Preparation and submission of permit applications for three Varroa mite control products

Kevin Bodnaruk
AKC Consulting Pty Ltd

Project Number: MT09082

MT09082

This report is published by Horticulture Australia Ltd to pass on information concerning horticultural research and development undertaken for:
Almond
Apple & Pear (Apple - Marketing Projects)
Avocado
Cherry
Dried Prune
Summerfruit
Vegetables
Melon.

The research contained in this report was funded by Horticulture Australia Ltd with the financial support of:
Australian Melon Association Inc
Canned Fruits Industry Council of Australia
the almond industry
the apple and pear industry
the avocado industry
the cherry industry
the dried prune industry
the summerfruit industry
the vegetables industry
the onion industry.

ISBN 0 7341 2591 7

Published and distributed by:
Horticulture Australia Ltd
Level 7
179 Elizabeth Street
Sydney NSW 2000
Telephone: (02) 8295 2300
Fax: (02) 8295 2399

Horticulture Australia

HAL Project Number: MT090082

PREPARATION AND SUBMISSION OF PERMIT APPLICATIONS FOR THREE VARROA MITE CONTROL PRODUCTS.

Final Report

Prepared by K P Bodnaruk

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

Prin**cipal 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 permit approvals for three miticides for the control of Varroa mite for use in honey production.

AKC Consulting Pty Ltd acknowledges the funding support provided by the Horticulture Australia Limited for this project.

TABLE OF CONTENTS

MEDIA SUMMARY

Varroa mite *(Varroa destructor* and *V. jacobsoni)*, is a highly destructive ectoparasites of honeybees. It attacks adults, larvae, and pupae with the capacity to adversely affect honeybees and hive viability. In fact, if left untreated, colonies of honeybees will collapse within two years of an infestation occurring.

The pest is found in all major production regions of the world, except mainland Australia. Given the importance of honeybee initiated pollination to Australian agriculture, Varroa mite has been recognized as a significant biosecurity threat. In order to maintain this Varroa mite free status, various biosecurity measures have been implemented, e.g., port surveillance (sentinel hives)[1] and industry based risk mitigation strategies[2]. Nevertheless, recognizing that while prevention via border security is critical, should an incursion reach an escape situation, access to management options will be needed.

To this end, various Australian industries are seeking APVMA approval to allow the use of three Varroa mite control options in the event of an incursion. These are products based on the two synthetic pyrethroids tau-fluvalinate (Apistan®) and flumethrin (Bayvarol®) and the amidine amitraz (Apivar®). As the availability of miticides approved for use in bee hives is limited, gaining approval to access the nominated products would of benefit to the industry enabling a speedy response in the event of an incursion.

[1] ibid.
[2] Biosecurity or Disease Risk Mitigation Strategy for the Australian Honey Bee Industry

Technical Summary

The production of a number of horticultural and agricultural crops in Australia requires pollination in order to bear satisfactory marketable yields. Without the activity of honey bees (*Apis mellifera*) the pollination and the successful production of these crops would be jeopardised. In fact it has been estimated that the benefit to Australian agriculture of honeybee pollination to be between AUD$4 and 6 billion annually[3].

In addition, the value of honey and beeswax production in Australia is estimated at approximately $70 million[4]. The profitability of the industry is dependant, in part, upon having healthy productive bee hives. However, incursions of exotic pests such as Varroa mite would adversely affect the industry as infestations can not only reduce the productivity of the bee hives but also threaten their viability.

This project prepared and submitted minor-use applications for the three miticides to the Australian Pesticides and Veterinary Medicines Authority (APVMA). Gaining approval to access the three nominated Varroa mite control products for apiarists would therefore not only be of benefit to the honey bee industry but also the broader agricultural community.

[3] Barry, S. *et al*. (2010). Future surveillance needs for honeybee biosecurity, RIRDC, Project No. PRJ-003317, Pub No. 10/107.
[4] ABARE 2009. Australian commodities June Quarter 09. Vol 16 No 1.

