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Australian Pesticides and Veterinary Medicines Authority

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Dimethoate
Proposed Regulatory Decisions
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Submissions and technical reports

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1 INTRODUCTION

This volume accompanies the proposed regulatory decisions for the reconsideration of dimethoate.

It contains full details of the outcomes of the 2016 re-assessment of re-entry intervals and the summary of all submissions received during this reconsideration and toxicology studies received since 2011.

2 RE-ENTRY INTERVALS ASSESSMENT 2016

Since the completion of the OHS assessment the US EPA Exposac calculator (US EPA 2013) has been revised to include more exposure data. This has been adopted for use in APVMA assessments of re-entry exposure.

The exposure of workers depends on how much chemical residues is available on the crop leaves and surfaces to be transferred across to workers (the dislodgeable foliar residue or DFR) and how much of that available residue can transfer across to people occurs during a particular activity (the transfer coefficient). The calculator uses an initial dislodgeable foliar residue (DFR) of 25 per cent of the spray applied and the dissipation rate (per cent per day) to calculate the amount of DFR on a crop for each day after spraying. The DFR calculated for each day is then used together with transfer coefficient (TCs), (from actual exposure monitoring of individuals doing specific tasks on specific crop types) to calculate the amount of chemical that an individual can be exposed to during a standard working day for each day after spraying. The re-entry interval is set as the first day that the margin of exposure of that individual is at acceptable levels, when compared to the No Observable Adverse Effect Level (NOAEL) of exposure for that chemical.

The 2013 version of the Exposac calculator assumes an initial Dislodgeable Foliar Residue of 25 per cent of the spray applied (previously 20 per cent). The dissipation rate of 13 per cent was based on the five day half-life calculated from DFR data from studies of dimethoate sprayed on tomatoes, leaf lettuce and apples in the USA.

The standard worker weight in APVMA assessments is 70 kg. The No Observable Adverse Effect Level (NOAEL) used was 0.2 mg/kg bw/day oral dose from a 14–57 day study in humans. The dermal absorption factor used was 5.1 per cent. As this was a human study the acceptable Margin of Exposure (MOE) is 10 or more which allows for a ten-fold safety factor for variation between individuals.

The application rates in grams of active per hectare used were calculated from the label instructions and the product concentration of 400 g/L dimethoate. This is then converted to pounds per acre (1000 g ai/ha = 0.892 lb ai/A) for use in the Exposac calculator. Where the label directions specify a rate per 100 L instead of a rate per hectare this is combined with information on maximum volumes of spray per hectare. Standard assumptions are maximums of 5000 L/ha for citrus, 4000 L/ha avocado and mango, 2500 L/ha for deciduous orchard trees, 1000 L/ha for grapevines, litchi trees (lychees), passionfruit vegetables and field crops, 600 L/ha for ornamental crops and 1500 L/ha for all other crops. Spray volumes were also checked against the 2001 Compendium of farming practices and the publication ‘Water rates used in horticulture: Biosecurity Victoria DPI, May 2012’. As the recommended re-entry periods are intended to protect farm workers in all situations it is appropriate to use the maximum likely spray rates for these calculations.

Additionally, following the APVMA publication of the OHS report, a submission was received regarding the suitability of the recommended 19 day re-entry interval for all evergreen tree crops. This had been based on the highest application rate of 150 mL/100 L from citrus uses, with a maximum spray volume of 5000 L/ha. In this submission the reported maximum spray volumes for other evergreen tree crops were 4000 L/ha for mangoes, avocadoes and citrus, and 1000 L/ha for lychees and longans. It was also noted in that submission that the maximum rate of 150 mL/100 L cited for citrus was not present on all labels and was of such limited applicability that the citrus industry would prefer it to be removed from labels.

In most cases a direct crop description or a recommended crop match is available in the new expanded Exposac calculator and has been used to calculate the re-entry intervals as noted in the table below. For tropical and subtropical fruits there are direct matches for avocado, banana, mango and papaya and for litchi it is recommended that apple is a suitable match. There was no listing for passionfruit so the settings for two other vine/trellis crops (kiwi fruit and grapes) were used and compared. There is a wide variability in the label use rates and the descriptions for tree crops across labels so the REIs have been calculated for the maximum, medium and lowest use rates across all available crop types for comparison.

