



Know-how for Horticulture™

**Preparation of
pesticide minor-use
applications in various
vegetable crops**

Kevin Bodnaruk
AKC Consulting Pty Ltd

Project Number: VG04073

VG04073

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Level 1

50 Carrington Street

Sydney NSW 2000

T: (02) 8295 2300

F: (02) 8295 2399

E: info@horticulture.com.au

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**PREPARATION OF PESTICIDE MINOR-USE
APPLICATIONS IN VARIOUS VEGETABLE CROPS.**

Final Report

Prepared by K P Bodnaruk

AKC Consulting Pty Ltd,
26/12 Phillip Mall,
West Pymble NSW 2073

Principal Investigator:

K.P. Bodnaruk

AKC Consulting Pty Ltd
26/12 Phillip Mall,
West Pymble NSW 2073

Telephone: (02) 94993833

Facsimile: (02) 94996055

Email: akc_con@zip.com.au

Purpose of the Project:

To obtain desk-top permit approvals for a range of pesticides in minor vegetable crops.

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MEDIA SUMMARY

A lack of available pest and disease management tools can be detrimental to minor vegetable industries. This is caused by a range of factors, such as: the development of new and emerging crops; pesticide resistance; integrated pest management; the increasing desire of horticultural industries to access improved pesticide choices; and the disinclination of many manufacturers to seek registrations in minor crops.

To try and achieve a better outcome, Horticulture Australia Ltd (HAL) and the Australian Vegetable and Potato Growers Federation (AusVeg) requested the preparation of pesticide minor-use applications covering a range of vegetables crops to be submitted to the Australian Pesticides and Veterinary Medicines Authority (APVMA). The project's goal was to obtain regulatory approvals for over 70 pesticide uses, previously identified as necessary through HAL project AH04009. The project team researched, collated and presented the necessary information to the APVMA in support of these permit applications.

To date approvals have been obtained for over 60% of the applications lodged with the APVMA. These approvals cover uses in such crops as Asian root and fruiting vegetables, brassica leafy vegetables, eggplant and chili. It is anticipated that further approvals will be gained for the majority of the outstanding permits sought.

Technical Summary

The issue of chemical access can be problematic for many small or emerging vegetable industries. This lack of pesticide access can adversely affect crop productivity and farmer profitability. This has arisen from a combination of: the introduction of new pests and diseases; pesticide resistance; integrated pest management; the disinclination of manufacturers to register pesticides in for minor crops; and regulatory pressures diminishing available pesticide options.

To try and achieve a better outcome, Horticulture Australia Ltd (HAL) and the Australian Vegetable and Potato Growers Federation (AusVeg) initiated project AH04009. The aim of the project was to identify, and gain regulatory approval for over 70 pesticide uses needed by a range of minor vegetable crops, within a 12 month timeframe.

This project prepared and submitted minor-use applications for these pesticides to the Australian Pesticides and Veterinary Medicines Authority (APVMA), and to date over 60% of the uses sought have been approved. Those not gaining approval have been as a result of permit applications being stalled by concerns raised by the APVMA. The types of concerns raised have been varied, however it appears that glasshouse uses in particular are less likely to gain regulatory approval.

The APVMA's legislation dictates that, in order to grant a minor use permit it must be satisfied, that the proposed use meets its safety and efficacy statutory requirements. Accordingly, the APVMA is increasingly raising concerns over glasshouse uses with respect to pesticide residues, crop safety and operator exposure.

To ensure that industry resources are more efficiently deployed it is suggested that industry and the APVMA liaise to develop a clearer definition of data requirements for glasshouse uses.

1.0 INTRODUCTION

1.1 CURRENT SITUATION

Before a pesticide can be used in Australia it must be approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA). In order to gain approval it must satisfy the APVMA criteria in areas such as efficacy, consumer safety, environmental safety and occupational health and safety. For a manufacturer to register a product they are required to submit a comprehensive data package to the APVMA. The costs for generating and collating such data are high and unfortunately many horticultural crops are too small individually for agrochemical manufacturers to consider expending the cost associated with registering their products for use. As a result, horticulturalists are often placed in situations where they risk severe crop losses from pests, weeds and diseases through lack of access to suitable pest management options.

The need for minor-uses has also increased due to a loss of access to older pesticides as a result of chemical reviews and company product portfolio rationalisation. Further the introduction of Quality Assurance programs dealing with the whole production process including pesticide use, demand that growers only exercise Good Agricultural Practices, i.e., practises are regulatory compliant. In addition, horticultural produce must meet minimum standards relating to quality, safety and consumer expectation emphasising the importance of the farmer ensuring that any pesticides applied are done so in accordance with relevant regulations.