1.0 INTRODUCTION

1.1 CURRENT SITUATION

Varroa mite *(Varroa destructor* and *V. jacobsoni)*, is a highly destructive ectoparasites of honeybees. It attacks adults, larvae, and pupae with the capacity to adversely affect honeybees and hive viability. In fact, if left untreated, colonies of honeybees will collapse within two years of an infestation occurring.

Mainland Australia is currently Varroa mite free (*V. jacobsoni* is now present in the Torres Strait[5]). Given the importance of honeybee initiated pollination to Australian agriculture, Varroa mite has been recognized as a significant biosecurity threat. In order to reduce the risk of incursions of Varroa mite, and other pests and diseases, various measures have been implemented, e.g., port surveillance (sentinel hives)[6] and industry based risk mitigation strategies[7]. Nevertheless, recognizing that while prevention via border security is critical, should an incursion reach an escape situation, access to management options will be needed.

To this end the Australian Honeybee Industry Council is seeking APVMA approval to allow the use of three Varroa mite control options currently available internationally, in the event of an incursion. These are products based on the two synthetic pyrethroids tau-fluvalinate (Apistan®) and flumethrin (Bayvarol®) and the amidine amitraz (Apivar®). As there are currently no miticides approved for use in commercial bee hives, gaining approval to access the nominated products would of benefit to the industry enabling a speedy response in the event of an incursion.

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 industry initiated user requests, following a targeted level of risk assessment, concomitant to

[5] Animal Health Australia (2009). Disease strategy: Bee diseases and pests (Version 3.2). Australian Veterinary Emergency Plan (AUSVETPLAN), Edition 3, Primary Industries Ministerial Council, Canberra, ACT
[6] ibid.
[7] Biosecurity or Disease Risk Mitigation Strategy for the Australian Honey Bee Industry

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 apiarists to use a product for the purpose outlined in the permit.

To obtain the relevant regulatory approval permit applications have been lodged with the APVMA. These applications must not only outline the proposed use but also provide a justification and data supporting the requested use. In project MT09082 data for three miticides 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.

3.0 RESULTS

3.1 PERMIT APPLICATIONS

Permit applications for the three miticides amitraz, flumethrin and tau-fluvalinate have been submitted to the APVMA. Details of which can be seen in Table 1.

Table 1. Details from the permits obtained as part of the project.

Permit No.	Active	Trade Name	Problem
PER12757	amitraz	APIVAR®	Varroa mites
	flumethrin	BAYVAROL®	
	tau-fluvalinate	APISTAN®	

4.0 DISCUSSION

The information submitted to the APVMA is to allow the regulator to undertake a risk assessment. The purpose of which was ensure that the APVMA is satisfied that the requested uses met the APVMA's minor-use criteria, were likely to be efficacious, were unlikely to result in adverse environmental and consumer exposure or potentially jeopardise trade. Information to address these areas, in support of the three permit applications, was sourced both locally and from overseas.

5.0 RECOMMENDATIONS

As part of any future projects it is recommended that:

- Consideration given to identifying and sourcing newer technologies for the control of Varroa mite, e.g., new miticides or miticide delivery mechanisms.
- If it is decided that such an approach should be adopted that thought be given to incorporating such elements as resistance management and reduced risk chemistry with regard to identifying options to meet the needs.

Attachment 1. Permit application.