Table 1: Calculated re-entry periods for all crops

Crop or situation	Crop types used in calculator	Highest product use rates	Grams of active/ha	Re-entry intervals and activity type
Abius, casimiroas, custard apple, santols, sapodillas, wax jambus	None recommended To be grouped with avocado	75 mL/100 L 2500 L/ha	750	Day 2 for hand harvesting once spray has dried for all other activities
Avocado	Avocado	75 mL/100 L 4000 L/ha	1200	Day 2 for hand harvesting Day 0 (once spray has dried) for irrigation, orchard maintenance, pruning, scouting, transplanting, weeding (hand),
Banana	Banana	75 mL/100 L 1500 L/ha	450	Day 0 (once spray has dried) for hand harvesting, irrigation, weeding
Citrus fruit high rate—not applicable to all products	Grapefruit, Lemon, Orange same result	150 mL/100 L 5000 L/ha	3000	Day 9 for hand harvesting Day 2 for hand pruning, scouting Day 0 (once spray has dried) for orchard maintenance, weeding, baiting/trapping, transplanting,
Citrus fruit low rate	Grapefruit, lemon, orange same result	75 mL/100 L 5000 L/ha	1500	Day 4 for hand harvesting Day 0 (once spray has dried) for hand pruning, irrigation (non-hand set), orchard maintenance, weeding, baiting/trapping, scouting, transplanting,
Grapes—restricted to pre-flower uses since Oct 2011	Grape wine, juice, table and raisin	75 mL/100 L 1000 L/ha	300	Day 11 for girdling, turning (table grapes) Day 6 for hand harvesting, leaf pulling, tying/training Day 0 for bird control, burndown, ditching, irrigation (hand set), pruning (hand), weeding (hand), propagating, scouting, transplanting, trellis repair

Crop or situation	Crop types used in calculator	Highest product use rates	Grams of active/ha	Re-entry intervals and activity type
Litchis (lychee)	Apple recommended	75 mL/100 L 1000 L/ha	300	Day 0 (once spray has dried) for; harvesting (hand), frost control, orchard maintenance, propping, pruning (hand), scouting, spreading bins, thinning fruit, training, transplanting, weeding (hand)
Mango	Mango	75 mL/100 L 4000 L/ha	1200	Day 9 for Fruit thinning (by hand) Day 2 for Hand Harvesting, Day 0 (once spray has dried) for Pruning and Scouting
Passionfruit	None recommended used Kiwi fruit	75 mL/100 L 1000 L/ha	300	Day 6 for hand harvesting (if picked from trellis) Day 0 (once spray has dried) for irrigation (hand set), pruning (hand), weeding (hand), scouting, transplanting, tying/training
Pawpaw (papaya)	Papaya	75 mL/100 L 2500 L/ha	750	Day 0 (once spray has dried) for harvesting (hand), irrigation (non-hand set), orchard maintenance, pruning (hand), scouting, transplanting, weeding (hand)
Pome fruit—not permitted since October 2011	Apple, Pear	75 mL/100 L 2500 L/ha	750	Day 5 for thinning fruit Day 0 (once spray has dried) for; harvesting (hand), frost control, orchard maintenance, propping, pruning (hand), scouting, spreading bins, training, transplanting, weeding (hand)
Stone fruit—restricted to prior to petal fall since Oct 2011	Apricot, Plum, Nectarine	75 mL/100 L 2500 L/ha	750	Day 5 for thinning fruit Day 0 (once spray has dried) for; harvesting (hand), fertilizing, irrigation (non-hand set), orchard maintenance, propping, pruning (hand), hand, scouting, spreading bins, training, transplanting, weeding (hand)
Non-tree crops berries and vegetables				
Blackberries	Blackberry	800 mL/ha	320	Day 0 (once spray has dried) for; hand harvesting, irrigation (hand set), pruning (hand), scouting, transplanting, tying/training, weeding (hand)
Raspberries	Raspberry	800 mL/ha	320	Day 0 (once spray has dried) for; hand harvesting, irrigation (hand set), pruning (hand), scouting, transplanting, tying/training, weeding (hand)
Strawberry	Strawberry	800 mL/ha	320	Day 0 (once spray has dried) for; canopy management, harvesting (hand), scouting, transplanting, weeding, hand
Blueberries	Blueberry high and low	750 mL/ha	300	Day 0 (once spray has dried) for; bird control, frost control, hand harvesting, irrigation (hand set), pruning (hand), scouting, transplanting, weeding (hand)
Artichoke globe	Artichoke globe	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), pruning (hand), scouting, thinning plants, transplanting, weeding (hand)

