Desktop Preparation of Vegetable Minor Use Permit Applications - 2009 - Growcom

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Project Number: VG08165

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This report is published by Horticulture Australia Ltd to pass on information concerning horticultural research and development undertaken for vegetables industry.

The research contained in this report was funded by Horticulture Australia Ltd with the financial support of the vegetables industry.

ISBN 0 7341 2389 2

Published and distributed by:
Horticulture Australia Ltd
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179 Elizabeth Street
Sydney NSW 2000
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DESKTOP PREPARATION OF PESTICIDE MINOR USE PERMIT APPLICATIONS IN VARIOUS VEGETABLE CROPS 2009

FINAL REPORT

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Date Submitted: **31 May 2010**

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

This project was facilitated by HAL in partnership with AusVeg and was funded by the Vegetable levy. The Australian Government provides matched funding for all HAL's R&D activities.

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1. MEDIA SUMMARY

Many smaller vegetable industries struggle to gain access to suitable chemistry to assist them in their pest management needs. Factors such as pesticide resistance; emerging pests or diseases; new cropping systems; an increasing move towards integrated pest management; and the disinclination of many manufacturers to seek registration in small acre crops all contribute to industry's struggles.

To try and alleviate the situation, Horticulture Australia Ltd (HAL) and the Australian Vegetable and Potato growers Federation (AUSVEG) requested assistance in the preparation of pesticide minor use applications in a range of vegetable crops to submit to the Australian Pesticides and Veterinary Medicines Authority (APVMA) via project VG08165. The key outcome of this project is the gaining approval from the APVMA for the use of listed pesticides identified and prioritised through grower wish lists, under the minor use permits scheme.

To date all applications have been submitted to the APVMA; all permits have been screened, all permits are either being assessed or assessment has been completed and are awaiting issuance.

2. TECHNICAL SUMMARY

The Australian Pesticides and Veterinary Medicines Authority (APVMA) are responsible for the approval and registration of all agro-chemical products that can be sold or used in Australia. The APVMA's Minor Use Permits System allows approved uses of agro-chemicals for appropriately qualifying situations.

Growcom has undertaken the task of preparing and submitting ten permit applications covering eleven identified crop / pest situations as stipulated by Horticulture Australia Ltd (HAL) via project VG08165. These applications included insect, disease and weed pests of crops such as: alliums (other than onions) capsicums, lettuce (greenhouse and hydroponic production only), beetroot, Brassica leafy vegetables, chicory, endive, onions, parsley, radicchio and spinach.

Table 1: *Crop/pest/ chemical situations submitted as minor use permit applications by Growcom.*

Item Code	Crop	Target pest	Product Name	Status
HAL338	Onions	General weeds	bentazone	31/10/09 - permit application received & acknowledged by APVMA
AVG1790	Brassica leafy vegetables, chicory, endive, radicchio, spinach	Grass weeds, including winter grass	clethodim	31/10/09 - permit application received & acknowledged by APVMA
HAL1718 & HAL1790	Onions. alliums other than onions	White rot (*Sclerotium*), Black mould (*Aspergillus niger*) & Botrytis (*Botrytis allii*)	Cyprodinil + fludioxonil	31/10/09 - permit application received and acknowledged by APVMA
HAL1575 & HAL1625	Onions capsicum, lettuce (GH & hydroponics)	Botrytis	fenhexamid	31/10/09 - permit application received & acknowledged by APVMA
HAL1694 HAL1760	Beetroot onion	Aphids, thrips (not WFT) Onion thrips	imidacloprid	31/10/09 - permit application received & acknowledged by APVMA 16/12/09 - onion component of application withdrawn.
HAL1797	Chicory, endive, radicchio, beetroot	Anthracnose, Downy mildew, Septoria	Metalaxyl + mancozeb	31/10/09 - permit application received and acknowledged by APVMA
HAL1795	Spring onions, parsley, coriander	RLEM, Rutherglen bug, Looper, Plague thrips	Lambda- cyhalothrin	31/10/09 - permit application received and acknowledged by APVMA

Item Code	Crop	Target pest	Product Name	Status
HAL1798	Spinach	Weeds	phenmedipham	31/10/09 - permit application received and acknowledged by APVMA

Each application was prepared in consultation with a key Plant Science company. Regulatory Affairs representatives of the Plant Science companies provided advice on the use patterns and where possible, supporting data for the permit applications. In some cases the Plant Science Company declined to support the application on grounds of insufficient information to satisfy their internal risk management requirements.

The project officer prepared and submitted the above-mentioned minor use applications to the APVMA.

