

**Desktop Preparation of
Pesticide Minor Use Permit
Applications in Various
Vegetable Crops 2007 -
Competitive Advantage**

Michael Tichon
Competitive Advantage

Project Number: VG06161

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Media Summary

The project objective was to obtain 10 permits for minor uses, i.e. to control pests and diseases in crops/situations which do not justify investment by companies to register the products.

The following permit applications were submitted:

1. Azoxystrobin for control of White rot in alliums (non-onion).
2. Clethodim for control of grasses, including Winter grass in parsnips and carrots.
3. Iprodione and fludioxonil, applied as seed dressings, to control *Rhizoctonia* in direct seed broccoli.
4. Metalaxyl-M, applied as a seed dressing, to control Damping off (*Pythium*) in direct seeded broccoli.
5. Phosphorous acid for control of Root rots (*Pythium* and *Phytophthora*) in parsley and coriander.

Permits for control of *Helicoverpa* spp in various crops by application of nuclear polyhedrosis virus were not applied for as the Vivus range of products are now registered for these uses.

Permit applications were prepared based on researching use of the products for similar situations in Australia and in other countries. Key concerns addressed in the permit applications were:

1. Safety of the products to people and the environment, including any potential residues remaining as a result of the application of the products onto the treated crops.
2. Safety of the products to the target crops.
3. Efficacy of the products against the target pests and diseases.

Applications for the direct seeded broccoli permits were delayed due to a requirement to obtain germination/crop safety data. Applications were submitted on the basis of petri dish and pot tests and before field data were available.

As a result of the data obtained, it is possible that APVMA may request additional (field) data in relation to the safety of broccoli seed treatments. It is anticipated field data will be available by the time APVMA requests such information, if APVMA does request the data.

The cooperation of Agronico in generating the broccoli seed data is greatly appreciated.

The permit for use of azoxystrobin to control White rot in non-onion alliums has been issued.

Technical Summary

The project objective was to obtain 10 permits for the following minor uses:

1. Azoxystrobin for control of White rot (*Sclerotium cepivorum*) in alliums (non-onion).
2. Clethodim for control of grasses, including Winter grass in parsnips and carrots.
3. Iprodione and fludioxonil, applied as seed dressings, to control *Rhizoctonia* in direct seed broccoli.
4. Metalaxyl-M, applied as a seed dressing, to control Damping off (*Pythium*) in direct seeded broccoli.
5. Phosphorous acid for control of Root rots (*Pythium* and *Phytophthora*) in parsley and coriander.

Permits for control of *Helicoverpa* spp in various crops by application of nuclear polyhedrosis virus were not applied for as the Vivus range of products are now registered for these uses.

Permit applications were prepared based on researching use of the products for similar situations in:

1. Australia, e.g. previously approved permits, similarity of current registrations and scientific literature, and
2. Other countries, e.g. Codex MRLs, registered uses in other countries and comparison of growing conditions in those countries with conditions in Australia, scientific literature and literature issued by various extension services.

Key concerns addressed in the permit applications were:

1. Safety of the products to people, including operators/users, bystanders and people consuming treated commodities. This was addressed by comparison with similarity of uses in Australia and in other countries and by established residue limits (e.g. Australian, Codex and other country MRLs).
2. Safety of the products to the environment. This was addressed by comparison with established uses for the products in Australia.
3. Safety of the products to the target crops, determined by comparison of uses on similar/related crops in Australia and overseas at comparable rates of application.
4. Efficacy of the products against the target pests and diseases, determined by comparison of uses on similar/related crops in Australia and overseas at comparable rates of application.

Applications for the direct seeded broccoli permits were delayed due to a requirement to obtain germination/crop safety data. Agronico initially conducted petri dish and pot tests and eventually field studies. The permit applications were submitted prior to field studies having been completed.

As a result of the data obtained, it was determined that APVMA might request additional (field) data in relation to the safety of broccoli seed treatments. It was

anticipated that field data would be available by the time APVMA requested such information, if APVMA did request the data.

The cooperation of Agronico in generating the broccoli seed data is greatly appreciated.

The permit for use of azoxystrobin to control White rot in non-onion alliums has been issued.

Introduction

In all states and territories in Australia, except Victoria, it is illegal to use an agricultural chemical product (pesticide) in any way other than that specified on the registered product label.

Registration of new products for specific uses requires considerable investment to generate data (including efficacy data) as well as application fees. Opportunity cost must also be considered in that an investment in developing one product or a specific use for a product can result in another product or use not being developed. As a result, most agricultural chemical companies concentrate on those products and uses that will yield the highest returns in the shortest time. As a result, "minor uses", i.e. those uses that have little prospect for significant returns on investment in obtaining registrations, suffer from a lack of registrations. Growers of crops classified as "minor crops" are therefore often left without effective tools to combat pests, diseases and weeds.

