1199
52124	Fortress 500 Liquid Seed Dressing Fungicide	Crop Care Australasia Pty Ltd	52124/1199
52218	Lupinflo Seed Dressing Fungicide	Sumitomo Chemical Australia Pty Limited	52218/0300 52218/0902
53162	Helmet Fungicide	Crop Care Australasia Pty Ltd	53162/0700
53517	Lanceaspor Fungicide	Lances Link Australia Pty Ltd	53517/1100
53624	Campbell Cyon 275sc Turf Fungicide	Colin Campbell (Chemicals) Pty Ltd	53624/0702 53624/1200
53803	Campbell Cyon 500sc Fungicide	Colin Campbell (Chemicals) Pty Ltd	53803/0101 53803/0401
53963	Sumitomo Sumisclex Broadacre Fungicide	Sumitomo Chemical Australia Pty Limited	53963/0401
54455	Farmoz Spiral Aquaflo Fungicide	Farmoz Pty Limited	54455/1101
54540	Farmoz Spiral 500 Liquid Seed Dressing Fungicide	Farmoz Pty Limited	54540/1001
55268	Compact 500 Fungicide	Simplot Australia (Turf & Horticulture) Pty Limited	55268/0202 55268/0602
55835	Rumble 500 Fungicide	Sipcam Pacific Australia Pty Ltd	55835/0602
58432	Tradewyns Procym 500 Fungicide	Tradewyns Pty Ltd	58432/0304



## ATTACHMENT 2: New Instructions for the use of procymidone products

### INSTRUCTIONS FOR SUPPLY AND USE OF SUSPENDED PRODUCT

These instructions apply to the use of procymidone products during the period of suspension.

Product may be supplied only if a copy of these instructions is securely affixed to the container.

**READ THESE INSTRUCTIONS** before using or otherwise handling the product.

<b>A: Turf Use only</b>
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NCRIS no.	Product name	Registrant/approval holder	Label approval no.
53624	Campbell Cyon 275sc Turf Fungicide	Colin Campbell (Chemicals) Pty Ltd	53624/0702 53624/1200
53162	Helmet Fungicide	Crop Care Australasia Pty Ltd	53162/700
55268	Compact 500 Fungicide	Simplot Australia (Turf & Horticulture) Pty Limited	55268/0202 55268/0602
50899	Sumitomo Sumiturf Fungicide	Sumitomo Chemical Australia Pty Limited	50899/0698

When using or otherwise handling the product, follow the instructions of the current label except as follows:

#### Signal Heading (S7)

DANGEROUS POISON

KEEP OUT OF REACH OF CHILDREN

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

#### Restrictions on use

DO NOT use this product in the home garden.

#### Re-entry period

RE-ENTRY: do not enter treated areas for 9 days after spray application unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing), chemical resistant gloves and boots. Clothing must be laundered after each day's use.

PRECAUTION: hand weeding and transplanting of turf should not be performed prior to 24 days after spray application unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing), chemical resistant gloves and boots. Clothing must be laundered after each day's use.

#### Storage and disposal

Store in a locked room or place away from children, animals, food, feedstuffs, seed and fertilisers.

#### Safety directions

WARNING - Contains procymidone which causes birth defects in laboratory animals. Women of child bearing age should avoid contact with procymidone.

Very dangerous particularly the concentrate. Poisonous if absorbed by skin contact or inhaled or swallowed. May irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and preparing the product for use. Wear cotton overalls

buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves and disposable mist mask. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day’s use, wash gloves and contaminated clothing.

**B: Seed Dressings**

NCRIS no.	Product	Registrant/approval holder	Label approval no.
52124	Fortress 500 Liquid Seed Dressing Fungicide	Crop Care Australasia Pty Ltd	52124/1199
54540	Farmoz Spiral 500 Liquid Seed Dressing Fungicide	Farmoz Pty Limited	54540/1001
50898	Sumitomo Sumisclex 500 Liquid Seed Dressing Fungicide	Sumitomo Chemical Australia Pty Limited	50898/0698 50898/0998
52218	Lupinflo Seed Dressing Fungicide	Sumitomo Chemical Australia Pty Limited	52218/0300 52218/0902
53963	Sumitomo Sumisclex Broadacre Fungicide	Sumitomo Chemical Australia Pty Limited	53963/401

When using or otherwise handling the product, follow the instructions of the current label except as follows.

**Signal Heading (S7)**

DANGEROUS POISON

KEEP OUT OF REACH OF CHILDREN

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

**Restrictions on use**

DO NOT use this product in the home garden.

**Withholding period (for Product No. 53963)**

Faba beans: Do Not Harvest for 9 Days After Application

**Storage and disposal**

Store in a locked room or place away from children, animals, food, feedstuffs, seed and fertilisers.

**Safety directions**

WARNING - Contains procymidone which causes birth defects in laboratory animals. Women of child bearing age should avoid contact with procymidone.