The APVMA has a regulatory mechanism, i.e., a Minor Use Permit Scheme, by which smaller industries are able to seek access to much needed pesticide tools. This permit scheme adds some flexibility to the approval process and provides a mechanism whereby minor-uses, following a targeted level of risk assessment, concomitant to the importance of the crop and pesticide use in that crop, can be granted approval. The outcome of which is usually the issuing a time-limited permit enabling growers to use a product for the purpose outlined in the permit.

To obtain such minor-use approvals permit applications must be lodged with, and approved by the APVMA. These applications must not only outline the proposed use but also provide a justification and data supporting the requested use. In project VG04073 data for the 76 proposed uses was sought, collated and submitted to the APVMA.

2.0 METHODOLOGY

In order to prepare the desk-top permit applications the necessary information was gathered through a process of data mining. This involved 'building' the permit applications and justifications via a series of iterative steps during the course of the project. These steps involved consultation with various industry participants and covered such activities as supporting data collection, i.e., overseas labels, confirmation of pest status via liaison with local researchers and seeking clarification and feedback from industry on specific requests. Once the available information was collected and collated a permit application was generated and submitted.

The steps involved are outlined below in more detail.

Step 1. The project team discussed data requirements and application structure with the APVMA. An outcome of these discussions was the development of a specific format for application justifications (see attached example). This format is based upon the format of the Registration Overview required by the APVMA for chemical registrations.

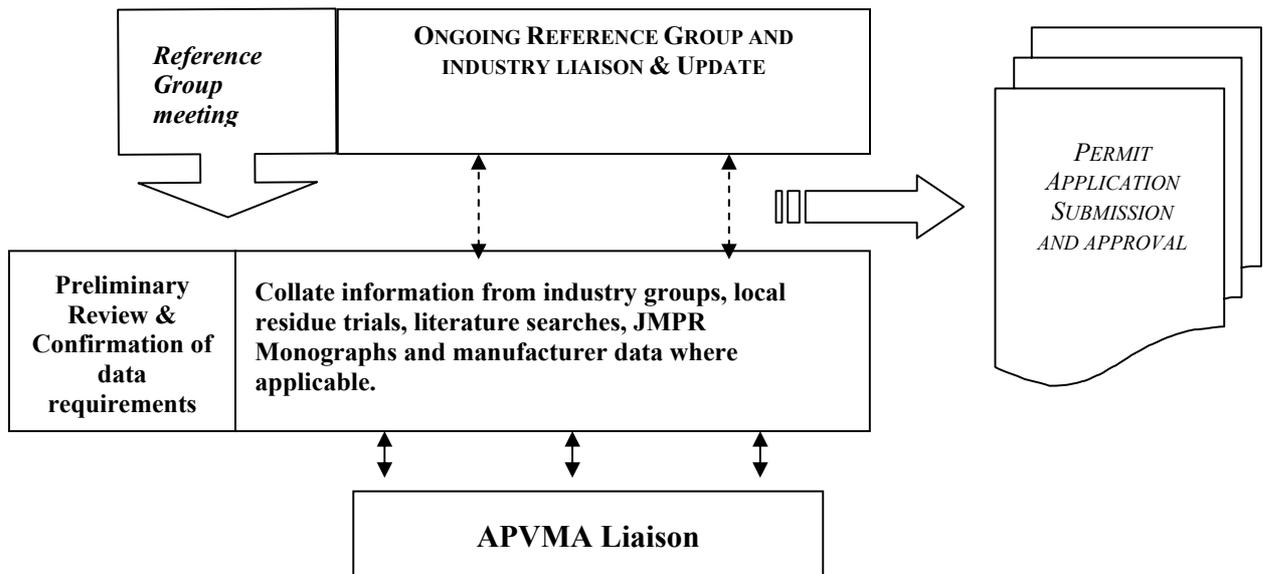
Step 2. Discussions were then held with APVMA regarding to determine the most efficient method for dealing with the 76 requests. As a consequence of these discussions it was agreed that permit applications would be consolidated on a pesticide by pesticide basis.

Step 3. Supporting data and or additional information, needed to comply with APVMA requirements, was then sought. The team then liaised with industry representatives and chemical manufacturers where uncertainty over a requested use existed.

Step 4. Data was the collated and permit applications prepared and submitted. All permit applications were lodged within a 6 month period of the commencement of the project.

Through the above process liaison was maintained with members of the Project Reference Group, i.e., Ausveg IDM, Minor Use Co-ordinator and HAL Plant Health Portfolio Manager.

The process to be followed is represented diagrammatically in the flowchart below.



3.0 RESULTS

3.1 PERMIT APPROVALS

Outlined in Table 1 are the permit approvals granted by the APVMA to date. These approvals cover 35 crops and 15 different pesticides.

Table 1. Permits obtained as part of the project.

