

Desktop preparation of pesticide minor-use permit applications in vegetable crops 2012

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Project Number: VG12072

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Desktop preparation of Pesticide Minor Use Permit Applications in Various Vegetable Crops 2012

Final Report

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Purpose of the Project:

To obtain minor use permit approvals from the Australian Pesticides & Veterinary Medicines Authority (APVMA) for a range of pesticides in minor vegetable crops.

This project has been funded by HAL using the vegetable industry levy and matched funds from the Australian Government.

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MEDIA SUMMARY

Small vegetable industries often have their development and productivity hampered by an absence of suitable chemical pest and disease management tools. There are a range of factors which contribute to this lack of suitable options: lack of financial return on investment for chemical manufacturers leading them to not register minor uses; pests developing resistance to current chemistry options; new pests and diseases emerging within the crop; and the need for 'softer' chemistry to assist with Integrated Pest Management (IPM) practices.

Determination of these gaps in management tool options took place via industry consultation in project MT10029. Horticulture Australia and the Australian vegetable industry then set about meeting those needs via Project VG12072, with the goal of preparing minor use permit applications covering a range of vegetable crops. These applications were then submitted to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for assessment. The project team researched, collated and submitted information in support of the requested uses to the APVMA.

All permit applications were submitted prior to the end of August 2013. To date these applications are still within their statutory timeframes for assessment and no approvals have been granted by the APVMA. It is anticipated that most approvals will be gained by the end of December 2013. This will then enable the relevant vegetable crops to gain access to desired pesticide management tools.

Product registration is the preferred method for horticulture crops to gain access to pesticides. However, in certain circumstance, minor use permits are more achievable. These permits are generally issued only for a short period of time (up to 10 years, but more commonly 2 to 3 years). It is recommended that there be suitable provisions in place for their renewal when appropriate. If possible, there should be negotiations with chemical registrants to progress uses to registration so that they are more permanent.

TECHNICAL SUMMARY

Chemical access for minor vegetable commodity groups can be problematic due to a number of factors: lack of financial return on investment for chemical manufacturers leading them to not register minor uses; pests developing resistance to current chemistry options; new pests and diseases emerging within the crop; and the need for 'softer' chemistry to assist with Integrated Pest Management (IPM) practices.

Determination and prioritisation of these chemical access needs took place via industry consultation in the project MT10029 – Managing pesticide access in horticulture. This project is funded by Horticulture Australia Ltd (HAL) using the vegetable industry levy and across industry funds, with matched funds from the Australian Government. Once those needs were determined, HAL put in place project VG12072, with the goal of preparing minor use permit applications covering a range of vegetable crops. This project resulted in the preparation of eleven applications which were then submitted to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for assessment. The project team researched, collated and submitted information in support of the requested uses to the APVMA.

All permit applications were submitted prior to the end of August 2013. As part of their assessment, the APVMA requested storage stability data on frozen samples tested in support of a number of applications. This data was sought by the project officer and supplied where available to the APVMA. Where the data was unavailable, it was suggested that further confirmatory data could be generated within the life of a permit if they should grant it. This proposal has been acceptable to the APVMA. Much of the residue data that was supplied to accompany the application was generated over ten years ago and the samples used were generally stored for considerable periods in a frozen state before analysis. To ensure fewer difficulties in the future it is suggested that checking be undertaken prior to the project tendering to ensure that supporting data meets the APVMA's requirements. Otherwise the requested permit applications do not qualify as desktops, as has been the case in this project. Table 1 lists the applications which were deemed to have deficiencies in their supplied data and how those deficiencies were addressed.