3. INTRODUCTION

Before a pesticide can be used in Australia it must be approved by the APVMA. In order to gain approval the registrant must show that the pesticide satisfies APVMA data requirements in areas such as efficacy, consumer safety, environmental safety and occupational health and safety. The cost of generating and collating this data is high. As a result, many small horticultural crops that do not generate large volumes of product sales are deemed too small a market for the registrant to invest resources in registering use pattern in these crops.

Thus many horticulture producers of these minor crops are at risk of crop losses from pests, weeds and diseases for which they have no legal pest management options. Legal access to pesticides is also required to prevent illegal use of AGVET chemicals in order to better manage the risks to trade, health and the environment.

Other factors also impact upon the rising need for minor use permits. These include loss of access to older chemistry due to chemical reviews and Plant Science company consolidation and subsequent portfolio rationalisation, pesticide resistance, emerging pests or diseases, new cropping systems, and an increasing move towards integrated pest management.

The APVMA has a regulatory mechanism – a Minor Use Permit Scheme – by which smaller industries are able to seek access to much needed pest management tools. This permit scheme adds some flexibility to the approval process and provides a mechanism whereby minor uses can be granted under guide lined circumstances. The outcome of this scheme is usually the issuing of a time-limited permit that enables growers to use a product for the purpose stipulated in the permit.

To obtain such as permit, applications must be lodged with and approved by the APVMA. These applications must outline the proposed use and provide a justification and supporting data for the request.

In project VG08165 data for 11 proposed uses was sought, collated and submitted to the APVMA as eight applications consolidated by active.

4. METHODOLOGY

Before issuing a minor use permit the APVMA must undertake a risk assessment to be satisfied that the proposed use is efficacious, safe to users, the environment and will not result in violative residues. The eleven permit requests were all deemed to be a 'desktop' applications, meaning the applications could be submitted based on existing local and overseas datasets. Where appropriate, extrapolations from relevant crop groups were made.

To gather this information the following strategies were employed:

- Liaison with the APVMA, HAL Plant Health Minor Use Permit and Pesticide Regulation Coordinators on approaches to the permit applications.
- Data mining:
  – searches were conducted on recognised local and international public domain regulatory databases such as maintained by the Australian Bureau of Statistics, HAL horticulture statistics handbook, Ausveg production data, World Trade Organisation / Food and Agriculture Organisation, Codex Alimentarius.
  – Provision of HAL vegetable industry generated research and development (R&D) data to determine use patterns/generate maximum residue limits to support some of the proposed permit applications.
- Plant Science company linkages – contact was made with pesticide manufacturers/ and registrants to source relevant local and international data.
- Supply chain linkages, Crop agronomists, resellers, crop consultants, researchers and peak industry bodies, were all consulted for their knowledge of national and regionally specific information on host-pest-crop-pesticide relationships.

Permit applications were informed by the datasets gathered from the above strategies. The justifications were based on knowledge gained about the crop itself, the pest as an issue for industry, and overseas and Australian labels and maximum residue limits (MRLs). Once the available information was collected and collated a permit application was generated and submitted to the APVMA.

The steps involved in doing a permit application are outlined below in more detail.

Step 1. The list of requested permit applications was assessed for possible consolidation of the applications by active, resulting in three consolidations.

Step 2. Public domain searches were conducted to provide the APVMA with information on crop production information on the crop plus its edible portion(s). This also included information on marketing and whether the crop is exported or not.

Step 3. Public domain searches were conducted to provide the APVMA with information on the pest and how it affects the crop i.e. the damage caused and areas of plant affected. Wherever possible, information was also provided on the cost of crop losses to growers.

Step 4. Public domain searches were conducted to provide the APVMA with information on relevant MRLs (both Australian and international) and basic chemical properties such as mode of action and resistance management classification for the crop in question or crops of similar CODEX groupings. The, Department of Employment, Economic Development and Innovation Infopest database was also used for this task.

Step 5. Use patterns were established using those already registered for crops of a similar CODEX grouping or as per previous permits or HAL R&D projects. Consultation with Plant Science companies assisted to ensure that the chosen use pattern would be suitable.

Step 6. Consultation with Plant Science companies was undertaken to source relevant Australian and overseas data to support the permit justification to provide to the APVMA.

5. RESULTS & DISCUSSION

The permit applications were submitted to the APVMA over a period of four months form October 2009 with the final permit applications submitted by the end of February 2010. No permits have been issued to date.