Category 21

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Application for a Minor Use Permit (Agriculture)

SECTION 1: THIS SECTION MUST BE COMPLETED FOR ALL PRODUCTS

1. FEE & CATEGORY DETAILS

Proposed category number: **21**

Refer to Ag MORAG on the APVMA website for a description of Category 21 requirements

Fee enclosed: $ 350 ☒ YES ☐ NO ☐ FEE EXEMPT

NOTE: Fee exemptions only apply to Australian, State or Territory governments for activities in support of their core business. For further details refer to: http://www.apvma.gov.au/MORAG_ag/vol_2/category_21.html

2. APPLICANT CONTACT DETAILS

Full name of applicant (can be a company): Name of contact person: Position/title: ACN / Overseas equivalent number:	Australian Honey Bee Industry Council (AHBIC) Stephen Ware Executive Director 63 939 614 424
Street address:	
Postal address:	

Email: ahbic@honeybee.org.au	Telephone: 0418 976 643	Facsimile:

3. APPROVED PERSON DECLARATION

(THIS MAY BE THE APPLICANT/CONTACT PERSON NOMINATED ABOVE, OR MAY BE A CONSULTANT ACTING ON BEHALF OF THE APPLICANT)

I hereby declare that the information provided with this application is complete and correct.

Full name of approved person (can be a company): Position/title:	
Postal address:	

Name of contact person in the company:		
Email:	Telephone:	Facsimile:

Correspondence about this application should be addressed to: ☒ Applicant/registrant or ☐ Approved person

Signature (MUST be in ink): _____ Date:

False declaration may lead to prosecution under the Agricultural and Veterinary Chemicals Code Act 1994.

NOTE: When an applicant elects to appoint a different approved person, a letter of authority is required. Refer to MORAG Volume 1 'Procedures for making an application' for additional information on approved persons.

4. PROPOSED PRODUCT & USE REGIME			
Product trade name	Apistan® Bayvarol® Apivar®		
Active constituent(s) and amount (g/kg or g/L)	Containing: 824 mg tau-fluvalinate per strip as the only active constituent. 3.6 mg flumethrin per strip as the only active constituent. 500 mg amitraz per strip as the only active constituent.		
Crop or situation	Beehives		
	Is the crop grown in ☒ field, ☐ undercover (protected) or ☐ both.		
Target disease, pest or purpose (include common and scientific names)	Common Name	Varroa mites	
	Scientific name	*Varroa destructor* and *V. jacobsoni*	
Application rate, spray volume and addition of wetters (or other proposed additives/mixtures)	Application rate (eg. 100mL or 100g product / 100L and/or 1L or 1kg / ha)	Spray volume (eg. 500L/ha)	Addition of wetter (eg. plus 200mL/100L – please specify wetter)
	2-4 strips per brood chamber	Not applicable	Not applicable
Timing of application/growth stage (eg. apply at budburst, blossom bloom etc.)	Hang the strips in the hives in the spring before the first honey flow.		
Maximum number of applications and interval between applications.	Maximum number of applications per crop, season or year (please specify)	Minimum re-treatment interval (days) between consecutive applications	
	Two treatments annually	If mite infestations are severe, an autumn treatment can be made after all surplus honey has been removed	
Application method & equipment	Application method (e.g., foliar, drench, in-furrow, aerial)	Application equipment (e.g., knapsack, air-blast sprayer, boom spray)	
	Manual placement within hives	Not applicable	

Proposed withholding periods (food and/or livestock feed crops only)	Harvest - number of days or weeks between last application and harvest (or Nil)	Grazing & Cutting for Livestock (or Nil)
	N/A	N/A
Any special precautions / critical use comments (eg. target larvae < 10mm in length; thorough coverage is essential; IPM or resistance management issues etc.)	The strips should not be used during peak honey flow periods. The strips should remain in the hive for 6-8 weeks, and then removed.	

NOTE: please complete ALL fields. In situations where instructions are NOT APPLICABLE please include N/A, if not known please state NOT KNOWN.

5. JUSTIFICATION FOR THE PROPOSED MINOR USE

Describe the purpose of the application. Where alternative products are currently registered for the proposed use in Australia those products should be listed and reasons provided against each as to why they are either unsuitable or ineffective.

