



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



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Omethoate: Regulatory Decisions

The reconsideration of the active constituent omethoate, registration of products containing omethoate and approvals of their associated labels

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia up to the point of retail sale. Its statutory powers are provided in the Agvet Codes scheduled to the Agricultural and Veterinary Chemicals Code Act 1994.

The APVMA has legislated powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time. The reconsideration process is outlined in sections 29L to 34 of Part 2, Division 4 of the Agvet Codes.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical, or its label. The scope of each reconsideration can cover a range of areas including human health (toxicology, public health, occupational health and safety), the environment (environmental fate and ecotoxicology), residues and trade, chemistry, efficacy or target crop/animal safety. However, the scope of each reconsideration is determined on a case-by-case reflecting the specific issues raised by the new research or evidence.

The reconsideration process includes a call for data from a variety of sources, a scientific evaluation of that data and, following public consultation, a regulatory decision about the ongoing use of the chemical or product. The data required by the APVMA must be generated according to scientific principles. The APVMA conducts science and evidence-based risk analysis with respect to the matters of concern, analysing all the relevant information and data available.

In undertaking reconsiderations, the APVMA works in close cooperation with external experts including the Department of the Environment and Energy, the Department of Health, Food Standards Australia New Zealand (FSANZ), and the state departments of agriculture, as well as other expert advisers as appropriate.

This document sets out the regulatory decisions (RD) relating to the active constituent omethoate and products containing omethoate when used in accordance with the approved label instructions.

This RD and supporting technical reports on omethoate are available from the [APVMA website](#). The technical reports are:

- the [toxicology report](#)
- the [Occupational Health and Safety \(OHS\) report](#)
- the [residues and dietary risk assessment](#).

EXECUTIVE SUMMARY

Introduction

Omethoate (O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate) is a systemic organophosphorus (OP) insecticide and acaricide used to control insects and mites in horticulture and agriculture, as well as in the home garden. Omethoate has been registered in Australia for over 40 years.

Along with other pesticides of this class, its mode of action is through inhibition of the enzyme acetylcholinesterase. This inhibition results in the over-stimulation of those parts of the nervous system that use acetylcholine to transmit nerve impulses. The APVMA began its reconsideration of omethoate together with that of the related chemical, dimethoate, in April 2004.

The scope of the reconsideration included the following aspects of active constituent approvals, product registrations and label approvals for omethoate:

- toxicology
- Occupational Health and Safety (OHS)
- residues including dietary exposure and trade.

As part of the toxicology assessment for omethoate, health-based guidance values for omethoate have been amended or established:

- the acceptable daily intake (ADI) has been amended from 0.0003 to 0.0004 mg/kg bw
- an acute reference dose (ARfD) for omethoate of 0.003 mg/kg bw has been established.
- there were no changes required to the poisons schedule of omethoate

The toxicology report included the recommendation that there were no objections to the ongoing approval of omethoate active constituents.

As part of the OHS assessment, amendments to the safety directions for the agricultural products and the one home garden product have been recommended. New re-entry periods and additional precautions have been set for the agricultural products.

The residues and dietary assessment did not support any uses of omethoate that could result in residues on food commodities. The remaining supported uses are:

- barrier spraying (not in-crop) for red legged earth mite
- use on ornamentals.

Regulatory decisions

After consideration of all data and assessments, and all submissions in response to the proposed regulatory decisions, the APVMA has made the following regulatory decisions to:

- affirm the active constituent approvals for omethoate
- vary the relevant label particulars for products containing omethoate to remove the instructions for use on food producing plants and to upgrade the safety directions (as listed in appendix A)
- affirm the product registrations and varied label approvals as the necessary label variations have now been made.

The reconsideration of omethoate is concluded

These regulatory actions conclude the reconsideration of the active constituent omethoate, products containing omethoate and their associated label approvals.

Phase out period—period of permitted supply—MRL changes

The APVMA has determined that subsection 81(3) is to apply in respect of the earlier approved version of labels that have been varied to allow a period of one year for their continued supply. After that period all product that is supplied should bear the varied approved label.

The APVMA is proposing to delete all current MRLs associated only with the previously approved uses of omethoate from the MRL Standard once the phase out period for the supply of previous version of varied labels of omethoate products has ended. However it is noted that the use of dimethoate may also result in residues of omethoate in crops. Dimethoate is also being reconsidered and MRLs for omethoate have been recommended in the [dimethoate proposed regulatory decision report](#) to account for any residues of omethoate arising from the use of dimethoate. Therefore there will be some MRLs for omethoate in food crops remaining in the Standard after these reconsiderations have both been finalised and any periods for the legal use of previous versions of varied labels of either omethoate or dimethoate products has ended.

1 INTRODUCTION

Omethoate (O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate) is a systemic organophosphorus (OP) insecticide and acaricide used to control insects and mites in horticulture and agriculture, as well as in the home garden. Along with other pesticides of this class, its mode of action is through inhibition of acetylcholinesterase activity.