Table 1. Data deficiencies for permit applications

Item code	Situation	Deficiency	Action taken
HAL1558 APVMA ref# 14164	Clethodim (all products) / Brassicas (field) / Resistant Rye & Winter grass	Request storage stability data – samples stored greater than 6 months	Sourced Valent storage stability data and forwarded to APVMA. APVMA reviewing data.
AVG806 APVMA ref# 14166	Fenarimol (Rubigan SC) / Snow & sugarsnap peas (field and PC) / Powdery Mildew	Request storage stability data – samples stored between 20 – 31 months. Requested residue transfer data from animal feed studies.	Sought data for storage and feed studies from Dupont. No data available. Decision made to withdraw the permit.
AVG805 APVMA ref#1420	Oxythioquinox (Morestan) / Snow & sugarsnap peas (field & PC) / Powdery mildew & two-spotted mite	Request storage stability data – samples stored 3 years. Requested residue transfer data from animal feed studies.	Sought storage stability data from Bayer. None available. Requested permit be issued with new data generated within life of the permit. Advised of second deficiency. Sought JMPR data on feed studies and supplied to APVMA. Data still deemed insufficient. Decision made to withdraw application.
AVG933 & 935 APVMA ref# 14337	Trifluralin (all products) / Swedes & turnips / Annual weeds	Request storage stability data – samples stored 2.5 years	Sought storage stability data from Nufarm. Unable to supply the required data. Sourced US EPA document on trifluralin residues with storage stability mentioned and supplied to APVMA.
AVG874 APVMA ref# 14341	Pymetrozine (Chess) / Celery / Aphids	Requested storage stability data	Sought storage stability data from Syngenta. Syngenta supplied data directly to the APVMA.
AVG973 APVMA ref# 14385	Prometryn / Various root vegetables / Grass and broadleaf weeds	Requested storage stability data - samples stored 2 years	Sought storage stability data from Syngenta. Syngenta supplied data directly to the APVMA.
HAL1375 APVMA ref# 14384	Pyriproxyfen / Brassicas / Silver whitefly	Requested further field phase, analytical phase and storage stability data	Sought storage stability data from Sumitomo. Supplied to APVMA.

When assessing permits, the APVMA has statutory timeframes allocated depending on the modules of assessment. All permits were submitted to the APVMA for assessment prior to the completion of the project, however the timeframes stipulated for assessment will exceed the life of this project. Table 2 lists the permits' evaluation commencement dates and their assessment timeframes as stipulated by the APVMA.

Table 2. Evaluation assessment timeframes

Item code	Situation	Evaluation commencement date	Assessment timeframe
HAL1558 APVMA ref# 14164	Clethodim (all products) / Brassicas (field) / Resistant Rye & Winter grass	Received 26 April 2013	8 months
AVG806 APVMA ref# 14166	Fenarimol (Rubigan SC) / Snow & sugarsnap peas (field and PC) / Powdery Mildew	Received 26 April 2013	Permit withdrawn (deficient – storage stability & stock feed)
HAL2004 APVMA ref# 14282	Fluazifop (all products) / Taro & other Asian root veg / Couch & Guinea grass	8 July 2013	5 months
HAL1600 APVMA ref# 14336	Methoxyfenozide (Prodigy) / Lettuce (leafy – field & PC)* / Cluster caterpillar, looper, cutworm*	12 August 2013	5 months
AVG805 APVMA ref# 14204	Oxythioquinox (Morestan) / Snow & sugarsnap peas (field & PC) / Powdery mildew & two-spotted mite	Received 13 May 2013	Permit withdrawn (deficient – storage stability & stock feed)
AVG973 APVMA ref# 14385	Prometryn (all products) / Taro & other Asian root veg / Weeds	Received 23 August 2013	APVMA cannot advise until deficiency is addressed (deficient – storage stability)
AVG989 APVMA ref# 14202	Propachlor (all products) / Carrots / Fleabane	25 July 2013	8 months
AVG617 APVMA ref# 14203	Propyzamide (all products) / Globe artichoke / Weeds	31 May 2013	8 months
AVG874 APVMA ref# 14341	Pymetrozine (Chess) / Celery / Aphids	Received 31 July 2013	APVMA cannot advise until deficiency is addressed (deficient – storage stability & stock feed)
HAL1375 APVMA ref#14384	Pyriproxyfen (Admiral) / Brassicas / Silverleaf whitefly	Received 23 August 2013	APVMA cannot advise until deficiency is addressed (deficient – field phase, analytical phase and storage stability data)
AVG933 & 935 APVMA ref# 14337	Trifluralin (all products) / Swedes & turnips / Annual weeds	Received 29 July 2013	APVMA cannot advise until deficiency is addressed (deficient – storage stability)

The project officer will continue to follow the progress of the permits past the life of the project and report to industry and HAL on their progress.