Very dangerous particularly the concentrate. Poisonous if absorbed by skin contact or inhaled or swallowed. May irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and preparing the product for use. Wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves and disposable mist mask. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day’s use, wash gloves and contaminated clothing.

## C: Horticultural Use

NCRIS no.	Product	Registrant/approval holder	Label approval no.
53803	Campbell Cyon 500sc Fungicide	Colin Campbell (Chemicals) Pty Ltd	53803/0101 53803/0401
52095	Fortress 500 Fungicide	Crop Care Australasia Pty Ltd	52095/0100 52095/0801 52095/1199
54455	Farmoz Spiral Aquaflo Fungicide	Farmoz Pty Limited	54455/1101
53517	Lanceaspor Fungicide	Lances Link Australia Pty Ltd	53517/1100
55835	Rumble 500 Fungicide	Sipcam Pacific Australia Pty Ltd	55835/602
50883	Sumitomo Sumisclex 500 Fungicide	Sumitomo Chemical Australia Pty Limited	50883/0199 50883/0399 50883/0400 50883/0698 50883/1002
58432	Tradewyns Procym 500 Fungicide	Tradewyns Pty Ltd	58432/304

When using or otherwise handling the product, the current label may include instructions for using the product on green beans, grapes, lettuce, stone fruit (except blossom blight), strawberries and tomatoes. **DO NOT follow those instructions.**

In all states and territories the following are new instructions for the use of procymidone. All other label instructions apply unless specified below.

### Prohibited Crop Uses

DO NOT apply to green beans, grapes (except for use on grapes grown for wine production), lettuce, stone fruit (except for control of blossom blight), strawberries, and tomatoes.

### Signal Heading (S7)

DANGEROUS POISON

KEEP OUT OF REACH OF CHILDREN

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

### Directions for use - restraints

DO NOT use this product in the home garden.

### Directions for use – critical comments

Stone fruit for control of blossom blight only:

DO NOT APPLY AFTER SHUCK FALL

Grapes:

Do Not Use On Table Grapes or Grapes Used For the Production of Dried Fruit. Use on Wine-grapes only

### Withholding periods

Faba beans, Navy beans, Stonefruit (blossom blight control), Wine-grapes, Potatoes: Do Not Harvest For 9 Days After Application

### Re-entry period

RE-ENTRY: do not enter treated areas for 9 days after spray application unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing), chemical resistant gloves and boots. Clothing must be laundered after each day's use.

RE-ENTRY (grapes only): grape girdling should not be performed prior to 24 days after spray application unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing), chemical resistant gloves and boots. Clothing must be laundered after each day's use.

**Storage and disposal**

Store in a locked room or place away from children, animals, food, feedstuffs, seed and fertilisers.

**Safety directions**

WARNING - Contains procymidone which causes birth defects in laboratory animals. Women of child bearing age should avoid contact with procymidone.

Very dangerous particularly the concentrate. Poisonous if absorbed by skin contact or inhaled or swallowed. May irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and preparing the product for use. Wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves and disposable mist mask. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and contaminated clothing

### ATTACHMENT 3 – Procymidone Residue Evaluation Report, Residue Data

#### Strawberry

The APVMA residues assessment for the use of procymidone on strawberry was completed in 1997. The registered use pattern is for application of 4 or more sprays at 75 g ai/100L, with a withholding period of 1 day. An MRL of 5 mg/kg was recommended on the basis of Australian trial data.

The data from Australian and overseas trials are tabulated below.

Trial Site, Year, Form.	Application		DAT	Residues	Comments
	Rate or Spray Conc.	No. (interval)			
TAS, 1994 <sup>①</sup> 500 SC	88.5 g ai/100L (1.2×)	10 (6 – 8 days)	0	2.6	
			1	<u>2.3</u>	
			3	2.3	
			7	2.2	
		10	1.8		
	150 g ai/100L (2×)	10 (6 – 8 days)	0	6.2	
			1	4.1	
			3	4.0	
			7	3.5	
		10	4.3		
VIC, 1993 <sup>①</sup> 500 SC	75 g ai/100L (1×)	10 (4 – 11 days)	0	5.6	
			1	<u>3.9</u>	
			3	2.8	
			7 <sup>②</sup>	3.9	
			7 <sup>③</sup>	3.7	
		150 g ai/100L (2×)	10 (4 – 11 days)	0	12
1				11	
3				7.3	
7 <sup>②</sup>				6.7	
		7 <sup>③</sup>	6.6		
FRA, 1980 50% WP	750 g ai/ha (1×)	3	0/2 3/4	<u>4.9, 5.2</u> 2.1, 2.4	JMPR 1981
FRA, 1980 50% WP	750 g ai/ha (1×)	3	0/2 3/4	<u>3.8, 3.6</u> 2.1, 1.9	JMPR 1981
FRA, 1980 50% WP	750 g ai/ha (1×)	3	0/2 3/4	<u>2.9, 2.7</u> 2.3, 2.3	JMPR 1981
FRA, 1978 50% WP	750 g ai/ha (1×)	3	0/2	<u>3.0</u>	JMPR 1981
SPA, 1987 50WP	750 g ai/ha (1×)	1	0	<u>4.2</u>	JMPR 1993
			0	<u>4.9</u>	
			0	<u>4.8</u>	

<sup>①</sup>Limit of determination = 0.01 mg/kg; recoveries were 90 and 97% at 0.05 and 5 mg/kg, respectively.