The problem of minor crops is not confined to Australia. Most countries are developing or have developed systems for authorising the use of pesticides in situations which would not justify agrochemical companies investing in obtaining registrations.

In Australia, authorisation to use agricultural chemicals in "minor use" situations is provided by the issuing of "minor use permits". Such permits are based on the submission of available information (from companies, public literature, etc and gathered within Australia and from overseas).

Typically, the Australian Pesticides and Veterinary Medicines Authority (APVMA) requests confirmation that registrants of products do not have data to indicate the proposed minor use would be ineffective or cause damage to humans, the environment, crops or trade and that the companies do not object to the permit being issued before the permit is issued.

The project, as defined, was intended to:

1. Collect information from registrants of products that might support the issue of specified minor use permits.
2. Collect publicly available information in support of the minor use permits.
3. Submit the permit applications to APVMA.
4. Manage the permit application process to issue of the permits.

Ten projects were assigned including:

1. Control of grasses in parsnips and carrots.
2. Control of *Rhizoctonia* spp in direct seeded broccoli by use of seed treatments.
3. Control of *Rhizoctonia* spp and Damping off in direct seeded broccoli by use of metalaxyl-M seed treatments.

4. Control of *Helicoverpa* spp in various crops by application of nuclear polyhedrosis virus.
5. Control of Root rots in parsley and coriander by application of phosphorous acid.

Project Description

METHODS

The permit applications were intended to involve collecting and collating information and submitting the collated information in appropriately formatted dossiers to APVMA. However, due to concerns expressed by one company (Bayer Cropscience), it became necessary to obtain field data for fungicidal seed treatments proposed to be used on direct seeded broccoli.

Agronico collaborated in obtaining required laboratory and field data. Details of the data required and methods employed are provided in the discussions for the relevant permit applications below.

Non-field data used in support of the applications were obtained by:

1. Companies providing in-house information. Syngenta was the main company that willingly provided information in support of applications. Where generic products were involved, there was little incentive for companies to provide data to support the permits.
2. Literature searches.
3. Examination of overseas regulatory authority data including product labels and product reviews.
4. Examination of overseas residue databases including the Codex MRLs database.

RESULTS AND DISCUSSION

HAL1214 -- Alliums (other than onions)/White Rot/Azoxystrobin

Objective

Obtain permit to allow non-onion allium growers to use azoxystrobin at 200 g active constituent/ha at 7-14 day intervals to control White rot caused by *Sclerotium cepivorum*.

Comments

Data submitted included:

1. Efficacy (based on overseas approvals for the same purpose).
2. Environmental data based on arguments showing use would not cause adverse environmental effects.
3. OH&S information showing the proposed use would not pose greater risks to those associated with use of azoxystrobin in currently registered situations.
4. Residue data, largely based on information supplied by Syngenta.

The application was submitted and APVMA has now issued the permit (PER10349, in force until 30 June 2011).

HAL1530 -- Parsnip/Grasses including winter grass/Clethodim

Objective

Obtain a permit for use of clethodim at a rate of 150 - 500 mL/ha to control grass weeds, including Winter grass in parsnips.

Comments

A single application was submitted requesting a permit to control grass weeds (including Winter grass) in carrots and parsnips.

Data showing efficacy of clethodim against grass weeds, including Winter grass were obtained from USA, Poland and Finland. These data showed the safety of clethodim to parsnips and carrots and were used in support of the application. In addition, the proposed uses were compared with currently registered uses for clethodim in Australia.

Residue issues were addressed by comparison with MRLs/Tolerances established in other countries, including New Zealand.

As the use pattern, including rates of application were not different to currently registered uses, no environmental toxicology, no toxicology or OH&S data were submitted to APVMA.

Issue of the permit is still pending.

HAL1529 -- Carrot/Grasses including winter grass/Clethodim

Objective

Obtain a permit for use of clethodim at a rate of 150 - 500 mL/ha to control grass weeds, including Winter grass in carrots.

Comments

A single application was submitted requesting a permit to control grass weeds (including Winter grass) in carrots and parsnips.

Data showing efficacy of clethodim against grass weeds, including Winter grass was obtained from USA, Poland and Finland. These data showed the safety of clethodim to parsnips and carrots and were used in support of the application. In addition, the proposed uses were compared with currently registered uses for clethodim in Australia.

Residue issues were addressed by comparison with MRLs/Tolerances established in other countries, including New Zealand.

As the use pattern, including rates of application were not different to currently registered uses, no environmental toxicology, no toxicology or OH&S data were submitted to APVMA.

Issue of the permit is still pending.

HAL1632 -- Broccoli/Rhizoctonia/Fludioxonil

Objective

Obtain a permit to allow growers adopting direct seeding of broccoli to use fludioxonil (Maxim 100 FS at a rate of 50 mL/100kg seed) as a seed dressing to control *Rhizoctonia*.