Item Code	Crop	Problem	Active	Permit issued
AVG1138	Eggplant	Grey leaf Spot (Stemphylium solani)	chlorothalonil	PER8743 21/4/06 to 30/4/09
AVG744	Root veg - radish	Alternaria & Downy Mildew	chlorothalonil	
AVG1029	Beans - green & processing	wireworm	chlorpyrifos	PER8490 7/2/06 to 6/2/07
AVG1021	Brassica leafy vegetables	African Black Beetle and Wireworm	chlorpyrifos	
AVG1037	Celery	Wireworm	chlorpyrifos	
AVG1022	Silverbeet & spinach	African Black Beetle and Wireworm	chlorpyrifos	
AVG1139	Chilies & paprika	Grasses including winter grass	clethodim	PER8489 24/10/05 to 12/10/10
AVG776	Leafy veg. - silverbeet & spinach	Grasses including winter grass	clethodim	
AVG1100	Leafy veg - endive & chicory	Anthracoze & Downy Mildew	copper - oxide, oxychloride or hydroxide	PER8538 4/11/05 to 31/10/10
AVG1045	Brassica leafy vegetables	Downy mildew	copper - oxychloride or hydroxide	
AVG826	Eggplant	Late Blight, Bacterial spot, speck & canker	copper - oxychloride or hydroxide	
AVG1097	Snow & Sugar Snap peas	Bacterial leaf spot	copper + mancozeb	
AVG1164	Chilies & paprika	Bacterial spot	copper hydroxide	
AVG1096	Snow & Sugar Snap peas	Leaf & pod spots & Downy mildew	copper hydroxide	

Item Code	Crop	Problem	Active	Permit issued
AVG1058	Asian root vegetables	Downy Mildew, late Blight	copper oxychloride	
AVG1091	Horseradish	White Blister Rust	copper oxychloride	
AVG1098	Broccoli, cabbage & cauliflower	Seedling damping off (Rhizoctonia)	iprodione	PER8769 21/3/06 to 31/3/08
AVG1063	Asian fruiting vegetables	Downy Mildew, Fusarium, Anthracnose, Alternaria	mancozeb	PER8767 11/5/06 to 31/3/08
AVG775	Peas - processing	Leaf blight & leaf rust	mancozeb	
AVG490	Spring onions & shallots	Neck rot (Botrytis), Purple Blotch (Alternaria)	mancozeb	
AVG647	Cucurbits	Cucumber moth	methomyl	PER8790 3/3/06 to 31/3/11
AVG467	Snow & Sugar Snap peas	Western Flower Thrips	methomyl	
AVG1143	Root veg - celeriac	Weeds	metolachlor	PER8788 22/3/06 to 21/9/08
AVG1060	Asian root vegetables	Weeds	metribuzin	PER8828 3/3/06 to 31/12/08
AVG1113	Snow & Sugar Snap peas	Weeds	metribuzin	
AVG720	Eggplant	Heliothis	nuclear polyhedrosis virus	PER8537 7/9/05 to 7/9/10
AVG673	Snow & Sugar Snap peas	Heliothis	nuclear polyhedrosis virus	
AVG1092	Horseradish	Weeds	pendimethalin	PER8766 4/11/05 to 30/11/10
AVG1149	Root veg - beetroot	Grass and broadleaf weeds	pendimethalin	
AVG1129	Leafy veg - silverbeet & spinach	Aphids	pymetrozine	PER8525 7/9/05 to 7/9/10
AG1132	Chilies & paprika	Weeds	trifluralin	PER8929 30/3/06 to 30/3/11
AVG206	Eggplant	Weeds	trifluralin	
AVG722	Eggplant	Anthracnose	zineb	PER8786 10/5/06 to 10/5/11
AVG779	Leafy veg - silverbeet & spinach	Anthracnose	zineb	

3.2 PERMIT APPLICATIONS PENDING

Listed in Table 2 are the permit applications still with the APVMA. The success, or otherwise, of a number of these permit applications is problematic. From ongoing liaison with the APVMA it appears that whilst initially identified as candidates for desk-top permit applications a number of the requested uses are unlikely to be approved (see comments in status column).

Table 2. Permit applications for which approvals are pending.

Item Code	Crop	Problem	Active	Date submitted	Application reference number	Status
AVG758	Chicory	Red Legged Earth Mite	alpha-cypermethrin	25.5.2005	9203	Anticipated by August 06.
AVG86	Leeks	onion thrips	alpha-cypermethrin	25.5.2005		
AVG1027	Spring onions & shallots	Onion thrips	alpha-cypermethrin	25.5.2005		
AVG705	Cucumber (greenhouse)	Alternaria leaf spot	azoxystrobin	14.10.2005	8927	Success uncertain due to ongoing issues relating to OH&S concerns from glasshouse application.
AVG1190	Beans - green & processing	Redlegged earth mite	bifenthrin	1.9.2005	8789	Anticipated by August 06.
AVG1130	Celery	Redlegged Earth Mite	bifenthrin	1.9.2005		
AVG743	Root veg - beetroot	Black spot (Alternaria wilt)	difenoconazole	14.10.2005	8928	Awaiting response from agencies and States. Anticipated by August 06.