<sup>②</sup> After 9 sprays <sup>③</sup> After 10 sprays

Residues in strawberries at 0 to 2 days after treatment at 1× are in rank order: 2.3, 2.7, 2.9, 3.0, 3.6, 3.8, 3.9, 4.2, 4.8, 4.9, 4.9, 5.2 mg/kg, with an HR of 5.2 mg/kg and an STMR of 3.85 mg/kg. The data suggest that the current MRL may require revision.

#### Stone fruit

Registered uses of procymidone on stone fruit include pre-harvest sprays at 37.5 g ai/100L from 10% blossom up until harvest and/or a post-harvest dip at 500 ppm. The withholding period for the pre-harvest use pattern is 1 day.

Residues data for pre-harvest application to stone fruit as sourced from JMPR reports, are tabulated below.

Crop	Trial Site, Year, Form.	Application		DAT	Residues	Comments
		Rate or Conc.	Spray No. (interval)			
Cherry	AUS, 1977 50 WP	37.5 g ai/100L	5	0/1	<u>6.2, 2.9</u>	JMPR 1981
	AUS 1978 50 WP	37.5 g ai/100L		1	<u>5.5, 2.6</u>	JMPR 1990
Peach	AUS, 1978, 50 WP	37.5 g ai/100L	2 – 9	0	<u>4.1</u>	JMPR 1990
		37.5 g ai/100L	2 – 9	1	<u>11.4</u>	JMPR 1990
		37.5 g ai/100L	2 – 9	1	<u>2.2</u>	
		25 g ai/100L	2 – 9	0	<u>4.8</u>	
		25 g ai/100L		1	<u>7.4</u>	
	25 g ai/100L		1	<u>1.6</u>		
	NZ, 1980, 50 WP	30 g ai/100L	2	0/1	<u>2.4</u>	JMPR 1981

The current MRL of 10 mg/kg for stone fruits should accommodate residues expected from both pre-harvest and post-harvest uses. The data suggest that residues ranging 2.2 to 11.4 mg/kg could be expected from pre-harvest sprays at 0 to 1 day after application at the 1× spray concentration. The above data set includes residues following application at 0.7×<sup>1</sup> as these are considered to be within GAP.

On the basis of the data above, residues in rank order are: 1.6, 2.2, 2.4, 2.6, 2.9, 4.1, 4.8, 5.5, 6.2, 7.4 and 11.4 mg/kg, with an HR of 11.4 mg/kg and an STMR of 4.1 mg/kg.

The spread of results indicates that only the pre-harvest use pattern may be accommodated by the existing MRL, without taking into account the post-harvest dip use.

### Grapes

Limited data from JMPR reports are tabulated below. The data suggest that the current MRL of 2 mg/kg may not be appropriate in relation to the existing use pattern and a withholding period of 5 days.

Trial Site, Year, Form.	Application		DAT	Residues	Comments
	Rate or Spray Conc.	No. (interval)			
Italy, 1989, 50 WP	100 g ai/100L (2.7×)	1	0 7	1.77 0.05	JMPR 1990
	100 g ai/100L (2.7×)	1	0 7	2.94 1.98	
	100 g ai/100L (2.7×)	2	10	1.9	
NZ, 1979, 50 WP	40 g ai/100L (1×)	1	3 9	1.3 1.3	JMPR 1990
	60 g ai/100L (1.6 ×)	1	3 9	2.0 3.3	
ITA, 50 WP	61.6 g ai/100L (1.6 ×)		5 5	2.83, 2.72, 2.11, 3.19	JMPR 1993

### Tomatoes

Relevant data for tomatoes are tabulated below. Again, it appears that the existing MRL of 2 mg/kg with a withholding period of 2 days may not be appropriate.

<sup>1</sup> ± 25 – 30% rule, FAO Manual 2002.

Trial Site, Year, Form.	Application		DAT	Residues	Comments
	Rate or Spray Conc.	No. (interval)			
FRA, 1980, 50 WP	750 g ai/ha (1 – 2×)	3	0/1	2.7	JMPR 1981
		3	3/4	1.7	
			0/1	2.0	
			3/4	1.7	
ITA, 1991, 50 WP	500 g ai/ha (0.8 – 1.3×)	4	0/1	0.48	JMPR 1993
			0/1	0.93, 1.08 ①	
			0/1	0.56	
			0/1	0.78	
			0/1	0.39, 0.37	
			0/1	0.35	

① at 3 DAT.