Listed in Table 2 are the permit applications being assessed by the APVMA and its agencies. All permits have been submitted to the APVMA for assessment and are proceeding though their system.

Table 2. Permit applications for which approvals are pending

Item code	Crop	Problem	Active Ingredient	Status (comments by APVMA)
AVG1790	Brassica leafy vegetables, chicory, endive, radicchio, spinach	Grass weeds, including winter grass	clethodim	Evaluation APVMA concerns about data integrity
HAL1718 & HAL1790	Onions. alliums other than onions	White rot (*Sclerotium*), Black mould (*Aspergillus niger*) & Botrytis (*Botrytis allii*)	Cyprodinil + fludioxonil	evaluation
HAL1575 & HAL1625	Onions capsicum, lettuce (GH & hydroponics)	Botrytis	fenhexamid	evaluation
HAL1694	Beetroot	Aphids, thrips (not WFT)	imidacloprid	31/10/09 - permit application received & acknowledged by APVMA
HAL1797	Chicory, endive, radicchio, beetroot	Anthracnose, Downy mildew, Septoria	Metalaxyl + mancozeb	31/10/09 - permit application received and acknowledged by APVMA APVMA concerns about data integrity further data submitted 23/12/09.
HAL1795	parsley, coriander	RLEM, Rutherglen bug, Looper, Plague thrips	Lambda- cyhalothrin	31/10/09 - permit application received and acknowledged by APVMA
HAL1798	silverbeet baby spinach, Spinach	Weeds	phenmedipham	31/10/09 - permit application received and acknowledged by APVMA Concerns from APVMA about data integrity. New report sourced from HAL & submitted to APVMA. Ongoing discussions with registrant & APVMA. No registrant support for baby spinach, spinach.

The APVMA requested further information on storage stability studies for clethodim, phenmedipham, Metalaxyl + mancozeb. This situation arose due to the length of time field phase pre Good Laboratory Practice residue samples had been stored before laboratory analysis. This situation arose due to the uncertainty surrounding the collapse of Crop Protection Approvals (CPA) in 2004.

Where possible, Growcom sourced storage stability data from the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and from the pioneer/lead registrants.

The CPA had been tasked with managing the vegetable industries minor use permit requirements, but has since being replaced by the HAL minor use permit coordinator Peter Dal Santo, who has implemented a strategic approach to minor use permit applications, including regular discussion with registrants on proposed minor use permit projects.

Other problems Growcom encountered in this project included missing reports, again which were the result of the problems arising from the sudden collapse of the CPA.
The new strategic approach by HAL Plant Health for the coordination of minor use permits, should alleviate the problems Growcom encountered in this project of permit applications all of which were initiated under the old CPA model.

6. PERMIT APPLICATIONS WITHDRAWN

The following permit applications were withdrawn for various reasons, such as lack of registrant support, APVMA concerns on data integrity, which mostly about storage stability of the target active in vegetable product residues, and as detailed in Table 3 below.

Table 3. Vegetable permit applications withdrawn.

Item code	Crop	Problem	Active Ingredient	Status (comments by APVMA)
HAL1850	Spring onions	RLEM, Rutherglen bug, Looper, Plague thrips	Lambda- cyhalothrin	The Spring onion component was removed from consolidated permit application, because APVMA would not allow data extrapolation from onion to spring onion.
HAL338	Onions	General weeds	bentazone	.Application for spring onions withdrawn, following lack of manufacturer support.
HAL1760	onion	Onion thrips	imidacloprid	16/12/09 The Alliums other than onions component of the application was withdrawn due to the imminent registration of the Allium crop group.

All the other permit applications are proceeding through the APVMA multi-agency evaluation phase.

7. RECOMMENDATIONS

The major outcome of this project is that pesticides that could not be legally used by vegetable growers should become be available, thus providing growers with a broader range of options in the control of key pests of vegetable crops, across a range of production regions nationally.

This project has been part of a larger programme of HAL funded research that has been conducted over the past few years. Although the outcomes of this project have been met there is an ongoing need for growers to have access to newer and better pesticides with a focus on reduced risk chemistry and goo IPM fit. Similar projects should be planned and conducted in the future to ensure the timely issuance of permits by the APVMA and freeing up the HAL Minor Use Permits Coordinator to focus on stakeholder coordination rather than operational procedures that can be cost effectively managed through the HAL desk top tender process. The problems encountered by Growcom relating to permit requests from the CPA days should be nearing an end and researchers undertaking future HAL desktop permit tenders would not be likely to encounter the problems of data integrity and lack of stakeholder consultation, especially with registrants that this project encountered.