Omethoate has been registered in Australia for over 40 years. In April 2004 the APVMA began its reconsideration of omethoate together with that of dimethoate and released the [Reconsideration of approvals and registrations relating to dimethoate and omethoate—review scope document](#), which outlined the reasons and scope of the reconsideration and included a call for public submissions.

The scope of the reconsideration included the following aspects of active constituent approvals, product registrations and label approvals for omethoate:

- toxicology
- Occupational Health and Safety
- residues including dietary exposure and trade.

As of November 2016 there were 4 active constituent approvals for omethoate and 21 registered products containing omethoate. One product is registered for home garden use and 20 for agricultural use.

Products registered for use in agricultural crops may be applied by ground boom, airblast, handheld sprayers or backpack sprayer. The 800 g/L products were approved for the control of a variety of insect or mite pests of cotton, pome fruit, bananas, citrus, lupins, onions, potatoes and flowers. The 290 g/L products were approved for the control of aphids and mites in cereals, pastures and some field crops.

Omethoate is in Schedule 7 of the Poisons Standard (the SUSMP¹) with a cut-off to Schedule 6 at 30 per cent or less, and a cut-off to Schedule 5 for pressurised spray packs containing 0.2 per cent or less of omethoate. There are no changes recommended to the Schedule for omethoate resulting from this reconsideration.

The toxicology assessment for omethoate was published in November 2011 and the OHS assessment in June 2015. The residues assessment was published in March 2016.

The APVMA considered the conclusions in these assessments to develop proposals for regulatory decisions for omethoate. In May 2016 the [Omethoate proposed regulatory decision report](#) was published for a public consultation period of three months ending 4 August 2016. Holders of active approvals and product registrations were given a separate notice of the proposed decision with submissions invited until 8 September 2016.

In total, twelve submissions were received during the consultation period and these have been assessed and taken into consideration by the APVMA as part of its final regulatory decisions for the reconsideration of omethoate.

¹ www.tga.gov.au/publication/poisons-standard-susmp

2 SUBMISSIONS RECEIVED DURING THE CONSULTATION PERIOD

2.1 List of submissions

Following the APVMA publication of the PRD report in May 2016, twelve submissions were received from holders of active approvals and product registrations (4), a state government (1), and representatives of growers that use omethoate (7). A summary of the submissions and the assessment of them is included in Appendix D.

Table 1: List of submissions to the Omethoate proposed Regulatory Decisions report

Order of receipt	Submitter	Issue
1	Poppy grower representative, Tasmania	Proposing the retention of the use of omethoate on poppies at early stages of crop development only
2	Poppy grower representative, Tasmania	
3	Nursery and greenhouse industry representative	Information provided on standard water volumes used that supported a reduction of the re-entry period
4	Agronomist / Consultant NSW	Disagrees with the proposed decisions.
5	Holder of product registration	Query regarding timing of label changes
6	NSW Department of Primary Industries, Biosecurity and Food Safety NSW	Supports the proposed changes
7	Holder of product registrations and active approvals	Importance of omethoate and intentions to conduct further residues trials post review
8	WA Farmers Grains section	Note importance of omethoate for control of broad acre pests. Barrier spray use pattern may require MRLs
9	Grains Research and Development Corporation	Uses on cereals, pulses and oilseeds
10	Holder of product registration	Importance of omethoate and intentions to conduct further residues trials post review.
11	Holder of product registrations and active approvals	Response regarding maintenance of label approvals
12	Australian Banana Growers' Council	Request consideration of 10 week withholding period

2.2 Changes to the reconsideration outcomes since the PRD

Submissions made in regard to use on broad acre crops, bananas and poppies were considered by the APVMA, and it was determined that there was insufficient residues information to support permanent uses on these crops.

Information from the nursery industry regarding spray volumes used on ornamental and greenhouse crops was used to recalculate the re-entry periods for these crops. For hand harvesting of cut flowers the re-entry period is 29 days. For all other activities in nursery crops the re-entry period is until the spray has dried.

The restraint 'Do not apply to any tree crop or plantation (including Eucalyptus spp) by air' has been added to the labels of 800 g/L omethoate products. This recommendation was included in the OHS report as summarised in the PRD but had been omitted from the proposed label changes.

3 RECONSIDERATION DECISIONS

On the basis of the evaluation of the submitted data and information, the APVMA has made the following decisions with regard to the continued approval of the active constituent omethoate, registration of omethoate products and their associated label approvals in Australia.

3.1 Affirm approvals of the active constituent

The APVMA has affirmed the approval of the active constituents listed in Table 8 in appendix B.

3.2 Vary particulars of label approvals, and affirm products with varied labels

The APVMA determined that it was NOT SATISFIED that the products listed in Table 9 in appendix B met the safety criteria as defined in sections 5A of the Agvet Code when they were used according to the instructions for use on the previously approved labels listed in Column 5 of Table 9.