Crop or situation	Crop types used in calculator	Highest product use rates	Grams of active/ha	Re-entry intervals and activity type
Asparagus	Asparagus	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, transplanting, weeding (hand)
Beans, green	Bean snap	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, weeding (hand)
Beetroot	Beet, garden	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, thinning plants, weeding (hand)
Broccoli	Broccoli	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, thinning plants, transplanting, weeding (hand)
Cabbage (head)	Cabbage	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), harvesting (mechanically assisted), irrigation (hand set), scouting, thinning plants, transplanting, weeding (hand)
Carrot	Carrot	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, weeding (hand)
Capsicum	Pepper, bell	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, transplanting, tying/training, weeding (hand)
Cauliflower	Cauliflower	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, thinning plants, transplanting, tying/training, weeding (hand)
Celery	Celery	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, transplanting, weeding (hand)
Chilli	Pepper, chilli	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), pruning (hand), scouting, transplanting, weeding (hand)
Eggplant	Eggplant	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), pruning (hand),scouting, thinning fruit, transplanting, tying/training, weeding, hand
Greenhouse vegetable	Greenhouse vegetable	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand watering), pinching, pollination, propagating, pruning (hand), scouting, transplanting, turning, tying/training, weeding (hand)
Melons	Watermelon, Cantaloupe	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), harvesting (mechanically-assisted), irrigation (hand set), pruning (hand), scouting, thinning fruit, training, transplanting, turning, weeding (hand)

Crop or situation	Crop types used in calculator	Highest product use rates	Grams of active/ha	Re-entry intervals and activity type
Onion	Onion, bulb	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, thinning plants, weeding (hand)
Parsnips	Carrot	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, weeding (hand)
Peas (green)	Pea, green	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, weeding (hand)
Potato	Potato	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, weeding (hand)
Radish	Turnip	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, thinning plants, weeding (hand)
Rhubarb	Celery	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, transplanting, weeding (hand)
Sweet corn	Corn, sweet grain	800 mL/ha	320	Day 6 for; detasseling (hand), harvesting (hand) Day 0 (once spray has dried) for; irrigation (hand set), scouting, topping, weeding (hand)
Sweet potato	Potato, sweet	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, transplanting, weeding (hand)
Tomatoes	Tomato and Processing Tomato	750 mL/ha	300	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), pruning, hand, scouting, transplanting, tying/training, weeding (hand)
Turnip	Turnip	800 mL/ha	320	Day 0 (once spray has dried) for; harvesting (hand), irrigation (hand set), scouting, thinning plants, weeding (hand)
Zucchini	Squash, summer	750 mL/ha	300	Day 0 (once spray has dried) for; harvesting (hand), harvesting (mechanically-assisted), irrigation (hand set), pruning (hand), scouting, thinning fruit, training, transplanting, turning, weeding (hand)

Crop or situation	Crop types used in calculator	Highest product use rates	Grams of active/ha	Re-entry intervals and activity type
Broad acre crops, field crops				
Grain legumes adzuki beans, beans-field, borlotti beans, cowpea, lentils, lupins, mung bean, navy bean, peas (field), pigeon pea	Bean, dry, and Pea, dry	Lentils RLEM 90 mL/100 L 1000 L/ha	360	Day 0 (once spray has dried) for; irrigation (hand set), scouting
Chick peas	Chickpea	800 mL/ha	320	Day 0 (once spray has dried) for; irrigation (hand set), scouting
Soybean	Soybean	800 mL/ha	320	Day 0 (once spray has dried) for; irrigation (hand set), scouting, weeding (hand)
Canola	Canola	85 mL/100 L 1000 L/ha	340	Day 0 (once spray has dried) for; scouting
Cereals	Barley, Corn (field), Wheat (spring) Wheat (winter)	High rate mites 90 mL/100 L 1000 L/ha	360	Day 0 (once spray has dried) for; irrigation (hand set), scouting, weeding (hand)
Maize	Corn (field)	500 mL/ha	200	Day 0 (once spray has dried) for; irrigation (hand set), scouting, weeding (hand)
Sorghum	Sorghum (grain)	500 mL/ha	200	Day 0 (once spray has dried) for; scouting, weeding (hand)
Cotton	Cotton	75 mL/100 L 1000 L/ha	300	Day 0 (once spray has dried) for; scouting, weeding (hand)
Oilseeds	Soybean, Safflower, Peanut, Sunflower	75 mL/100 L 1000 L/ha	300	Day 0 (once spray has dried) for; irrigation (hand set), scouting, weeding (hand)
Peanuts	Peanut	350 mL/ha	140	Day 0 (once spray has dried) for; irrigation (hand set), scouting, weeding (hand)
Sesame	Canola	500 mL/ha	200	Day 0 (once spray has dried) for; scouting
Sunflower	Sunflower	800 mL/ha	320	Day 0 (once spray has dried) for; bird control, scouting
Leucaena	Forage crop Nursery crop	340 mL/ha	136	Shrub to small tree sized tropical forage crop Day 0 (once spray has dried) for; irrigation (hand set), scouting
Lucerne	Alfalfa Forage crop	750 mL/ha	300	Day 0 (once spray has dried) for; irrigation (hand set), scouting