Comments

The permit to enable use of fludioxonil was one of a number of applications submitted requesting APVMA issue permits to enable growers adopting direct seeding of broccoli to use fungicidal seed treatments to control *Rhizoctonia*. One of the permits included iprodione.

Bayer Cropscience did not agree to support the permit application for iprodione unless crop safety data were generated.

Discussions were held with Peter Dal Santo (AgAware Consulting Pty Ltd) who advised the permit was essentially required for Tasmania only and that Agronico had a direct interest in the permit. As a result of this advice, discussions were held with Agronico who agreed to undertake germination studies.

Initially, Odin Franssen of Agronico conducted laboratory (petri dish) germination studies. The results indicated no significant differences in germination between the fludioxonil treatments and the untreated control but some root stunting was observed

in various treatments. It was therefore decided that pot germination studies would be conducted.

Pot trials indicated that while germination was not statistically significantly different from the untreated control by the statistical tests used, there did appear to be a linear trend indicating reduced germination with increased rates of application of iprodione. It was therefore decided that a field study be conducted.

Results of the field study are not yet available.

Rather than waiting for "conclusive" results from the field tests, and on the basis of no significant adverse effects in laboratory studies, it was decided that the application for the permit be submitted to APVMA.

Efficacy of fludioxonil was supported by reference to uses in other crops for control of *Rhizoctonia* spp and by registrations or other fludioxonil formulations for control of *Rhizoctonia* spp in Australia and reference to overseas registrations for fludioxonil as a seed dressing on broccoli.

Residues were addressed by reference to the chemistry of fludioxonil and overseas MRLs/Tolerances, including the Codex MRL for fludioxonil on broccoli.

Toxicology, environmental effects and OH&S issues were addressed by reference to other similar uses approved in Australia.

Issue of the permit is still pending.

The cooperation of Odin Franssen and Agronico in generating germination data is greatly appreciated.

HAL1633 -- Broccoli/Rhizoctonia/Iprodione

Objective

Obtain a permit to allow growers adopting direct seeding of broccoli to use iprodione as a seed dressing to control *Rhizoctonia*.

Comments

It was originally anticipated that Bayer Cropscience would support the application. However, Bayer advised they would not support the permit unless it could be demonstrated that the proposed use would not result in crop damage.

Discussions were held with Peter Dal Santo (AgAware Consulting Pty Ltd) who advised the permit was essentially required for Tasmania only and that Agronico had a direct interest in the permit. As a result of this advice, discussions were held with Agronico who agreed to undertake germination studies.

Initially, Odin Franssen of Agronico conducted laboratory (petri dish) germination studies. The results indicated no significant differences in germination between the iprodione treatments and the untreated control but some root stunting was observed. It was therefore decided that pot germination studies would be conducted.

Pot trials indicated that while germination was not statistically significantly different from the untreated control by the statistical tests used, there did appear to be a linear trend with reduced germination as rate of iprodione applied increased.

To test if effects observed in the pot trials would occur in field use, a field study was initiated. Results of the field study are not yet available.

Rather than waiting for "conclusive" results from the field tests, and as laboratory studies did not indicate any significant adverse effects, it was decided that the application for the permit be submitted to APVMA.

Residue issues were addressed in the application by discussing the breakdown of iprodione and by reference to overseas data and current Australian MRLs.

OH&S, toxicology and environmental effects were addressed by comparison with currently registered uses of iprodione.

The permit has now been issued (PER10588, in force until 30 April 2013).

The cooperation of Odin Franssen and Agronico in generating germination data is greatly appreciated.

HAL1631 -- Broccoli/Rhizoctonia & Damping off/Metalaxyl-M

Objective

Obtain a permit to allow growers adopting direct seeding of broccoli to use metalaxyl-M as a seed dressing to control *Rhizoctonia* and Damping off.

Comments

Initial discussions with Syngenta confirmed metalaxyl-M was not effective against *Rhizoctonia* spp. Syngenta advised they would not support an application for a permit to allow use of metalaxyl-M against *Rhizoctonia*.

In response to this advice, the permit objective was changed to focus on Damping off, normally caused by *Pythium* spp.

The permit to enable use of fludioxonil was one of a number of applications submitted requesting APVMA issue permits to enable growers adopting direct seeding of broccoli to use fungicidal seed treatments to control *Rhizoctonia*. One of the permits included iprodione.

Bayer CropScience did not agree to support the permit application for iprodione unless crop safety data was generated.

Discussions were held with Peter Dal Santo (AgAware Consultants Pty Ltd) who advised the permit was essentially required for Tasmania only and that Agronico had a direct interest in the permit. As a result of this advice, discussions were held with Agronico who agreed to undertake germination studies.