However the APVMA has determined that the relevant particulars of the label approvals for these products could be varied in such a way to amend the instructions for use of products so that they meet the safety criteria when used according to those varied instructions.

Therefore the APVMA has VARIED the instructions for use of these products as described in appendix A. The varied labels now bear the label approvals listed in Column 6 of Table 9.

These variations to label instructions now satisfy the requirements for continued registration of products and the APVMA has affirmed the product registrations listed in Table 9 as the labels have now been varied.

3.3 Supported uses

The following uses of omethoate are supported as they are not likely to result in residues on food commodities:

- barrier spraying for red legged earth mite—agricultural products
- use on ornamentals—home garden and agricultural products.

3.4 Unsupported uses

Taking into consideration the conclusions of the assessments listed above, all uses of omethoate on food producing crops are not supported and have been removed from the varied labels.

3.5 Label instructions

The amendments that have been made to the label instructions for each group of products are summarised in appendix A.

In addition to the removal of unsupported use patterns from the directions for use of the products listed, the APVMA has also amended the first aid and safety directions for each product and added precautions and re-entry periods appropriate to the remaining use patterns.

3.6 Label approval numbers

The APVMA has also varied the label approval numbers to uniquely identify the labels varied as an outcome of this reconsideration. The new label numbers are [product number]/R1216

3.7 Phase out periods

The APVMA has determined that subsection 81(3) is to apply in respect of the earlier approved version of labels that have been varied, to allow a period of one year for their continued supply. After that period all product that is supplied should bear the varied approved label.

4 AMENDMENTS TO STANDARDS

4.1 Active constituent standards

The APVMA considers that the current active constituent standard, including impurity limits for omethoate is appropriate and has not made any changes to this standard.

4.2 Health-based guidance values

There are no changes to the current health-based guidance values as listed below.

Acceptable daily intake (ADI)

The ADI is currently 0.0004 mg/kg bw/d. During this reconsideration, the ADI was revised to 0.0004 mg/kg bw/d, based on a no observed adverse effect level (NOAEL) of 0.04 mg/kg bw/d for inhibition of cholinesterase activity in a two-year rat dietary study, and using a 100-fold safety factor.

Acute reference dose (ARfD)

Prior to the commencement of this reconsideration there was no Australian ARfD for omethoate. An ARfD of 0.003 mg/kg bw has now been established based on a NOAEL of 0.25 mg/kg bw for inhibition of cholinesterase activity in an acute oral neurotoxicity study in rats, and using a 100-fold safety factor.

Poisons schedule

Omethoate is currently listed in Schedule 7 of the SUSMP with a cut-off to Schedule 6 at 30% or less, or to Schedule 5 in pressurised spray packs containing 0.2% or less of omethoate. There have been no changes recommended to the SUSMP as a result of this reconsideration.

First aid instructions, warning statements and safety directions including personal protective equipment (PPE)

The APVMA will add the first aid instructions, precautions and safety directions recommended for this reconsideration to the First Aid Instruction and Safety Directions (FAISD) Handbook as this reconsideration has now been finalised.

These are listed in full as part of the label variations detailed in appendix A.

4.3 Residues definition

There are no changes to the residues definition for omethoate resulting from this reconsideration. The Australian residue definition for omethoate is: *Omethoate*.

4.4 MRL Standards

The APVMA is proposing to delete all current MRLs associated only with the previously approved uses of omethoate from the MRL Standard once the phase out period for the supply of previous version of varied labels of omethoate products has ended. However it is noted that the use of dimethoate may also result in residues of omethoate in crops. Dimethoate is also being reconsidered and MRLs for omethoate have been recommended in the [dimethoate proposed regulatory decision report](#) to account for any residues of omethoate arising from the use of dimethoate. Therefore there will be some MRLs for omethoate in food crops remaining in the Standard after these reconsiderations have both been finalised and any periods for the legal use of previous versions of varied labels of either omethoate or dimethoate products has ended.

Appendix C includes the list of the recommended amendments to Table 1 and Table 4 of the APVMA MRL Standard.



APPENDICES

APPENDIX A—SUMMARY DIRECTIONS FOR USE FOR PRODUCTS CONTAINING OMETHOATE

Home garden product (2 g/L aerosol)—changes made to the directions for use

Use patterns that have been deleted

Table 2: Uses deleted from the 2 g/L home garden product

Crop	Pest	Rate	WHP	Changes made
Food producing crops				
Vegetables, herbs	Aphids, thrips, whiteflies, caterpillars (eg cabbage white butterfly, cabbage moth)	Spray foliage thoroughly from a distance of 30 cm	7 days	Deleted
Citrus	Citrus leaf minor, aphids, mealybug, thrips, bronze orange bug			Deleted
Apples	Thrips, woolly aphid, mites, codling moth			Deleted

Use patterns that remain on the label

Table 3: Uses that remain on the label of the 2 g/L home garden product

Crop	Pest	Rate	WHP	Changes made
Use type				
Flowers, ornamental trees and shrubs	Aphids, thrips, caterpillars, bugs (eg lacebug), mealybugs, mites, whiteflies	Spray foliage thoroughly from a distance of 30 cm	N/A	Retained
Eucalyptus	Leaf eating beetles	Spray foliage thoroughly from a distance of 30 cm	N/A	Retained

First aid instructions 2 g/L home garden product—no change

If sprayed on skin, wash thoroughly. If sprayed in mouth, rinse mouth with water. If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766.