Crop or situation	Crop types used in calculator	Highest product use rates	Grams of active/ha	Re-entry intervals and activity type
Pasture	Forage crop	350 mL/ha	140	Day 0 (once spray has dried) for; irrigation (hand set), scouting
Tobacco	Tobacco	80 mL/100 L 1500 L/ha	480	Day 0 (once spray has dried) for; canopy management, harvesting (hand), harvesting (mechanically-assisted), irrigation (hand set), scouting, transplanting, weeding (hand)
Ornamentals and tree crops				
Ornamentals	Floriculture crop	75 mL/100 L 600 L/ha	180	Day 0 (once spray has dried) for; cut flowers harvesting (hand)container moving, irrigation (hand set), pinching, pruning (hand), scouting, transplanting, weeding (hand)
Ornamental shrubs	Nursery crop	75 mL/100 L 600 L/ha	180	Day 0 (once spray has dried) for; container moving, grafting, harvesting (hand), irrigation (hand set), pinching, propagating, pruning (hand), scouting, transplanting, tying/training, weeding (hand)
Ornamental farm and forest trees highest rate (NSW)	Forestry, Nursery crop Christmas tree	400 mL/100 L 1500 L/ha	2400	Day 9 for irrigation (hand set) Day 7 for harvesting (hand) (Christmas tree/ seed cones) Day 1 for pruning (hand), shaping, scouting Day 0 (once spray has dried) for; container moving, grading/tagging, transplanting, weeding (hand)
WA only: eucalypts, kurrajong, flame trees umbrella trees	Forestry, Nursery crop	25 mL/8 L 1500 L/ha	1875	Day 7 for Irrigation (hand set) Day 5 for Harvesting (hand) (Christmas tree/ seed cones) Day 0 (once spray has dried) for; container moving, grading/tagging, pruning (hand), shaping, scouting, transplanting, weeding (hand)
Farm and forest trees lower rate	Forestry, Nursery crop, Christmas tree	75 mL/100 L 1500 L/ha	450	Day 0 (once spray has dried) for; container moving, grading/tagging, harvesting (hand) (christmas tree/ seed cones), irrigation (hand set), pruning (hand), shaping, scouting, transplanting, weeding (hand)
Duboisia	Nursery crop	75 mL/100 L 1500 L/ha	450	Shrub to small tree sized native pharmaceutical crop Day 0 (once spray has dried) for; container moving, grafting, harvesting (hand), irrigation (hand set), pinching, propagating, pruning (hand), scouting, transplanting, tying/training, weeding (hand)
Protea and wildflowers	Floriculture crop	75 mL/100 L 600 L/ha	450	Day 0 (once spray has dried) for; cut flowers harvesting (hand)container moving, irrigation (hand set), pinching, pruning (hand), scouting, transplanting, weeding (hand
Oil tea tree	Nursery crop	340 mL/ha	136	Shrub to small tree sized native oil crop Day 0 (once spray has dried) for; container moving, grafting, harvesting (hand), irrigation (hand set), pinching, propagating, pruning (hand), scouting, transplanting, tying/training, weeding (hand)

3 SUMMARY OF SUBMISSIONS PROVIDED TO THIS RECONSIDERATION

Submissions received in 2004

In 2004, during the three month consultation period after publication of the scope of the dimethoate review the APVMA received submissions of data and use pattern information from product registrants and the chemical coordinators representing the states and territories, as well as public submissions from:

- the Australian Custard Apple Growers Association (29 June 2004) noting areas of production, lack of alternatives, importance of dimethoate particularly as a post-harvest treatment and noting that custard apples are an inedible peel crop.
- NSW Farmers Federation (30 June 2004) noting the importance of dimethoate and omethoate in agricultural quality assurance schemes and to control a range of insects and mites. They noted that there was a lack of effective alternatives to dimethoate for post-harvest fruit fly control.
- Queensland Fruit and Vegetable Growers (29 June 2004) noting the significance of dimethoate to interstate trade. They also advised that dimethoate was mostly applied by spray with enclosed tractor cabs and use of conveyor belts and forklifts for post-harvest treatment of fruit.
- Horticulture Australia Limited (2 July 2004) submission with residues data from supervised trials from a range of crops and OHS information including work rates, re-entry activities and examples of post-harvest handling systems.
- the Australian Mango Industry Association (2 July 2004) noting the areas of production, lack of alternative post-harvest treatments and that mangoes are classified as an inedible peel tropical fruit.
- Avocados Australia (2 July 2004) noting the critical importance of dimethoate as a post-harvest insecticide for interstate trade, noting that pre-harvest treatment is less effective and that avocado is regarded as an inedible peel fruit.
- Horticulture Access Solutions (30 June 2004) noting irradiation as an alternate to dimethoate for post-harvest quarantine treatment of fruit flies.
- The South Pacific Melon Group (2 July 2004) and the Australian Melon Association Inc (2 July 2004) concerning the lack of suitable alternative treatments for exported melons.

Submissions received 2005–11

After the consultation period had ended, the APVMA received additional submissions from:

- the Australian Horticulture Exporters Association (6 June 2005) concerned about the potential loss of access to dimethoate for treatment of exported produce.
- a private veterinarian (13 Dec 2004) concerned about the potential toxicity of dimethoate to humans and dogs.

In 2006 and 2007, the APVMA identified a lack of residues data to support the Australian use patterns for many crops. The APVMA consulted with user, industry and government representatives, advising that, without that data the APVMA would not be able to support ongoing use of dimethoate on these crops.

The APVMA participated in meetings with states and territory chemical coordinators and interstate quarantine authorities, Low Chill Australia (stone fruit grower group), Growcom, Plant Health Australia and the National Fruit Fly Strategy working group. As a result of these discussions, Horticulture Australia Ltd funded research to generate residues data for certain crops treated with dimethoate.

From 2008 to 2012, the APVMA participated in the Dimethoate and Fenthion Response Coordination Committee teleconferences and attended industry meetings to present updates on the progress of the fenthion and the dimethoate reviews.

In May 2010, Horticulture Australia Ltd (HAL) submitted additional residues data for dimethoate in a range of crops. The APVMA assessed this and all other submitted residues information for dimethoate and published the results in the first *Dimethoate Residues and Dietary Risk Assessment Report* (August 2011).

Submissions received in 2011 in response to proposed suspension of dimethoate products

In August 2011, the APVMA:

- published the residues and dietary exposure assessment which determined that existing label directions were not acceptable for many crops due to acute dietary risks
- proposed that all products containing dimethoate be suspended and proposed that modified instructions be issued for use of these products during the suspension
- requested information that could be used to refine the dietary risk assessment or to assist in developing interim, modified instructions during the proposed suspension period.

The proposed suspension and consultation on new use instructions attracted a significant level of interest from a wide range of stakeholders. The APVMA attended stakeholder meetings and participated in teleconferences with stakeholder groups regarding the proposed suspension. The APVMA received submissions from:

- Queensland Strawberry Growers Association Inc. (7 September 2011) requested permission to use two more sprays of dimethoate on strawberries (ending 28 October 2011) to allow trade to Vic, NSW and SA; requested prioritisation for replacement permits for spinetoram and maldison
- Summerfruit Australia (13 September 2011) did not agree that action is necessary, contributed market surveillance residues data for consideration, 23 September 2011 requested consideration of allowing use pre-flowering only for western flower thrip
- Stone fruit producer, Victoria (13 September 2011), agreed with proposed removal of uses but not with the timing
- Cherry Growers Australia Inc (16 September 2011) did not agree that action is necessary, noted importance of dimethoate for fruit fly control and lack of alternates