Item Code	Crop	Problem	Active	Date submitted	Application reference number	Status
AVG1189	Asian root vegetables	Whitefly, Thrips and Aphid	imidacloprid	16.9.2005	8832	Some concerns raised by Bayer and States over efficacy. Uncertain of success.
AVG252	Peppers - Greenhouse & field	Greenhouse Whitefly & thrips (not WFT)	imidacloprid	16.9.2005		
AVG1095	Snow & sugar snap peas	Helicoverpa, Looper and Leafminer	indoxacarb	14.10.2005	8932	Concerns raised over residues. Longer WHP proposed.
AVG1195	Brassicas	Downy Mildew	peroxyacetic acid + hydrogen peroxide	1.9.2005	8791	Ongoing issues relating to OH&S due to glasshouse applications.
AVG1193	Bulb vegetables	Botrytis rot	peroxyacetic acid + hydrogen peroxide	1.9.2005		
AVG1196	Cucurbits	Powdery Mildew	peroxyacetic acid + hydrogen peroxide	1.9.2005		
AVG1196	Lettuce (Glasshouse)	Powdery Mildew	peroxyacetic acid + hydrogen peroxide	1.9.2005		
AVG1194	Peppers	Powdery Mildew	peroxyacetic acid + hydrogen peroxide	1.9.2005		
AVG11094	Tomatoes (Glasshouse)	Powdery Mildew	peroxyacetic acid + hydrogen peroxide	1.9.2005		
AVG1151	Eggplant	aphids, jassids, mites, thrips & WFT	phorate	14.10.2005	8930	Residue concerns have been raised by the APVMA. Unlikely to be approved.
AVG399	Leafy veg - endive & chicory	Aphid, Thrips and Jassid	phorate	14.10.2005		
AVG1150	Peppers - field	aphids, jassids, mites, thrips & WFT	phorate	14.10.2005		
AVG478	Spring onions &	Onion Maggot,	phorate	14.10.2005		

Item Code	Crop	Problem	Active	Date submitted	Application reference number	Status
	shallots	Thrips and Jassid				
AVG845	Celery	Green Peach Aphids	pirimicarb	14.6.2005	8524	Residue concerns have been raised by the APVMA. Uncertain of success.
HRB1170	Coriander	Aphids	pirimicarb	14.6.2005		
AVG752	Leafy veg - chicory	Aphids	pirimicarb	14.6.2005		
AVG612	Sweet corn	Aphids	pirimicarb	14.6.2005		
AVG825	Eggplant	Sclerotinia rot & Botrytis rot	procymidone	14.10.2005	8934	Issues addressed
AVG800	Snow & Sugar Snap peas	Sclerotinia rot, Botrytis rot	procymidone	14.10.2005		
AVG1128	Silverbeet & spinach	Weeds	propachlor	14.10.2005	8931	Concerns raised over crop safety. APVMA waiting for company response.
AVG1127	Snow & sugar snap peas	Weeds	propachlor	14.10.2005		
AVG1188	Asian root vegetables	Hawk Moth, Cluster Caterpillar, Cane Grub, Heliothis, WFT	spinosad	14.10.2005	8933	Residue concerns raised over use in wasabi. Anticipated by August 06.
AVG1141	Root veg - celeriac	Western Flower Thrips	spinosad	14.10.2005		

3.3 PERMIT APPLICATIONS ABANDONED

Listed below in Table 3 are a number of pesticide uses that were not sought. These applications were not progressed either because an approved use already existed, i.e., via an existing permit or registration, or was opposed by the manufacturer.

Table 3. Requested uses not pursued as part of VG04073.