Safety directions 2 g/L home garden product—amended

Will irritate the eyes. May irritate the skin. Avoid contact with eyes and skin. Repeated exposure may cause allergic disorders. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use.

Agricultural products (290 g/L)—changes to the directions for use

Use patterns that have been deleted

Table 4: Uses deleted from the labels of 290 g/L agricultural products

Crop	Pest	Rate	WHP	Changes made
Field crops				
Pastures, cereals, oilseeds and legume crops	Redlegged earth mite	400 mL/ha	Graze or cut for stock food 1 day	Deleted
	Blue oat mite		Harvest—no statement	
	Lucerne flea			
Pasture legumes, lucerne, faba bean, Vetch	Bluegreen aphid	400 to 200 mL/ha	Graze or cut for stock food 1 day	Deleted
	Cowpea aphid		Harvest—no statement	
Pasture	Spotted clover aphid	300 mL/ha	Graze or cut for stock food 1 day Harvest—no statement	Deleted
Poppy	Redlegged earth mite	400 mL/ha	Harvest—no statement	Deleted

Use patterns remaining on the label

Table 5: Uses that remain on labels of 290 g/L agricultural product labels

Crop	Pest	Rate	WHP	Changes made
Use Type				
Barrier spraying	Redlegged earth mite	300 mL/ha	Not required when used according to label directions	Retain: note new safety directions and re-entry directions

First aid instructions—no change

If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

Safety directions—amended

Product and spray are poisonous if absorbed by skin contact or inhaled or swallowed. Will irritate the eyes. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin and clothing. Do not inhale spray mist.

When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles.

When using the prepared spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves.

If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and face shield or goggles and contaminated clothing.

Restrains—added

Do not apply with boom spray equipment unless operators are protected by enclosed cabs.

Do not use open mixing/loading systems for boom spray and aerial equipment.”

Do not apply by spray equipment carried on the back of the user.

Re-entry periods—added

As appropriate for the remaining use as a barrier spray.

Field crops 290 g/L product (pasture, cereals, oilseed, legumes, lucerne, poppies and vetch)

Do not allow entry into treated areas for two days. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

Withholding periods

Not applicable as the remaining uses should not result in residues on food commodities.

Agricultural products (800 g/L)—changes to the directions for use

Use patterns that have been deleted

Table 6: Uses deleted from the labels of 800 g/L agricultural products

Crop	Pest	Rate	WHP	Changes made
Tree and vine crops				
Apples, Pears	Two-spotted mite, European red mite, Woolly aphid	65 mL/100L to 75 mL/100L	7 days	Deleted
Citrus	California red scale, aphids	50 mL/100L to 75 mL/100L	7 days	Deleted
Glen Retreat mandarins	California red scale	65 mL/100L	7 days	Deleted
Bananas				
Banana	Corky scab caused by flower thrips	Bell injection 50mL/5L 40 to 60 mL of mix	6 weeks	Deleted
		Individual plant treatment 125mL/100L 500ml of spray mix	4 days	Deleted
Field crops				
Cotton	Thrips, mirids, aphids, jassids	140-280 mL/ha	21 days	Deleted
Lupins WA only	Blue-green aphid, cowpea aphid, green peach aphid (suppression only)	250 mL/ha	14 days	Deleted
Vegetables				
Onions	Thrips, Lucerne flea	700 mL/ha or 65 mL/100L 35 mL/ha	14 days	Deleted
Potatoes	Aphids	75mL/100L	7 days	Deleted

Use patterns remaining on the label

Table 7: Uses that remain on labels of 800 g/L agricultural products

Crop	Pest	Rate	Changes made
Ornamentals			
Carnations, chrysanthemums, Pelargoniums, Roses, Callistemons, Eucalyptus spp, Grevillea spp., paperbarks, wattles	Aphids, lace bugs, mealybugs, mites, thrips, whiteflies	75 mL/100 L	Retained: note new safety directions and re-entry

First aid instructions—no changes

If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

Safety directions—amended

Very dangerous, particularly the concentrate. Product and spray are poisonous if absorbed by skin contact or inhaled or swallowed. Will irritate the eyes. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin and clothing. Do not inhale spray mist.

