FINAL REPORT

GRDC
GRAINS RESEARCH & DEVELOPMENT CORPORATION

PHA00010

Development of pre-emptive APVMA emergency permits for exotic plant pest incursion containment and control

PROJECT DETAILS

PROJECT CODE:	PHA00010
PROJECT TITLE:	DEVELOPMENT OF PRE-EMPTIVE APVMA EMERGENCY PERMITS FOR EXOTIC PLANT PEST INCURSION CONTAINMENT AND CONTROL
START DATE:	30.06.2013
END DATE:	30.06.2016
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Summary

Despite a strong quarantine system and lack of shared land borders, there will always be a risk of an exotic pest establishing in Australia. Should a new pest enter, one of the first steps for response in either an eradication or a management program, is the identification of methods of control. Emergency or minor use permits are therefore required to ensure that chemicals are available for response programs. This project has developed a pathway process for these permits and provided a review of chemical control options for 45 exotic pests, a gap analysis of requirements for emergency permits and data packages for permits for 20 high priority pests.

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Old or Archival Reports (Projects that concluded in 2007 or earlier)

The information contained in these older reports is now several years old, and may have been wholly or partially superseded or built upon in subsequent work funded by GRDC or others. Readers should be aware that more recent research may be more useful for their needs. Findings related to agricultural chemical use are also potentially out of date and are not to be taken as a recommendation for their use.

Conclusions

Early detection and response maximise the chances of successfully eradicating new pests. To increase the speed of the initial response, it is important that the industry takes steps to prepare for pest incursions. This includes the preparation of emergency use, minor use or 'shelf' permits i.e. data packages prepared to support the application for an emergency or minor use permit, but not lodged. Within this project, a proposed pathway for preparation of applications for emergency use, minor use or shelf permits has been developed which includes the following steps:
o Identification of key pest threats.
o Identification of chemical control options available for the control of specific pests.
o Identification and preparation of data packages that meet Australian Pesticides and Veterinary Medicines Authority (APVMA) data requirements (including overseas efficacy data or chemical residue or crop safety data).
o Preparation of minor use (Item 21) or emergency use (Item 22) permit applications.
o Submission of permit applications to the APVMA for assessment.

The main process for preparation of these permit types was determined to be the collation and review of information in the public domain through literature searches and label information from overseas countries. If a chemical has been shown to be effective for the control of a specific pest and is currently registered for the control of the specific pest overseas, as well as being used in Australia in a similar manner (e.g. same rates on the same crop to control endemic pests), then no additional residue or efficacy data will usually be required (noting that this remains the determination of APVMA). In such cases, no field trials would be required to generate data for these permit types. Should it be determined that further efficacy or crop residue data are required for application for a permit, it was proposed that this should only be undertaken in the event of an incursion of the pest into Australia. This, therefore, negates the considerable expense associated with the need for overseas trials.

To support the development of emergency, minor use or shelf permits, a desktop review of chemical control options for 45 exotic pests was undertaken in this project.

In addition, applications for emergency or minor use permits for 20 exotic pests were provided to APVMA to support biosecurity preparedness for the grains industry. This included the application for three chemical actives that have been used to support the response and ongoing management following the incursion of Russian wheat aphid (RWA) in May 2016. While the incursion of this pest was considered not technically feasible to eradicate, emergency permits have remained in place until full data packages from field trial results under Australian conditions are available to support label changes.

Recommendations

The following recommendations were identified from this project:

- The ability for a rapid response to a new pest incursion, through the deployment of emergency permits that support appropriate chemical control, has been shown to be a critical biosecurity preparedness activity for the grains industry, following the detection of RWA in 2016.
- Lodgement of applications for emergency permits as a preparedness measure for exotic pests that are not present in Australia can divert APVMA resources from more critical work. As a result, preparation of data packages and shelf permits (i.e. applications prepared but not lodged with APVMA) is currently considered a more suitable alternative to formal lodgement.
- Ongoing work has been supported by GRDC in project PHA00015 to ensure that up to date data packages are available that have identified the most appropriate chemical active and relevant overseas or Australian use pattern for control of a pest should it enter Australia. This work will also provide support for the grains industry for review of existing emergency permits should it be required over the course of this project.
- While the process of holding data packages or shelf permits is considered the best option for biosecurity preparedness, it should be noted there is considerable uncertainty surrounding the current regulatory system due to ongoing legislative reform, as well as uncertainty on the potential relocation of APVMA. A watching brief on these factors will be required in the next investment in this area (PHA00015) to determine if these issues will result in changes to the pathway outlined for development of emergency or minor use permits for biosecurity purposes.
- There are a number of issues that have the potential to adversely impact on the availability and/or suitability of existing pesticide options. These include reviews of chemicals both overseas and in Australia, withdrawal of chemicals and development of resistance to chemical actives. Consideration should be given to engaging with the registrants with regards to new pesticides being developed both in Australia and internationally. This could include exploring the possibility of collaborating on data generation, residue and efficacy, against the relevant biosecurity threat to ensure such data were available in the event of an incursion in Australia.

Outcomes

The Biosecurity Plan for the Grains Industry has identified 54 high priority pests or diseases (collectively called pests) which are exotic to Australia, many of which would require use of chemicals (fungicides, insecticides or pesticides) as part of an eradication program or for initial management should eradication be deemed to be not technically feasible. There are also many other exotic pests that are considered medium risk to the industry. Should a new pest enter Australia, chemicals will not be available until a permit is in place to support their use. For a new pest incursion into Australia, the two main options for permit types to support an eradication response or a management program for a newly established pest are emergency permits or minor use permits.