- exporter (30 August 2011), proposed three trials for rockmelon post-harvest be accepted to support interim use, proposed honeydew melons be supported in the interim
- AKC Consulting for HAL Australia (5 September 2011), submitted final copy of the 26 August 2011 residues report for melons
- Australian Melon Association Inc (12 September 2011), requested retain melons pre and post-harvest uses, request residues results be scaled to allow use of further data
- Australian Processing Tomato Research Council Inc.(9 September 2011), proposed interim use with longer withholding period of 21–28 days
- fruit grower WA (two letters)(9 September 2011), proposed alternate withholding period for apples and pears of 21 days or earlier (during fruit formation) to reduce fruit fly damage
- Berry Exchange (9 September 2011), propose that all Vaccinium berries be included in the use pattern and MRL for blueberries (includes bilberries as well as blueberries), supports use on raspberry and blackberry as those trials can be considered together, blueberry monitoring data provided
- Austchilli Pty Ltd (12 September 2011), proposed use of alternate dietary intake data and use of capsicum data for chilli with 7 day WHP
- Biosecurity QLD, DEEDI (13 September 2011):
  - proposed retain the specific vegetables eggplant, chilli, processed tomatoes, carrot, globe artichoke and celery
  - comments on whether residues data could be scaled, calculation of animal dietary burden and, seed dressing ,pasture crop seed and lupin uses
  - query whether additional residue data are required for all VP 0538 Podded pea (young pods)
- Nufarm (13 September 2011), requested consideration of pre-flowering use on grapes
- Bundaberg Fruit And Vegetable Growers (13 September 2011), proposed use of lower consumption figures for edible peel tropical fruits, use of residues monitoring data for carambolas to support dietary exposure calculations
- Ausveg (13 September 2011) proposed use of scaling of residues data also proposed support for specific vegetables brussels sprouts, cauliflower, broccoli, cabbage (drumhead only), beetroot, carrot, potato, radish, turnip, cucumber, eggplant, chilli peppers, celery and globe artichoke
- Pulse Australia (12 September 2011) comment on availability of alternate data—not required for the suspension decision
- Growcom (12 September 2011) proposals for Tropical inedible fruit—not required for the suspension decision.

These submissions and information were assessed and considered in the APVMA decision to suspend dimethoate products on 5 October 2011and to issue modified interim instructions for their use that mitigated the identified acute dietary risks.

Some products have since had new labels approved that have instructions for use that are consistent with the suspension instructions.

As noted in the residues report further residues data were required to support continued use of some of the interim use patterns that were permitted after the suspension.

Submissions received 2012–16

In May 2012 the APVMA sent additional data requirement notices to the holders of products requiring additional residues data. Since August 2011, the APVMA received additional residues studies for a range of crops from:

- AKC Consulting for HAL Australia (26 August 2011), submitted a final residues report for 10-HAL-006GLP rock melon and honey dew melon
- Cheminova and Ospray (7 November 2012 and 4 March 2013) additional residues studies for soybeans, cotton, field peas, barley, maize, sorghum, wheat, and four additional studies relevant to the toxicology and OHS assessments
- Horticulture Australia Limited (27 March 2013 with updates 13 May 2014) additional study data for berry fruits (blueberries, blackberries and raspberries), oranges, avocadoes and pineapples (permit only for pineapples)
- Plant Health Australia (23 April 2013) on behalf of the Grains Research and Development Corporation additional two residues studies on mungbeans, navybeans, soybeans and peanuts.

These studies have been assessed by the APVMA and have been included in the Dimethoate Residues and Dietary Risk Assessment Report (updated June 2016), which incorporated new information submitted since August 2011.

Since the publication of the OHS report in March 2013:

- One joint submission was received from Avocados Australia, the Australian Mango Industry Association, Citrus Australia and the Australian Lychee Growers Association in May 2015 requesting that the APVMA re-examine the recommended re-entry periods for evergreen tree crops and requesting that the re-entry periods be recalculated after consideration of their information regarding likely maximum application rates, water volumes. It also provided information regarding the likely maximum work rates per day for spray applications.
    - The re-entry periods for all crops have been recalculated using the US EPA Exposac REI calculator (March 2013 version) taking into consideration the information presented in this submission. These are presented in full Section 2 above.
- Cheminova and Ospray (7 November 2012) submitted four additional studies relevant to the toxicology and OHS assessments in support of the current maximum impurity level for O,O,S-TMP of 5 g/L. These are assessed in Section 4 of this document.

In March 2016 one holder submitted acute toxicology studies (six-pack) in support of their product which had been included in this reconsideration in July 2015. The studies are summarised below and are consistent with the published toxicology and OHS assessments.

4 DIMETHOATE—ASSESSMENT OF ADDITIONAL TOXICOLOGY STUDIES

Acute toxicology studies received March 2016

Agrogill Chemical Pty Ltd submitted six acute toxicology studies in response to the s32 Notice of 1 July 2015. The test material used in these studies was 98 per cent dimethoate technical material. All studies were performed by laboratories that were certified for good laboratory practice (GLP) and that complied with the relevant Organisation for Economic Co-operation and Development (OECD) test guidelines

The results of the acute toxicity tests on the dimethoate 98 per cent technical, including skin and eye irritation and skin sensitisation studies are summarised in Table 1 below. In the acute oral toxicity test lethargy, prostration, nasal irritation and abdominal breathing were observed in rats given the 300 mg/kg bw dose and 100 per cent mortality occurred at the 2000 mg/kg bw dose rate. No systemic effects including deaths or clinical signs were observed in any of the other studies. In the skin irritation study two of three rabbits had transient slight oedema. The eye irritation study in rabbits resulted in transient mild corneal opacity, conjunctival redness and chemosis observed in all three rabbits. There was no observed iritis or any changes to light responses. In the guinea pig maximisation test for sensitisation, slight to well-defined erythema and very slight oedema were observed one day after intradermal injection. Topical application on day 7 caused very slight to well defined erythema and oedema on day 10–no skin reactions were noted following challenge exposure.