Initially, Odin Franssen of Agronico conducted laboratory germination (petri dish) studies. The results indicated no significant differences in germination between the metalaxyl-M treatments and the untreated control but some root stunting was observed in various treatments. It was therefore decided that pot germination studies would be conducted.

Pot trials indicated that germination was not statistically significantly different from the untreated control by the statistical tests used. However, as there did appear to be a linear trend of lower germination with increased rate of application in the case of iprodione, it was decided that a field study be conducted.

Results of the field study are not yet available.

Rather than waiting for "conclusive" results from the field tests, and as no significant adverse effects were observed in the laboratory studies, it was decided that the application for the permit be submitted to APVMA.

As growers may not know the identity of organisms causing "Damping off" the permits for fludioxonil and metalaxyl-M were cross-referenced, suggesting that if the causal organism is known to be *Rhizoctonia*, fludioxonil be used, if it is known that the causal organism is *Pythium*, metalaxyl-M be used but if the identity of the organism is not known, a combination of metalaxyl-M and fludioxonil be used. The studies conducted by Agronico included combinations of fludioxonil and metalaxyl-M.

Efficacy of metalaxyl-M was supported by reference to uses in other crops for control of *Pythium* spp and by registrations or other metalaxyl-M formulations for control of *Pythium* spp in Australia and reference to overseas registrations for metalaxyl-M as a seed dressing on broccoli.

Residues were addressed by reference to the chemistry of metalaxyl/metalaxyl-M and overseas MRLs/Tolerances.

Toxicology, environmental effects and OH&S issues were addressed by reference to other similar uses approved in Australia.

Issue of the permit is still pending.

The cooperation of Odin Franssen and Agronico in generating germination data is greatly appreciated.

HAL1353 -- Beans (French & Green)/ *Helicoverpa* spp/NPV**Objective**

Obtain a permit to enable growers of beans to apply nuclear polyhedrosis virus for control of *Helicoverpa* spp.

Comments

The labels for the Vivus range of products have been approved to include control of *Helicoverpa* spp. on legume vegetables. This includes French and green beans. As the product is already registered for control of the target pest in the target situation, the permit is not required.

HAL1399 -- Capsicum (greenhouse and hydroponics/*Helicoverpa* spp/NPV**Objective**

Obtain a permit to enable growers of capsicums to apply nuclear polyhedrosis virus for control of *Helicoverpa* spp.

Comments

The label for the Vivus range of products has been approved to include control of *Helicoverpa* spp. on fruiting vegetables. This includes capsicums and chillis. As the product is already registered for control of the target pest in the target situation, the permit is not required.

HAL1257 -- Cucurbits/*Helicoverpa* spp/NPV**Objective**

Obtain a permit to enable growers of cucurbits to apply nuclear polyhedrosis virus for control of *Helicoverpa* spp.

Comments

The label for the Vivus range of products has been approved to include control of *Helicoverpa* spp. on cucurbits. As the product is already registered for control of the target pest in the target situation, the permit is not required.

HAL1540 -- Parsley & Coriander/Root Rot (*Pythium* and *Phytophthora*/Phosphorous acid)

Objective

Obtain a permit to allow growers of parsley and coriander to apply registered phosphorous acid products at a rate of 1800 g active constituent per hectare to control Root rots caused by *Pythium* spp and *Phytophthora* spp.

Comments

A permit (PER9480) has been issued by APVMA for the use of phosphorous acid to control *Phytophthora* in parsley and coriander. The permit allows phosphorous acid to be used at a maximum rate of 80 g active constituent in 100 L of water. Initially, there was some debate as to whether the current permit covered the uses proposed for this permit.

It was ultimately determined that the currently issued permit (PER9480) covers Crown rot rather than Root rots and the use rate was likely to be less than that required to control *Pythium*.

A permit application was eventually prepared and submitted to APVMA. The permit seeks to extend the uses permitted under PER9480 to include *Pythium* and *Phytophthora* Root rots and to permit higher rates of application.

Confirmation of efficacy and crop safety was based on general information about the activity of phosphonate fungicides, permits issued for phosphorous acid products and overseas (USA) registrations for phosphorous acid products.

As phosphorous acid is exempt from the requirements for MRLs, no residue data were submitted with the application.

As uses are similar to existing registrations and permits, no environmental effects, toxicology or OH&S data were submitted with the application.

Issue of the permit is still pending.

Technology Transfer

No specific actions have been undertaken to ensure adoption/use of the permits. The permits were specified in terms of target crops, target pests/diseases/weeds and the products to be used.

Recommendations

The concerns of Bayer CropScience were not unfounded in that there were indications of potential problems in use of iprodione as a seed dressing for direct seeded broccoli, although subsequent studies demonstrated effects were not significant. It is recommended that, in future, consideration be given to ensuring data are available to confirm safety of novel uses for existing products, e.g. seed dressings for new crops.