When opening the container and preparing spray for aerial spraying equipment wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves, water resistant footwear and full face-piece respirator with gas/dust cartridges.

When opening the container and preparing spray for boom spray equipment, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles.

When opening the container and preparing spray for high pressure hand wand, wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles.

If applying by boom spray equipment, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves.

If applying by high pressure hand wand, wear cotton overalls, over normal clothing, buttoned to the neck and wrists (or equivalent clothing) and a washable hat, elbow-length chemical resistant gloves and full face-piece respirator with gas/dust cartridges.

If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water.

After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.

Restraints—added

Do not apply by air blast equipment.

Do not apply with boom spray equipment unless operators are protected by enclosed cabs.

Do not use open mixing/loading systems for boom spray and aerial equipment.”

Do not apply to any tree crop or plantation (including *Eucalyptus spp*) by air

Do not apply by spray equipment carried on the back of the user.

Re-entry periods—added

Cut flowers hand harvesting

Do not allow hand harvesting of cut flowers for 29 days. If prior entry is required for hand harvesting, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day’s use.

Floriculture, nursery and greenhouse crops (ornamentals non-bearing) (except hand harvesting of cut flowers)

Do not allow entry into treated areas of nursery and greenhouse crops for all activities (other than hand harvesting of cut flowers) until the spray has dried. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day’s use.

Tree crops (forestry)

Do not allow entry into treated areas for 17 days for tree crops. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day’s use.

Withholding periods

Not applicable as the remaining uses should not result in residues on food commodities.

APPENDIX B—LIST OF ACTIVE CONSTITUENTS, PRODUCT REGISTRATIONS AND LABEL APPROVALS

Active approvals affirmed

Table 8: Active approvals affirmed

Approval Number	Active constituent name	Approval Holder
51857	Omethoate	Arysta Lifescience North America LLC
59132	Omethoate	Imtrade Australia Pty Ltd
69005	Omethoate	Agroserve Pty Ltd
69935	Omethoate	Arysta Lifescience North America LLC

Product registrations affirmed following variation of approved labels

Table 9: Product registrations affirmed following variation of approved labels

Product Number	Product name	Registration Holder	Label approvals cancelled	Label approvals varied	New label approval number
33051	Folimat Garden Insecticide	Arysta Lifescience North America LLC		1106	33051 /RV1216
33055	Folimat 800 Insecticide Spray	Arysta Lifescience North America LLC		01, 0499, 1099, 0701, 0803,0706	33055 /RV1216
45672	Le-Mat 290 SL Insecticide (Label names include Arysta O-Mat 290 SL Insecticide)	Arysta Lifescience North America LLC		3975, /02, 02, 1297, 1099, 0103, 0706, 58076,105622	45672 /RV1216
59576	All-Mitey 290 SL Insecticide	FMC Australasia Pty Ltd		0000, 0106,0609	59576 /RV1216
59872	Chemag Sentinel 800 Insecticide Spray	Imtrade Australia Pty Ltd		0905	59872 /RV1216
61682	Mite Master 290 Insecticide	Grow Choice Pty Limited		0107	61682 /RV1216
62022	4Farmers Omethoate 290 Insecticide	4 Farmers Australia Pty Ltd		0509	62022 /RV1216
63676	Imtrade Omen 290 Insecticide	Imtrade Australia Pty Ltd	0609 (June 2016)	102502	63676 /RV1216

Product Number	Product name	Registration Holder	Label approvals cancelled	Label approvals varied	New label approval number
65414	Farmalinx Ometho-Mite 290 SL Insecticide	Farmalinx Pty Ltd		50861	50861 /RV1216
66938	Mission Omethoate 290 Insecticide	Mission Bell Holdings Pty Ltd		54727	54727 /RV1216
68169	FMC Omethoate 290 Miticide	FMC Australasia Pty Ltd		57680	57680 /RV1216
69096	Rainbow Omethoate 290 Insecticide	Shandong Rainbow International Co., Ltd.		59972	69096 /RV1216
69166	Sabakem Omethoate 290SL Miticide & Insecticide	Sabakem Pty Ltd		60113	69166 /RV1216
69703	Conquest Ovid 290 Insecticide	Conquest Crop Protection Pty Ltd		61468	69703 /RV1216
69899	K-Mite 800 Insecticide	Shandong Rainbow International Co., Ltd.		62002	69899 /RV1216
70131	Apparent Matey 290 Insecticide	Apparent Pty. Ltd.		62585,102431	70131 /RV1216
80532	Genfarm Omethoate 290 Insecticide	Landmark Operations Limited		101058	80532 /RV1216
80673	Orbit 290 SL Insecticide	Adama Australia Pty Limited		101373	80673 /RV1216
80778	AC Omethoate 290 Insecticide	Axichem Pty Ltd		101616	80778 /RV1216
81882	Relyon Omethon 290 Insecticide	Ruralco Holdings Limited		104335	81882 /RV1216
82095	O-Mat 290 SL Insecticide	Arysta Lifescience Australia Pty Ltd		104990	82095 /RV1216