Table 1: Results of acute toxicity studies on dimethoate 98% per cent technical

Species	Strain	Sex	Route	Purity	Vehicle	Result	Reference
Rat	Wistar	Female	Oral	98%	Vegetable oil	LD_{50} 500 mg/kg bw	Sharma (2011a)
Rat	Wistar	Male and female	Dermal	98%	Distilled water	Dermal LD_{50} >2000 mg/kg	Sharma (2011b)
Rat	Wistar	Male and female	Inhalation full body	98%	DMSO	LC_{50} >9.6 mg/L	Verma (2011a)
Rabbit	NZW	Male	Dermal irritation	98%	Distilled water	Not irritating 500 mg dose	Sharma (2011c)
Rabbit	NZW	Female	Eye irritation	98%	Undiluted pulverised	Not irritating 100 mg dose	Sharma (2011d)
Guinea pig	Hartley	Male	Skin sensitisation (maximization test)	98%	Ethanol, acetone	Not sensitising 100 mg	Verma (2011b)

Conclusion

The results of these acute studies are consistent with those already reported in the dimethoate toxicology report (November 2011) and do not have an impact on the assessment of dimethoate.

References

Sharma AK (2011 a). Acute Oral Toxicity Study of Dimethoate 98% tech in Rats, Jai Research Foundation, Gujarat India, Study number 401-1-01-0851 (Final Report), Guidelines: OECD No 423 Dec 2001, GLP Yes

Sharma AK (2011 b). Acute Dermal Toxicity Study of Dimethoate 98% Tech in Rats, Jai Research Foundation, Gujarat India, Study number: 403-1-01-0852 (Final Report) Guidelines: OECD No 402 Feb 1997, GLP Yes

Sharma AK (2011 c). Acute Dermal Irritation Study of Dimethoate 98% Tech in Rabbits, Jai Research Foundation, Gujarat India, Study number: 406-1-01-0854 (Final Report), Guidelines: OECD No 404 April 2002, GLP Yes

Sharma AK (2011 d). Acute Eye Irritation Study of Dimethoate 98% Tech in Rabbits, Jai Research Foundation, Gujarat India, Study number: 407-1-01-0855 (Final Report), Guidelines: OECD No 405 (April 2002), GLP Yes

Verma R (2011).Acute Inhalation Toxicity Study of Dimethoate 98% Tech in Rats, Jai Research Foundation, Gujarat India, Study number: 405-1-01-0853 (Final Report), Guidelines: OECD No 403 (May 1981), GLP Yes

Verma R (2011).Skin Sensitization Study of Dimethoate 98% Tech in Guinea Pigs [Guinea Pig Maximization Test], Jai Research Foundation, Gujarat India, Study number: 408-1-01-0856 (Final Report), Guidelines OECD No 406 (July 1992), GLP Yes

Toxicology studies and documentation received 2011 and 2012

Cheminova A/S submitted three additional toxicology studies as part of their comments and responses to the toxicology and OHS assessments in 2011 and 2012 and the proposal by the Office of Chemical Safety to lower the impurity limit for O,O,S-trimethyl phosphorodithioate (OOS-TMP) from the current 5 g/kg to 3 g/kg.

All three toxicology studies were performed by laboratories that were certified for good laboratory practice (GLP) and that complied with the relevant Organisation for Economic Co-operation and Development (OECD) test guidelines.

Additionally Cheminova submitted a summary of documentation of dimethoate Batch 611/A indicating its measured impurity levels.

In 2011 Cheminova A/S also submitted a copy of Myers DP (2004). Dimethoate cross fostering study in CD rats. Huntingdon Life Sciences. This had not previously been submitted, however a detailed review of this study by the US EPA was available to the OCS and was considered as part of the toxicology assessment as follows:

> 'It was further noted that in a cross-fostering study in rats carried out to determine whether mortality was a result of dimethoate exposure during gestation or lactation, pup mortality was increased regardless of pre- or postnatal exposure to dimethoate at 3 and 6 mg/kg bw'.