INTRODUCTION

Product registration is the preferred method for horticulture crops to gain access to pesticides. Unfortunately, this is not always possible or feasible because manufacturers are required to submit comprehensive data packages to the Australian Pesticides and Veterinary Medicines Authority, APVMA who are the regulatory authority governing uses of such pesticides up unto the point of sale. The costs of generating such data are significant and are weighed against the value proposition of return on investment by the registrants. Many horticultural crops are too small for agrochemical manufacturers to consider expending the cost associated with registering their products for use. Growers may also experience pests developing resistance to current chemistry options; new pests and diseases emerging within the crop; and the need for 'softer' chemistry to assist with Integrated Pest Management (IPM) practices.

There are legislative provisions for such situations so that minor commodity groups are not disadvantaged by the lack of registered uses for their crops and are able to seek off-label permits to enable appropriate pesticide use. To obtain such a permit, appropriate applications must be lodged with and approved by the APVMA. These applications outline the proposed use pattern and provide a justification to support the use. This can be made using sound scientific argument and extrapolations from similar crops and uses (both local and international) or through the provision of efficacy and residue data specifically generated for the situation. In project VG12027 both of these options were employed to justify the requested applications to the APVMA.

MATERIALS & METHODS

The APVMA undertakes risk assessment of off-label permits prior to issuing approvals. In preparation of the permit applications, the project team attempted to address areas of product efficacy, crop safety and human safety by providing residue data from existing trials and offering scientific argument to extrapolate from similar crops and use patterns, thus satisfying the anticipated risk assessment elements. Table 3 lists the permit applications which were made to the APVMA via the project.

Table 3. Permit applications submitted via VG12072 which APVMA are still assessing

Item code	Crop	Problem	Active constituent	Date sent to APVMA	New reference No.
HAL1425 Abandoned see "Results" section.	Peppers & chilli (field & PC)	Jassids, leaf hoppers, mealy bugs & whiteflies	Buprofezin (all products)	n/a	n/a To be incorporated in PER12712 consolidation with PER12181
HAL1558	Brassicas (field)	Resistant Rye & Winter grass	Clethodim (all products)	22/04/2013	14164
AVG806	Snow & sugarsnap peas (field and PC)	Powdery Mildew	Fenarimol (Rubigan SC)	22/04/2013	14166 -Now withdrawn due to insufficient data
HAL2004	Taro & other Asian root veg	Couch & Guinea grass	Fluazifop (all products)	17/06/2013	14282
HAL1600 Modified see "Results" section.	Lettuce (leafy – field & PC)	Cluster caterpillar, loopers, cutworm	Methoxyfenozide (Prodigy)	23/07/2013	14336
AVG805	Snow & sugarsnap peas (field & PC)	Powdery mildew & two-spotted mite	Oxythioquinox (Morestan)	9/05/2013	14204–Now withdrawn due to insufficient data
AVG973	Taro & other Asian root veg	Weeds	Prometryn (all products)	20/8/13	14385
AVG989	Carrots	Fleabane	Propachlor (all products)	9/05/2013	14202
AVG617	Globe artichoke	Weeds	Propyzamide (all products)	9/05/2013	14203
AVG874	Celery	Aphids	Prometrozine (Chess)	9/07/2013	14341
HAL1375	Brassicas	Silverleaf whitefly	Pyriproxyfen (Admiral)	20/8/13	14384
AVG933 & 935	Swedes & turnips	Annual weeds	Trifluralin (all products)	23/07/2013	14337

In this process, the project team undertook the following strategies:

- Data mining - identification and utilization of relevant data already within the public domain and researcher community, i.e., from literature searches and previously funded HAL projects;
- Industry linkages – utilization of existing linkages within existing HAL projects such as MT10029, government organisations, peak industry bodies and national and state grower associations;
- Manufacturer linkages – utilization of linkages with chemical manufacturers to source necessary data held by relevant chemical companies.