Table 10: Product registrations that have lapsed since the publication of the PRD. No action required

Product Number	Product name	Registration Holder	Label approvals	Date registration stopped
61681	AW Omethoate 290 SL Insecticide	Agri West Pty Limited	61681/0107	30 June 2016

APPENDIX C—RECOMMENDED AMENDMENTS TO TABLE 1 AND TO TABLE 4 OF THE APVMA MRL STANDARD TO BE IMPLEMENTED AFTER PHASE OUT

Table 11: Recommended amendments to Table 1 of the APVMA MRL Standard

COMPOUND	FOOD	MRL (mg/kg)	
Omethoate			
DELETE:	MO 0105	Edible offal (mammalian)	*0.05
		Fruits	2
	VD 0545	Lupin (dry)	0.1
	VO 0445	Peppers, sweet [capsicums]	1
	VO 0448	Tomato	1
		Vegetables [except lupin; peppers, sweet; tomato]	2
ADD:	Appropriate MRLs as recommended in the review of dimethoate		

Table 12: Recommended amendments to Table 4 of the APVMA MRL Standard

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)	
Omethoate			
DELETE:	AL 0157	Legume animal feeds [fresh weight]	20
	AL 0545	Lupin, forage	0.5
	AS 0161	Straw, fodder (dry) and hay of cereal grains and other grass-like plants	20
	AM 0165	Miscellaneous fodder and forage crops [fresh weight]	20
ADD:	Appropriate MRLs as recommended in the review of dimethoate		

APPENDIX D—SUMMARY OF SUBMISSIONS RECEIVED IN RESPONSE TO THE PROPOSED REGULATORY DECISIONS REPORT

Following the APVMA publication of the PRD report in May 2016, twelve submissions were received during the consultation period. Four submission were received from holders of active approvals and product registrations, one was received from a state government, and seven were received from representatives of growers that use omethoate.

Holders of product registrations and active approvals

The holders of active approvals and product registrations made four separate submissions. These did not provide any additional information or scientific argument relevant to the assessment of use patterns. The submissions noted their intention to continue to support the products and included questions about timing of any required label changes and the proposed phase out period for legal supply of the previously approved labels. One holder noted their intention to commence residues studies across a range of crops (canola, cereals, pasture and legumes) with the aim of generating residues data that could possibly support a later application to add these uses back onto the label directions after the reconsideration has been finalised.

Poppy grower representatives, Tasmania

Two submissions were received that provided further information about the use of omethoate on poppies. They stated that omethoate is most commonly used on seedling poppies from emergence up until the 4–6 leaf stage after which the plants are robust enough to withstand red legged earth mites and omethoate is not required. One respondent noted that there is between 150–200 days from application to harvest and the other noted that it is a minimum of 120 days from application to harvest. In both submissions is stated that it is standard poppy industry practice not to graze stubbles post-harvest. Some processors sell poppy seeds for use in the culinary market (average consumption of poppy seed in Australia is 19 g/annum, in Germany 99 g/annum) but seed not sold into culinary markets is not sold as stock feed and is disposed in other ways such as for use in biodiesel or as a fuel source in furnaces.

The previous label directions did not specify any withholding period or stage of crop growth for application of omethoate to poppies. Residue data to support this use pattern on poppies are not available.

The APVMA assessed this submission and noted that, given the timing of application cited in the submission, residues in poppy seed are unlikely to exceed the current MRL of 0.05 mg/kg for omethoate on oilseeds during the proposed phase out period for the previous version of varied labels. However there is insufficient residues data to support a permanent use on poppies. The APVMA will consider any application for a permit for this early stage use pattern on its merits.

Nursery and greenhouse industry representative

One submission was received that questioned the recommended re-entry period of 9 days for ornamental plants. In this submission it was stated that water volumes commonly varied from 100 to 300 L/ha with lower water volumes used for systemic insecticides such as omethoate. It was also noted that seedling and tube stock are irrigated 1–2 times daily which could reduce the presence of omethoate. Crop heights range from 0.05–0.10 metres with container trees up to 4.0 metres. Re-entry activities were reported to be most common 2 days after treatment and PPE available includes hat, mask/respirator, goggles, gloves, long sleeves, long pants and boots.

In response to this submission, the recommended re-entry periods have been recalculated at 29 days for hand harvesting of cut flowers and 0 days ('when spray has dried') for all other activities in ornamental plants. See Appendix E for the details of this additional re-entry calculation. The varied labels now include these revised re-entry periods.

Agronomist and consultant NSW

This submission noted that this person disagrees with the proposed decision to restrict the use of 290 g/L omethoate products and noted the usefulness of omethoate in broad acre applications due to its systemic action and robust activity on key establishment pests. It was asked whether the APVMA had considered extending the withholding period for grazing and harvest in relevant field crops to allow the continued use. However there was no additional residues data or information about growing practices included in this submission.