Item Code	Crop	Problem	Product	Active	Reason
<i>AVG1148</i>	<i>Fennel</i>	<i>Downy mildew & Purple blotch</i>	<i>Kocide</i>	<i>copper hydroxide</i>	<i>PER7901 in place - Herb Assoc</i>
<i>AVG740</i>	<i>Parsley and coriander</i>	<i>Alternaria, leaf spot, Cercospora leaf spot, Botrytis, late & early blight</i>	<i>Bravo</i>	<i>chlorothalonil</i>	<i>PER7093 in place - Herb Assoc</i>
<i>HRB186</i>	<i>Coriander</i>	<i>weeds</i>	<i>Linuron</i>	<i>linuron</i>	<i>PER7103 in place - Herb Assoc</i>
<i>HRB195</i>	<i>Coriander</i>	<i>WFT, Heliothis</i>	<i>Lannate</i>	<i>methomyl</i>	<i>PER7097 in place - Herb Assoc</i>
<i>AVG1099</i>	<i>Brassicas</i>	<i>Grass weeds</i>	<i>Dual Gold</i>	<i>metolachlor</i>	<i>Registered</i>
<i>AVG1145</i>	<i>Fennel</i>	<i>Weeds</i>	<i>Dual Gold</i>	<i>metolachlor</i>	<i>PER7100 in place - Herb Assoc</i>
<i>AVG1116</i>	<i>Peppers</i>	<i>WFT</i>	<i>Success</i>	<i>spinosad</i>	<i>Registered</i>
<i>AVG445</i>	<i>Leafy veg - silverbeet & endive</i>	<i>WFT, Heliothis, Looper</i>	<i>Success</i>	<i>spinosad</i>	<i>Registered</i>
<i>AVG1167</i>	<i>Cucumber (GH & field)</i>	<i>Western Flower Thrips</i>	<i>Secure</i>	<i>chlorfenapyr</i>	<i>No company support</i>
<i>AVG1191</i>	<i>Cucumber (greenhouse)</i>	<i>Alternaria leaf spot</i>	<i>Ridomil MZ</i>	<i>metalaxyl + mancozeb</i>	<i>No company support</i>
<i>AVG408</i>	<i>Parsley</i>	<i>Western Flower Thrips</i>	<i>Success</i>	<i>spinosad</i>	<i>PER7362 in place - Herb Assoc</i>

4.0 DISCUSSION

The information required to support a desk-top permit application varied considerably between applications. For many the process involved was often lengthy and complex. Issues that often needed to be addresses included residue decline, animal feeding, confirmation of existence of the pest or disease, use pattern, crop safety and implication to trade, indicating that for a number of requests a desk-top application was inappropriate. However, it is understood that the list of requests was not recent and that this may have contributed, in part, to the difficulties encountered, i.e., given their age the regulatory environment and attitudes had changed.

Following submission of the permit applications queries were received regarding various aspects of the requested use, as indicated above. In the majority of cases these were dealt with successfully through the Minor Use Co-ordinator. However, a number have become stalled as the concerns raised by the APVMA, State reviewers, Federal agencies or manufacturers cannot be dealt with without data generation.

In some cases the concerns raised have related to the chemistry being requested, e.g., older organophosphates, and resultant residues. To address this situation it is suggested that industry place a greater emphasis on reduced risk chemistry, where practicable. The most problematic area, however, was that of uses requested for protected cropping, i.e., in glasshouses. The types of concerns raised have included residue levels, occupational health and resistance management. In many cases these are issues that cannot be addressed without data generation. As a consequence it is believed that Ausveg should consider dealing with protected crops using a separate approach to that of field grown vegetables as the information that will be needed is likely to considerable.

In order to address the issue of problematic permit applications it is suggested that greater initial examination of requests is required. It is proposed that Ausveg should consider developing a policy on reduced risk chemistry, i.e., potentially favouring newer over older problematic compounds where practicable. It is also proposed that a check-list be developed to cover the key areas of concern, as highlighted in VG04073, e.g., company support and no

residues concerns, prior to tender, i.e., to ensure that desk-top requests are in fact desk-top requests and to improve the likelihood of applications being successful.

5.0 RECOMMENDATIONS

As part of future projects it is recommended that:

- Ausveg develop a policy on reduced risk chemistry.
- that a checklist covering the major areas of concern be developed and completed prior to desk-top projects going to tender,
- that the checklist contain the following,
 - specific information on APVMA determinations regarding residues be provided,
 - specific information on the position of manufacturers be provided and
 - specific information from researchers confirming the existence of problem for which a minor use is requested.

Attachment I: Example of Minor Use permit Justification used in VG04073.

Alpha-cypermethrin - Minor Use Permit Application for Chicory, Leeks, Spring onions and shallots

PART 1 APPLICATION OVERVIEW

1.1 Introduction

Alpha-cypermethrin is a member of the cyano-group of pyrethroids (Group 3A Insecticide). It is a broad spectrum, non-cumulative insecticide with stomach and contact activity. It is fast-acting neurotoxin with no plant systemic action, it is readily degraded on soil or plants but with good residual activity on inert surfaces. The major target site of cypermethrin is the sodium channel of the nerve membrane. A sodium channel exposed to cypermethrin can remain open for an extended period of time resulting in repetitive nerve activity. It is approved for the control of a wide range of insect pest species in cotton, cereals, grain legumes, vegetables and fruit, in public health and in animal husbandry in Australia.

The availability of insecticides approved for use in Chicory (*Cichorium intybus*), Leeks (*Allium porrum*), Spring onions (*A. fistulosum*) and shallots (*A. aggregatum*) is limited. As a result gaining access to the compound would provide a significant benefit to growers.