It was not necessary to re-assess this study, given the availability of a reliable international assessment.

Summary of Barnett, J. F. (2011). Oral (Diet) Repeated Dose 14–Day Dosage Range Study of Dimethoate in Mice

This was a pilot, range-finding investigation for the 28 day study below. Groups of eight mice were exposed to dimethoate (98 per cent purity) at dietary concentrations of 0, 25, 100, 200 and 400 ppm ad libitum for 14 days. Reduced body weight gain was observed at 200 ppm and body weight loss at 400 ppm. Absolute and relative food consumption values and food efficiency were also reduced at 400 ppm. Terminal body weights, thymus and spleen weights and ratios of thymus and spleen weights to body weight were reduced at 400 ppm. Brain and RBC cholinesterase values were statistically significantly reduced in all exposure groups. This study was used to set the dose range used in the following study of immunotoxicity.

Summary of Barnett, J.F. (2011): Oral (Diet) Repeated Dose 28–Day Immunotoxicity Study of Dimethoate in Mice

Groups of 15 female Crl:CD1(ICR) mice were exposed to dimethoate (98 per cent purity, batch lot 611/A) at dietary concentrations of 0, 5, 25, 75 or 200 ppm ad libitum for 28 days (equivalent to 1.0, 5.0, 14.2, and 36.4 mg/kg bw per day, respectively). An additional group of 10 mice served as the positive control. Four days prior to termination, all mice were administered an intravenous dose of 0.2mL of sheep red blood cells (sRBCs). Positive controls also received 50 mg/kg per day cyclophosphamide intraperitoneally for four days prior to sacrifice (10 mg/mL). Observations for mortalities and clinical signs, and recording of bodyweight and feed consumption, occurred throughout the exposure period. Blood and brain samples were collected at termination for the analysis of ChE activity, except for the positive controls. All mice were necropsied,

examined for gross lesions and the spleen and thymus weighed. The spleen was retained for immunological evaluation. There were no deaths in any group, nor any treatment-related clinical signs other than tremors. There were statistically significant increases in whole body and abdominal tremors at 200 ppm (four mice). Mean body weights, body weight changes and feed efficiency values were statistically significantly reduced at 200 ppm during the exposure period. There was no treatment-related macroscopic findings or effect on spleen or thymus weights. In contrast absolute and relative thymus and spleen weights were significantly reduced (41%, 39% and 48%, 48%; $p<0.01$) in the positive controls. Statistically significant and toxicologically relevant inhibition of RBC cholinesterase occurred at 25, 75, and 200 ppm (40.5%, 72.0%, and 88.4% respectively; $p<0.01$) Statistically significant and toxicologically relevant inhibition of brain cholinesterase occurred at 5, 25, 75 or 200 ppm (11.7%, 51.6%, 76.7% and 86.4% respectively: $p<0.01$). Immunological evaluation revealed no treatment related change in spleen cell numbers or the spleen IgM antibody response to sRBCs. There were statistically significant decreases in the positive controls. The NOAEL for immunotoxicity was 200 ppm (equal to 36.4 mg/kg bw per day), the highest tested dose. Dimethoate was not immunotoxic at this dose, even in the presence of overt toxicity. This study was good laboratory practice (GLP) compliant.

Summary of documentation of dimethoate batch 611/A. 28 February 1997

Batch 611A has been used for most registration studies since 1982. This document presents mean values from testing of 97% dimethoate, 0.16% of isodimethoate (1.6 g/L) and <0.02% of omethoate (0.2 g/L). As of 1997 it had been used in 30 toxicological studies conducted on behalf of members of the Dimethoate Task Force.

Conclusion

The results of these studies do not affect the previously established health based guidance values for dimethoate.

References

Barnett, J. F. (2011). Oral (Diet) Repeated Dose 14-Day Dosage Range Study of Dimethoate in Mice Charles River Laboratories, Preclinical Services, USA, Study No.: 20007071 Unpublished report, CHA Doc. No.: 1259 DMT ; APVMA study number DPS 9681

Barnett, J.F. (2011): Oral (Diet) Repeated Dose 28-Day Immunotoxicity Study of Dimethoate in Mice Charles River Laboratories, Preclinical Services, USA, Unpublished report, CHA Doc. No.: 1260 DMT; APVMA study number DPS 9679

Myers DP (2004). Dimethoate cross fostering study in CD rats. Huntingdon Life Sciences.