Issues that potentially could affect the successful issuing of the permit applications were discussed at length with the Minor Use Coordinator, prior to the commencement of the project. Based on these discussions, consolidation of a number of permits on a crops and pest basis was ruled out for item codes: HAL2004 and AVG973; and AVG806 and AVG805.

Relevant searches were undertaken for previous and current similar use patterns which could be used for scientific extrapolation. This revealed that there were permit requests in existence which potentially could be slightly modified to incorporate some of the proposed use patterns. This was the case for HAL1425 (see Results – Permit applications abandoned). The APVMA was consulted as to the best method for limiting the number of permits they receive by including the uses in existing permits if possible.

Existing residue data was obtained from the HAL Minor Use Coordinator, scanned, copied then bound and examined for suitability to support the requested applications. Some anomalies were noted in the residue reports which were reported to the HAL Minor Use Coordinator. Where data was deemed to be insufficient, the offer was made to generate further confirmatory data within the life of a permit if issued. Permit applications were prepared based on the determined information and submitted with relevant supporting data packages to the APVMA for assessment.

Liaison was maintained with the HAL Minor Use Coordinator and HAL Plant Health Portfolio Manager throughout the process.

RESULTS

Permit Approvals

To date no permit approvals have been granted by the APVMA. Please refer to Table 2 of this report for the relevant timeframes for assessment. The project officer will continue to monitor the progress of the applications and supply the APVMA with any further data requirements beyond the completion date of the project.

Permit Applications Submitted to the APVMA

Permit Applications Abandoned

HAL1425 - Initial data mining determined that the APVMA is considering the consolidation of two buprofezin permits, PER12712 and PER12181. This consolidation already had an existing use for peppers, so that only a small extrapolation was required to include chillies to the host list. The pests under consideration already included various whiteflies, thus the addition of other sucking bugs such as jassids (leaf hoppers) and mealybugs was not difficult. The current registered label already includes uses for these pests in other crops, thus proving its efficacy against them. The Project officer and Minor Use coordinator had lengthy consultations with the APVMA and relevant state government experts on the suitability of the proposed inclusions and the manner in which the use pattern should be expressed. APVMA indicated that they would make their assessment to include the proposed uses, thus making the need for a separate permit as directed in HAL1425 redundant.

AVG805 – this application was submitted with old residue data supplied by the HAL Minor Use Permits Coordinator. The length of storage of the samples tested in this data was 3 years. APVMA requested storage stability data. The chemical registrant advised that none was available and it was agreed that further residue data could be generated within the life of the project. However, the APVMA then advised that stock feed residue transference data was required. Some data was sourced from old JMPR records, but this was also deemed to be insufficient. At this point it was agreed that the permit application should be withdrawn.

AVG806– this application was submitted with old residue data supplied by the HAL Minor Use Permits Coordinator. The length of storage of the samples tested in this data was between 20-31 months. APVMA requested storage stability and animal feed residue transfer data. The chemical registrant advised that none was available. At this point it was agreed that the permit application should be withdrawn.

Permit Applications Modified

HAL1600 was modified in its host and pest list as initial data mining determined that current permit PER12391 included a use for leafy lettuce to control native budworm, tomato grub and cluster caterpillar. As this is an existing permit, it needed to wait until it is renewed to amend the use pattern, so the HAL1600 request was modified to the host, lettuce (head) protected cropping and to include the pest Light Brown Apple Moth. There is potential to consolidate these permit uses in the future upon their expiry and subsequent renewal.

DISCUSSION

Due to the age of the data which was supplied in support of a number of the proposed permit applications, there was little recourse to answer questions posed by the APVMA in relation to various aspects of the data. Many of the samples taken for analysis were stored in a frozen state for a number of months before being processed as outlined in Table 1 of this report. The APVMA requested storage stability data for seven such circumstances and may yet request it for further applications as they progress in their assessment process. Where possible, chemical registrants were contacted to supply any data that they may hold and that data was forwarded to the APVMA.

TECHNOLOGY TRANSFER

Once the APVMA issues the requested permits, potential users will be notified via Industry communication networks.

RECOMMENDATIONS

For future projects, it is recommended that data supplied by the Minor Use Coordinator in support of desk top permits, be screened for suitability to meet APVMA requirements prior to industry approvals and project tendering.