1.2 Purpose of application

The purpose of this application is to gain an additional insect pest management option to enhance the production of Chicory, Leeks, Spring onions and shallots in Australia. Approval is sought from the APVMA to allow the use of products containing alpha-cypermethrin for the control of a Red legged earth mite (*Halotydeus destructor*) in chicory and Onion thrips (*Thrips tabaci*) in leeks, spring onions and shallots in all states.

1.3 Justification for proposed uses

1.3.1 Minor use status

The crops chicory, leeks, spring onions and shallots are, according to the APVMA *Guidelines for Determining Minor Uses*, minor crops since they are not listed as major commodities under Schedule 1.

1.3.2 Demonstrated need

Red legged earth mite (RLEM) in chicory and Onion thrips in leeks, spring onions and shallots can adversely affect the growth of the plants, impacting on both yield and quality. Alpha-cypermethrin is currently approved for the control of thrips in silverbeet, spinach and tomatoes and RLEM in silverbeet, spinach, pulse crops, winter cereals and canola. It is also registered for use in brassica vegetables, asparagus, lettuce and cotton.

Redlegged earth mite (RLEM) in chicory

There are no control options currently available for use against RLEM in chicory with grower reports of crop damage resulting from pest feeding. The approval of alpha-cypermethrin would provide the industry with a RLEM control option. Unchecked RLEM can cause severe damage to crop plants. Both nymphs and adults feed by lacerating leaves and sucking the exuded sap, causing a silvery or whitening of the foliage stunting growth. Heavy infestations can result in seedling death.

Onion thrips in leeks, spring onions and shallots

Onion thrips ‘graze’ over the surface of young leaves and puncture the tissue by piercing individual cells and sucking the contents. These cells lose their normal colour, and when many adjacent cells are damaged, the tissue appears as whitish silvery flecks. Substantial damage can be done to young plants, leaf distortion can develop and the plant growth may

be restricted with the leaves becoming desiccated and withered. Larvae and adults are found mainly in the narrow space between the tubular leaves of *Allium* species.

Besides direct damage caused by feeding of larvae and adults, Onion thrips can also be an important vector of diseases such as tomato spotted wilt virus in tomatoes and recently Iris yellow spot virus (IYSV) in onions and leeks¹.

There is currently only one control option available for the control of thrips in leeks (dimethoate – Group 1B Insecticide) and spring onions and shallots (diazinon via PER5736 – Group 1B Insecticide). The approval of alpha-cypermethrin (Group 3A Insecticide) would enable the use of a different chemical group in leeks, spring onions and shallots, which would be advantageous from a resistance management perspective. As part of a broader management strategy the industry intends to apply for a permit to allow the use of phorate as a soil treatment in the near future.

1.4 Proposed Use

The proposed Directions for Use are as follows:

Crop	Insects Controlled	State	Rate/ha	WHP	Critical Comments
Leeks, Spring onions and shallots	Onion thrips (<i>Thrips tabaci</i>)	All states	100-400 mL/ha OR 15-50 mL/100L	7	Apply when the infestation reaches economically damaging levels. The following spray volumes are recommended: <u>Ground application:</u> 100-400 L/ha. <u>Aerial application:</u> 10 L/ha minimum

¹ B. A. Coutts *et al.* 2003. Iris yellow spot virus found infecting onions in three Australian states. *Australasian Plant Pathology* 32(4) 555 – 557.

Crop	Insects Controlled	State	Rate/ha	WHP	Critical Comments
Chicory	Red legged earth mite (<i>Halotydeus destructor</i>)	All states	50-100 mL	7	100 mL – Pre-emergence. Apply by ground rig only. Treat infested paddocks after sowing but prior to crop emergence when soil is moist. Monitor red legged earth mite numbers and re-treat if necessary. 50 mL – Post crop emergence. Apply when mite numbers reach damaging levels.

Parts 2 to 4 - Chemistry, Manufacture, Toxicology, Metabolism and Kinetics

Products based upon alpha-cypermethrin, the resolved isomer of cypermethrin, are currently approved for a number of uses and in a range of crops and situations in Australia, i.e., relevant data has previously been provided by registrants. It is assumed that the various manufacturers, when gaining registrations for their products, would have already addressed chemistry and manufacture requirements as required by the APVMA. Issues relevant to toxicology and metabolism would also have been dealt with through Poison scheduling, calculation of the ADI and determination of first aid requirements.

Therefore, it is not believed necessary to provide additional data on chemistry, manufacture, toxicology, metabolism and toxicokinetics as part of this application. Additionally, as the proposed uses are also similar to existing approved uses it is argued that no additional data should be required to support these minor uses.

Part 5 a Residues

Residue data specifically generated on the crops in question is not provided, although it is requested that the APVMA take into consideration existing data available and tolerances established internationally in assessing the proposed uses, as follows.