Emergency permits support primary producers during emergencies or impending emergencies, such as outbreaks of pests and diseases, by allowing the use of a chemical product or an active constituent if there is a genuine belief that the use is required because of the emergency. Minor use permits are for situations where the use will be in a minor crop or for limited use in a major crop (as can occur in an eradication response). Shelf permits do not have a formal definition within APVMA but following discussion with the regulator, there have been situations identified where lodgement of a formal application is deemed to take resources away from other higher priorities. In this instance, data packages could be collated and discussion would occur with APVMA to ensure sufficient detail has been provided to enable lodgement. Data packages would be held by Plant Health Australia (PHA) and lodged only if required.

Within this project, a pathway was developed for emergency permits, minor use permits or shelf permits that will support the grains industry rapidly respond to the incursion of a new pest. This work provided data packages that were used to support the response and ongoing management following the incursion of RWA in May 2016. While the incursion was considered not technically feasible to eradicate, emergency permits will remain in place until full data packages from field trial results under Australian conditions are available to support label changes. The ability to rapidly put in place and update the emergency permits required for this incursion provided economic, social and environment benefits as there were no delays in the availability of chemicals that were appropriate and registered for use.

This project has lodged applications for emergency or minor use permits for 20 high priority pests and has also undertaken a review of chemical control options for 45 high or medium priority pests. This work provides the grains industry with important biosecurity preparedness outcomes that have been shown to have significant benefits in the event of new pest incursions.

Achievements/Benefits

Under this project, chemical control options for 45 pests have been identified. Analysis showed that many of the pests could

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potentially be managed by the same active constituent. Therefore, it was determined that a single application to APVMA for the minor use of a particular active constituent could be used to cover multiple pests. As a result of this work, Item 21 applications (application for a minor use permit for an agricultural chemical product) have been prepared for the following 20 pests:

Lambda-cyhalothrin# to control the following pests:
o Brassica pod midge (*Dasineura brassicae*)
o Cabbage seed weevil (*Ceutorhynchus assimilis*)
o Cabbage stem weevil (*C. pallidactylus*)
o Pollen (rape) beetle (*Meligethes aeneus*)
o Rape stem weevil (*C. napi*)
o Sunn pest (*Eurygaster integriceps*)
o Turnip moth (*Agrotis segetum*)

Deltamethrin# to control the following pests:
o Brassica pod midge (*D. brassicae*)
o Cabbage seed weevil (*C. assimilis*)
o Cabbage stem weevil (*C. pallidactylus*)
o Pollen (rape) beetle (*M. aeneus*)
o Rape stem weevil (*C. napi*)
o Sunflower moth (*Homoeosoma electellum*)
o Sunn pest (*E. integriceps*)
o Turnip moth (*A. segetum*)

Tebuconazole# (Group 3 fungicide) to control the following pests. Approved 4th December 2015 (PER81138):
o Karnal bunt (*Tilletia indica*)
o Wheat blast (*Magnaporthe grisea* (*Triticum* pathotype))
o Barley stripe rust (*Puccinia striiformis f.* sp. *hordei*)

Pirimicarb# to control the following pests:
o English grain aphid (*Sitobion avenae*)
o Greenbug (*Schizaphis graminium*)
o RWA (*Diuraphis noxia*)

Imidacloprid# seed treatment to control the following pests:
o Greenbug (*Schizaphis graminium*)
o Hessian fly (*Mayetiola destructor*)
o RWA (*D. noxia*)
o English grain aphid (*S. avenae*)

Maldison# to control the following pests:
o Hessian fly (*M. destructor*)
o Northern corn earworms (*Diabrotica barberi*)
o Southern corn rootworms (*D. undecimpunctata*)
o Western corn earworms (*D. virgifera*)
o Orange wheat blossom midge (*Sitodiplosis mosellana*)

Chlorothalonil# to control the following pests:
o Lentil anthracnose (*Colletotrichum truncatum*)

Propiconazole# to control the following pests:
o Karnal bunt (*T. indica*)
o Barley stripe rust (*P. striiformis f.* sp. hordei)

Chlorpyrifos# to control the following pests:
o RWA (*D. noxia*).

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Should an incursion of one of these pests occur, amendments will be required to ensure that a permit is specific to the pest target (i.e. does not cover multiple pest species). In this instance, an amendment to specify a single pest species can be processed rapidly by APVMA.

In addition to identification of chemical control options, the project identified potential gaps in contingency planning and identified new technologies that could be used to control 45 exotic pests. The project also considered the regulatory threats associated with the use of different chemicals for the control of more than 50 pests. This information will be considered when selecting chemicals for the control of specific pests and the preparation of future APVMA applications.

A pathway process has been developed for the application for emergency or minor use permits of exotic pests (see Attachment) which was used successfully for application for an emergency permit for the control of RWA in 2016.

Since the project commenced in June 2013, regular meetings have been held with APVMA and other stakeholders to determine the level of data required for emergency permit applications.

Intellectual property summary

Intellectual property (IP) has been developed in the form of reports provided of the potential chemical control options available for 45 high priority pests and data packages for submission of emergency permits for 15 pests of the grains industry. This information has been submitted to GRDC as outputs of this project and will be held in confidence by PHA. Information can be made available to the peak representative body(ies) of grains or government jurisdictions as required.

Additional information

Attachment

Draft pathway document for the development of emergency and minor use permits for control of exotic grain pests.

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