Varroa mite *(Varroa* spp.*)*, is a highly destructive ectoparasites of honeybees. It attacks adults and pupae severely affecting hives and has been characterized as the most important problem of apiculture globally. Infestations can severely reduce honey production through reduced foraging, increased adult mortality, increased drifting, hive abandonment and malformed adults. Left untreated, colonies of *Apis mellifera* will collapse within two years of an infestation occurring.

The primary impacts of Varroa feeding is on the brood, which causes decreased body weight of bees, deformed wings, smaller royal jelly-producing glands, reduced lifespan of adult bees and potentially most importantly to introduce pathogenic viruses into the bee colony.

New Zealand and Canadian experiences has shown that the cumulative effects of Varroa mite on a individual bees can result in a rapid reduction in the number of adult bees in a hive, abnormal brood, and hive abandonment by the bees. The final outcome, unless a treatment is used to reduce mite populations, is usually colony death. However, when mite populations are monitored and treated properly, pollination and honey production are rarely affected.

Colonies must be treated once or twice a year to maintain mite populations below economic injury levels. Mites in different parts of the world have developed some levels of resistance to a number of the miticides. As a consequence, the industry goal is to ultimately broaden the scope of options available through the inclusion of plant extracts, e.g., Thymol, and organic acids such as oxalic and formic acid, and other pesticides such as fenpyroximate. However, as a first step access is being sought to the currently available control options based on tau-fluvalinate, flumethrin and amitraz. t

6. MINOR USE CLASSIFICATION

The crop or situation is a minor use via (*check one box only*): For guidance on Schedules refer to Page 2 *Background details to the* [*Guidelines for Determining Minor Uses*]

☒	Schedule 1
☐	a proposed Schedule 2
☐	a proposed Schedule 3

For proposals seeking acceptance as a minor use under either Schedules 2 or 3 please provide supporting reasons: **The nominated crops are, according to the APVMA *Guidelines for Determining Minor Uses*, minor use since they are not listed as major under Schedule 1.**

7. PROPOSED END USERS Persons to be covered by the permit ***(check the most relevant*)**:	
☒ 'Persons generally' (includes everyone – ie. no restrictions)	
☐ A specific group or class of persons (eg licensed pest control operators, licensed aerial operators etc)	Details of end user/s (*if not 'Persons generally' as above*)**:**
☐ One or more nominated individuals	

8. PROPOSED DURATION OF USE, STATES OR REGIONS & AREA/TONNAGE TO BE TREATED		
Proposed duration of use:	First date of proposed use	Upon granting of the permit.
	Annual timing of use (ie. from Sep – Mar or ongoing throughout year)	In honey production bee hives are managed continuously. As a result it is likely that the product will be required throughout the year.
	Proposed permit duration (ie. 1, 2, 5, 10 yrs or ongoing)	10 years

Proposed use is to occur in:	All States ☒	QLD ☐	NSW ☐	SA ☐	TAS ☐	WA ☐	NT ☐	VIC ☐	ACT ☐
	OR								
	The use will be undertaken in a specific location/region only (please specify):								

Extent/area of proposed use per annum:	Specify the estimated area in hectares or tonnage of produce to be treated per annum:

SECTION 2: THIS SECTION MUST BE COMPLETED ONLY FOR PRODUCTS THAT ARE CURRENTLY REGISTERED IN AUSTRALIA

*In considering the application please complete the following questions and sections. Labels of most registered products may be obtained from the APVMA website at: **www.apvma.gov.au***

Rate and method of application

Is the rate and method of application similar to existing rates approved in other commodities/situations already registered for the product?

☒ Yes

If yes, please explain in the area provided below including appropriate examples from the approved label for the product

☐ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to operators/users and the environment. This may include the provision of supporting data and/or risk mitigation strategies.

The rate and method of application are comparable to that currently approved for the use of the three products for the control of Varroa mites in other countries, e.g., New Zealand and Canada, and the use in sentinel hives via APVMA permits.

Target Crop/Situation

Is the product currently registered for the proposed crop/situation OR has the crop been subject to phytotoxicity testing under the proposed use regime?