As noted in the Residues report for omethoate, there are not sufficient residues data to support an assessment of any alternate withholding periods for these crops. Therefore the APVMA is not able to establish alternate withholding periods.

NSW Department of Primary Industries, Biosecurity and Food Safety NSW

This submission included the advice that they support the proposed changes. However it was also noted in the submission that the loss of omethoate will reduce control options for resistance management. The submission discussed current uses of omethoate (mites and lucerne flea in cereals, pastures, oilseeds and legumes and aphids in lucerne and pulses). It also noted that the mites and lucerne flea can be controlled with other chemicals (e.g. alpha-cypermethrin, imidacloprid, bifenthrin, lambda cyhalothrin, chlorpyrifos etc.) and there are other options available for aphids.

WA Farmers (Grains section)

In this submission the WA Farmers noted their concern that the lack of availability of residue data will lead to the removal of omethoate for control of red legged earth mite, lucerne flea, and a number of other insects. They also noted that they considered that the use of omethoate as a barrier spray for red legged earth mite will not be effective for management of the issue and could have the potential for MRL violations if there were no MRL maintained for omethoate.

They requested that the APVMA allow a permit extension of the use patterns proposed for deletion, to allow industry to provide adequate residue data.

They also requested that the APVMA work with industry in the future to identify short comings in risk assessment data, prior to the release of proposed regulatory decisions. The APVMA notes that this reconsideration commenced in 2004 with a public consultation period and that feedback in 2006 to user groups in relation to dimethoate and omethoate indicated that there was a lack of residues data submitted. The residues report was published in March 2016 and clearly stated that there was a lack of residues data to support any uses.

Grains Research and Development Corporation

GRDC proposed that the APVMA could use the dimethoate residues studies, to support the use of omethoate on cereals, pulses and oilseeds on the basis that omethoate is a metabolite of dimethoate.

However, the APVMA has determined that it is not appropriate to use dimethoate data in place of that for omethoate as not all the dimethoate breaks down to omethoate, with significant amounts remaining as parent dimethoate in the short term. Thus the potential for omethoate residues is much higher from direct application of omethoate than from application of dimethoate. The metabolism of dimethoate is described in the published [residues report for the reconsideration of dimethoate](#).

GRDC also referred to 2 wheat residue studies summarised in the *Omethoate Residues and Dietary Risk Assessment Report* and questioned why they could not be used to support the use of omethoate of wheat. However, as noted in the residues report, these trials do not match current label use patterns or accepted good agricultural practice (GAP) for the use of omethoate and are not sufficient to support the establishment of an alternative GAP.

GRDC indicated that omethoate is required by the grains industry particularly for control of red-legged earth mite. GRDC indicated that application in autumn is more commonly used in grain production. The later, spring application, is used more commonly in pulses and pastures to protect yield and to reduce the number eggs and mites that may affect any future crop.

GRDC also referred to the results of the National Residues Survey (NRS) monitoring of grain samples in 2011–2012 and 2013–2014 in which there were no detections above half the MRL for all grain crops and an additional personal communication that the NRS did not have any detections of omethoate in the general organophosphate screen (LOR 0.01 mg/kg).

There is currently insufficient residues information for the APVMA to support the continued use of omethoate on these crops. However based on the information provided about the usual practice of application in spring and autumn, the period between application and harvest and the NRS monitoring results, a 12 month phase out period for supply of the previously approved labels is acceptable.

Australian Banana Growers' Council

This submission included a proposed 10 week withholding period (which is greater than the previous label withholding period of 6 weeks) for the bell injection use pattern and/or a longer phase out period in which they could generate more residues data. The industry does not support application by throat spray and considers that it is not a technique that is currently used. In support of the bell injection use pattern they had a submission from a banana marketing company stating that their suppliers use omethoate at a minimum 11 weeks prior to harvest and also stating that of 104 chemical tests since 2010 there has only been one detection of omethoate above the LOR of (0.01 mg/kg) that being 0.02 mg/kg.

In this submission it was also argued that the OHS risks to workers were lower for the bell injection method because the application method is targeted, equipment is not carried on the back of the user and the insecticide is contained within the banana bell. It was also argued that the proposed 17 day re-entry period was not practical as workers needed to check for new bells to be treated every 5 days and not likely to be appropriate for the bell injection techniques as it should not result in application of omethoate onto accessible surfaces.

Limited residue data (from one trial) are available for application by bell injection 86 days (approximately 12 weeks) before harvest (Residues report for product 33055, 19 June 2001). The trial reported residues in skin and pulp only and did not report the relative weights of each. It is therefore not possible to determine residues in the whole fruit which is the portion of the commodity that the MRL applies to. However, omethoate residues in the skin were below current omethoate fruits MRL of 2 mg/kg.