It is the premise of this application that sufficient data via the sources outlined below, particularly existing Australian and Codex MRLs should be sufficient to establish either permanent or temporary MRLs in Australia for these minor uses.

If required the industry may be amenable to conducting confirmatory trials or monitoring if necessary under the life of a permit.

Leeks, spring onions and shallots – existing relevant tolerances

Codex MRLs exist for cypermethrin at 0.1 mg/kg for bulb onion and 0.5 mg/kg for leeks. These were based on multiple applications of 60 g ai/ha with a 7 day harvest interval for leeks and multiple applications at 50-70 g ai/ha with a 7 day harvest interval for bulb onion². MRLs also exist in the US, Europe and Japan at 0.1 mg/kg for bulb onion. In the US an MRL of 6.0 mg/kg has also been set for green onion.

The use regime proposed in this application is similar to that used to establish the above limits in related bulb (*Allium* spp.) vegetable commodities, and it is argued that due to leeks, spring onions and shallots being in the same bulb vegetable Codex crop group as the existing MRLs quoted above that sufficient data should exist to enable extrapolation and establishment of a specific entry for these commodities, i.e., 0.1 mg/kg for spring onions and shallots and 0.5 mg/kg for leeks. An MRL of 0.5 mg/kg may also be applicable to spring onion and shallots due to above ground exposure will be similar as with leeks.

Chicory – existing relevant tolerances

MRLs exist for the related commodity endive (*Cichorium endivia*) in the US at 10.0 mg/kg and in Europe at 2.0 mg/kg. In addition, an MRL exists at Codex for the leafy vegetables

² 1982 JMPR Pesticide Residues in Food - FAO

lettuce³ and spinach⁴ at 2.0 mg/kg. In Australia MRLs exist for lettuce at 2.0 mg/kg and Leafy vegetables at T2.0 mg/kg.

The use regime proposed in this application is similar to that used to establish the above limits in related leafy vegetable commodities, and it is argued that due to chicory being in the same Leafy vegetable Codex crop group as those existing MRLs quoted above that sufficient data should exist to enable extrapolation and either establishment of a specific entry for chicory, or agreement that it would meet the existing Australian temporary MRL in leafy vegetables at T2.0 mg/kg.

³ 1979 & 1984 JMPR Pesticide Residues in Food - FAO

⁴ 1982 JMPR Pesticide Residues in Food - FAO

Part 5 b – Overseas trade aspects of residues in food commodities.

The industry does not anticipate that the proposed use would constitute a potential risk through trading of the commodity. Leeks are exported with the main market being Japan⁵. However, it is unlikely that detectable residues would result, as the product would be applied early in the life of the crop. If residues were to occur residue violations are unlikely due to the existence of a Codex MRL and with the proposed use regime being similar to that reviewed to arrive at the Codex MRL (JMPR 1982) similar residues should result and as such not exceed the Codex MRL.

Australian exports of Spring onions and shallots are very low, approximately 0.2% of total production⁶. Concerns over residue are not anticipated due to the timing of applications and proposed use pattern.

A small amount of chicory is exported, approximately 40 tonnes in 2002/03. Concerns over residue are not anticipated due to the timing of applications and proposed use pattern.

Furthermore, according to APVMA residue guidelines, neither of the crops in question are included in Residue requirements Part 5B “*Overseas trade aspects of residues in food commodities*”, and as such are not considered significantly traded commodities of which residue violations if they were to occur would be considered likely to prejudice Australia’s trade.

Livestock feeding

The feeding of crop by-products or trash to livestock is considered unlikely. If feeding were to occur violative residues would not be anticipated as; byproducts from the above crops would be unlikely to form a large part of an animals daily ration, the current animal MRLs accommodate topical livestock applications for the control of ectoparasites, and the use

⁵ The Australian Horticulture Statistics Handbook 2004.

⁶ The Australian Horticulture Statistics Handbook 2004.

pattern of the compound in other registered crops where their byproducts (or trash) are already fed to livestock such as pastures, grain legumes and cereals.

There are animal MRLs for cattle edible offal (mammalian) at 0.05 mg/kg and cattle meat (mammalian) at 0.5 mg/kg in Australia and meat (mammalian) at 0.2 mg/kg and edible offal (mammalian) at 0.05 mg/kg at Codex. There is an Australian MRL of 5 mg/kg for primary animal feed commodities (PAFC). The anticipated residue in fat from the feeding of PAFC, using a transfer factor of 0.06⁷, would be $0.3 \times 5 \times 0.06 = 0.09$ mg/kg if fed at 30% of the diet. Assuming residues are at the nominated MRL levels and the commodities were fed at 30% of the diet, the anticipated residues in fat would be 0.009 mg/kg for leeks, 0.0118 mg/kg for spring onions and shallots, and 0.036 mg/kg for chicory. All well below the relevant Australian and Codex MRL levels.