☐ Yes

If yes, please outline in the area provided below brief details including any supporting data and attach that data with your application.

☒ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to the crop. This may include a discussion on extrapolation of crop tolerance based upon existing registrations in botanically related commodities, or where the use pattern or chemistry is such that adverse effects are unlikely.

Adverse effects on bees are considered unlikely as the three products are approved for use in honey production in a number of countries at use patterns similar to that proposed for Australia.

Target Pest/Disease

Is the product proposed for this use currently registered against the target pest/disease in another crop/situation for which efficacy is being based, including situations where bridging or limited bioequivalence data is being presented?

☒ Yes

If yes, please explain in the area provided below how the existing registration in other commodities is relevant (ie. can be extrapolated) to the proposed use in demonstrating that equivalent efficacy will be achieved, including reference to any bridging or bioequivalence data which is being presented.

☐ No

If no, please provide supporting data or a valid scientific argument in the area provided below which demonstrates that the proposed use will be efficacious. Scientific arguments will be considered on their merits. Examples can include scientific arguments (ie. extrapolation) based upon the chemicals known activity (ie. Mode of Action) and registration status against similar pests/diseases. Additionally relevant data from trials or published literature may be provided.

Specific data to the use pattern (crop & insects) supporting the control of the nominated pest is not presented. It is believed unnecessary, as data via existing approved use patterns in other countries should provide sufficient evidence to support extrapolation. Also, as the pest has as yet not arrived in Australia local mite specific data is unavailable.

Crop Residues (food-crops only) - MRLs

Is a current Maximum Residue Limit (MRL) established, or has exemption from requiring an MRL been given for the chemical on this commodity?. Note: MRLs can be obtained from the MRL Standard available on the APVMA website at: http://www.apvma.gov.au/residues/mrl_standard.shtml

☒ Yes

If yes, in the area below please provide details on that MRL or exemption.

☒ No

If no, in order to enable an MRL to be established please indicate if you are providing either (and detail this in the area below):

- ☐ supporting residue data, or
- ☐ a valid scientific argument which demonstrates that the proposed use will not result in detectable residues, or
- ☒ a valid scientific argument based upon extrapolation from registered uses in a similar commodity and its MRL.

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

Compound	Aus	EU	USA	NZ	
amitraz	–	0.2	1	0.1	
flumethrin	T*0.05	Exempt		–	0.05
tau-fluvalinate	T*0.01	*0.01	0.02	0.1	

Crop Residues – livestock feeding

Is the raw commodity, or waste or by-products from processing, fed to livestock or sold for use as livestock feed?

OR is the commodity subject, or likely to be subject, to a Commodity Vendor Declaration (CVD) or By-Product Vendor Declaration (BVD)?

☐ Yes ☒ No

If yes, please provide details against each area listed below.

The portion of the commodity that is fed to livestock	Not applicable
Species of livestock consuming treated produce	-
Amounts which may be fed and proportion of diet	-
Details of the CVD or BVD applicable to the commodity	Not applicable

Trade (food-crops only)

Is the commodity subject to export trade?

☐ Yes ☒ No

If yes, please provide details against each area listed below.

Quantity of produce exported (incl. $ value)	The industry does not anticipate that the proposed uses would constitute a potential risk through trading of the commodity. Australia does export honey but violative residues are not anticipated as the nominated chemicals have been widely used throughout the world, i.e., relevant standards are already in place.
Countries of destination	N/A
Proposed mechanisms for ensuring the treated commodity will meet importing country MRL requirements	N/A

Please indicate if any supporting data is attached/provided for;
☒ **Residues and trade considerations (food and feed producing crops only)**
☒ **Occupational Health and Safety**
☒ **Environmental Safety**
☒ **Efficacy and Crop/Host Safety**
☒ **Other data or information**

Please return the fully completed application form with Sections 1 & 2 only to:

The Screening Officer
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604