The acute dietary exposure estimates based on the highest residue reported in this one trial were acceptable (55% of ARfD for children and 15% for the general population). Therefore the residues assessment included the recommendation that the bell injection use with a 12 week withholding period could be acceptable for a phase out period. However further residue data would need to be generated to confirm the dietary exposure estimate and the residues in whole fruit for MRL establishment - the available information is not sufficient to support this use pattern long term. The assessment also recommended that bananas that receive an omethoate bell injection treatment should not receive a post-harvest treatment with dimethoate, to ensure that the omethoate acute dietary exposure remains acceptable.

Based on the information that current practice for treatment of bananas occurs at 11 weeks prior to harvest, the residues monitoring data, the advice that workers do not carry spray equipment on their backs and that the industry does not support the throat injection technique it is acceptable to allow a 12 month phase out period for this use pattern. The available information is not sufficient to support a permanent use pattern.

APPENDIX E—ADDITIONAL RE-ENTRY PERIOD CALCULATIONS FOR NURSERY AND GREENHOUSE

The re-entry periods published in the May 2016 PRD were based on assumed application rates of 0.9 kg ai/ha of treated foliage. For floriculture, nursery and greenhouse crops this is equivalent to an application volume of 1500 L/ha of a spray mix of 75 ml product/100 L or the treatment of 0.2 ha with 300 L of spray mix of 75 ml product/100 L.

The submission on behalf of the nursery industry indicated that they considered water volumes of 100 to 300 L/ha were more likely for the use of omethoate. The APVMA has consulted the results of other surveys of growers and has decided to recalculate the re-entry periods based on an application volume of 600 L /ha.

This is the equivalent of 0.36 kg ai/ha of treated foliage. For floriculture, nursery and greenhouse crops this is equivalent to 600 L/ha of a spray mix of 75 ml product/100 L or the treatment of 0.2 ha with 120 L of spray mix of 75 ml product/100 L. The results of the re-entry calculations are shown in Table 13 below.

Table 13: Calculated re-entry periods for ornamental crops 800 g/L products

Crop or situation as described on label	Specific situation	Relevant Activities	REI
Carnations, chrysanthemums, Pelargoniums, Roses, Callistemons	Floriculture crops	Hand harvesting of cut flowers	Hand harvesting 29 days
	Floriculture crops	Container moving, grafting, hand pruning, scouting, hand weeding, transplanting, propagating, pinching, tying/training	0 days (until the spray has dried)
	Nursery crop (ornamentals, non-bearing plants)	Container moving, grafting, hand harvesting, hand pruning, scouting, hand weeding, transplanting, propagating, pinching, tying/training	0 days (until the spray has dried)
	Greenhouse crop (ornamentals, non-bearing plants)	Container moving, grafting, hand harvesting, hand pruning, scouting, hand weeding, transplanting, propagating, pinching, tying/training	0 days (until the spray has dried)

The US EPA calculator (US EPA 2013) default assumptions have been used for these estimations of REIs because there were no data provided regarding measured worker exposures or dislodgeable foliar residues (DFR) during or after the use of omethoate. These include an initial dislodgeable foliar residues (DFR) of 25% of the omethoate applied and a dissipation rate of 10% per day. The No Observable Adverse Effect Level (NOAEL) used was 2.5 mg/kg bw/day from a three week dermal exposure study in rabbits (Flucke and Luckhaus 1979) and the acceptable Margin Of Exposure (MOE) was 100 or more.

ABBREVIATIONS

ADI	Acceptable daily intake (for humans) a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable risk to health
AChE	Acetyl cholinesterase—an enzyme essential for the regulation of nerve tissue function
Agvet Code	Agricultural and Veterinary Chemicals Code, Schedule to the Agricultural and Veterinary Chemicals Code Act 1994
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	acute reference dose the estimated amount of a substance in food or drinking-water, (expressed on a body weight basis), that can be ingested or absorbed over 24 hours or less, without appreciable health risk
ChE	Cholinesterase
EC	Emulsifiable concentrate—a liquid formulation
EU	European Union
FAISD	First Aid Instruction and Safety Directions
GAP	good agricultural practice
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MOE	Margin of exposure a measure of occupational exposure to a compound being the ratio of the no-observed effect-level to the estimated exposure dose
MRL	maximum residue limit
NEDI	National estimated daily intake (of chemical)
NESTI	National Estimated Short-Term Intake
NOAEL	no observable adverse effect level
NOEL	No Observed Effect Level
NOEC	No Observable Effect Concentration (applicable to inhalational studies)
OCS	Office of Chemical Safety within the Australian Government Department of Health
OHS	occupational health and safety
OP	organophosphorus pesticide
PPE	personal protective equipment such as gloves and overalls
SC	suspension concentrate
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (formerly the Standard for the Uniform Scheduling of Drugs and Poisons)

US	United States
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US EPA	US Environmental Protection Agency
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WHO	World Health Organization
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