⁷ 1981 JMPR Pesticide Residues in Food - FAO

Parts 6 and 7 - Occupational Health and Safety (OHS) and Environment

The use regimes proposed in this application are similar to existing uses already approved in other commodities in both the broad-acre and horticultural sectors, with respect to rate, frequency of application and equipment. It is argued that due these existing use patterns already approved that sufficient data already exists to support these minor uses in that their use will not present any additional risks to either the environment or operator safety, provided users follow and adhere to existing label statements with respect to personal protective equipment, environmental precautions and proper product storage and disposal.

PART 8 - EFFICACY & CROP SAFETY

8.1 Efficacy

Specific data to these use patterns (crop/pests) supporting the control of the nominated pests is not presented. Although as outlined below reasons are provided as to why crop/pest specific data for these minor uses are believed unnecessary, where sufficient data via existing registered use patterns in major crops and similar or closely related pests should provide sufficient evidence to support extrapolation, without the need for crop/pest specific data.

Alpha-cypermethrin has been used extensively in the control of thrips and RLEM in other crops. Its popularity is due, in part, to the quick knockdown and length of residual control provided.

Onion thrips in leeks, spring onions and shallots

Thrips (Thysanoptera) are grouped into two suborders, Terebrantia and Tubulifera. Most pests are in the Terebrantia. Terebrantia consists of a large number of minor pests and a few major pests. The majority of the major pests belong to the family Thripidae, e.g., *Thrips tabaci* (Onion thrips) and *T. imaginis* (Plague thrips). As Onion thrips and Plague thrips are closely related it is believed that efficacy against the two species would be comparable from the use of a synthetic pyrethroid such as alpha-cypermethrin. Furthermore cypermethrin based products are registered for the control of Onion thrips in the United States of America on bulb vegetables (*Allium* species) (see attached label). The proposed use regime in this application is consistent with existing Australian use patterns against this pest in tomatoes and similar to those approvals that exist in Nth America.

Some similarly approved/registered use patterns for basis of extrapolation.

Country	Product	Crop	Insects Controlled	Rate	Critical Comments
Australia	Dominex Duo (APVMA #54446)	Tomatoes	Plague thrips (<i>Thrips imaginis</i>)	Low volume = 130 mL/ha High volume = 18mL/100L	See approved label.
Australia	Permit PER5831	Silverbeet and spinach	Plague thrips (<i>Thrips imaginis</i>)	100-400 mL/ha OR 15-50 mL/100L	Applications of Alpha-cypermethrin should be rotated with other chemical group insecticides where possible, and used in conjunction with monitoring.

Country	Product	Crop	Insects Controlled	Rate	Critical Comments
United States	Ammo 2.5 EC Insecticide ⁸ (US EPA Reg # 279-3027-34704)	Bulb vegetables	Onion thrips (<i>Thrips tabaci</i>)	4-5 FL OZ/A (120-150 mL/ha or 40-50 g ai/ha)	Apply in a minimum of 20 gallons of water per acre by ground or 3 gallons per acre by aircraft. Begin applications when pests appear.

Red legged earth mite (RLEM) in chicory

Specific data is believed unnecessary as alpha-cypermethrin is registered for the control of Red legged earth mite in a number of crops in Australia, including silverbeet, spinach, pulse crops, winter cereals and canola. The proposed use regime in this application is consistent with existing Australian use patterns against this pest in silverbeet, spinach, pulse crops, winter cereals and canola and therefore it is argued that the widespread use of alpha-cypermethrin based products, over many years in the registered crops, at the proposed rates would be adequate supporting information to establish that control will be obtained in these minor crops.

⁸ See attached label.

Some similarly approved/registered use patterns for basis of extrapolation

Country	Product	Crop	Insects Controlled	Rate/ha	Critical Comments
Australia	Dominex Duo (APVMA #54446)	Winter cereals, chickpeas, faba beans, lupins, field peas, canola and pasture.	RLEM	50-100 mL	As per current label claims
Australia	Permit PER5831	Silverbeet and spinach	Plague thrips (<i>Thrips imaginis</i>)	100-400 mL OR 15-50 mL/100L	

8.2 Crop Safety

Crop effects are considered unlikely as no special precautions are noted for the various crops for which alpha-cypermethrin or cypermethrin are currently approved. These encompass a wide range of broad-acre and horticultural crops including cereals, cotton, grain legumes, oilseeds, pastures, pome fruit, stone fruit, ornamentals, tobacco and vegetables.

Furthermore, as outlined above under efficacy and in Part 5 under residues existing regulatory standards in MRLs and label use patterns exist for alpha-cypermethrin in related *Allium* spp. and leafy vegetables at similar use regimes in either Australia or other international jurisdictions such as Nth America and Europe which lends further support that alpha-cypermethrin is unlikely to present any unacceptable risks to these crops.