

# FINAL REPORT

AKC00001

## Registration for minor use chemicals for the grains industry

### PROJECT DETAILS

PROJECT CODE: AKC00001

PROJECT TITLE: REGISTRATION FOR MINOR USE CHEMICALS FOR THE GRAINS INDUSTRY

START DATE: 01.07.2004

END DATE: 30.06.2007

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### Summary

Minor and specialty grains industries can suffer from a lack of suitable pest management options needed to ensure sustainable production. The chemical industry tends not to pursue uses of agricultural chemicals for these smaller markets. The minor use project has sought to secure grain grower access to suitable pest management options not currently covered by existing approvals. The project has successfully achieved regulatory approvals through ongoing liaison with the regulators, researchers and relevant grains industry stakeholders. This has been achieved through consultation, timely submissions and communication of results.

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## Conclusions

The current project has achieved a number of significant successes, however there is still a need for minor and specialty grains crops to require access to pesticides via permits. Despite a number of initiatives at the policy and operational level instigated by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Department of Agriculture, Fisheries and Forestry (DAFF), little real progress has been achieved.

Two major impediments remain: those of data protection and product liability. Current regulations in Australia potentially penalise a manufacturer should they provide data in support of a permit application through loss of data protection. In addition, the mechanism for a company gaining additional years of data protection (through the addition of minor crop) has not been finalised. As a result, there is no incentive for a manufacturer to pursue minor crops. In terms of liability, manufacturers currently cannot limit their liability with regard to permits. As a result, a number of manufacturers have taken a position to not support any permit application. Until this can be resolved, some manufacturers will be reluctant to fully engage with the grains industry to gain approvals for minor uses.

## Recommendations

1. Any future project aimed at obtaining pesticide approvals should critically evaluate submissions made by industry bodies to ensure they are essential for the continued sustainable production of that crop. Projects that are not considered essential or a priority by the industry body should not be pursued.
2. Any future project should be linked to GRDC funded research involving pesticides. This is to ensure any pesticide related work is carried out on compounds that have manufacturer support i.e. are likely to gain regulatory approval.
3. The project team, via liaison with the APVMA, should determine data requirements to obtain regulatory approval. Where data needs to be generated, an estimate of cost should be obtained and possible funding sought from industry bodies, agencies and chemical manufacturers. If funding is not forthcoming, further action should not be taken.
4. Further discussions should be held with relevant industry groups in Canada and the US to identify opportunities for future co-operation.
5. Linkages be formally developed between GRDC and other Research and Development corporations e.g. Horticulture Australia Limited (HAL) and Rural Industries Research and Development Corporation (RIRDC), with regard to possible co-operation in data generation.

## Outcomes

The project was initiated as minor and specialty grains and oilseed industries can suffer from a lack of suitable pest management options approved for use. This lack of options can significantly impair an industry's productivity and is primarily the result of such factors as resistance, new pests, new crops, emerging technologies and lack of commercial attractiveness. The implications can be reduced productivity, illegal off-label use of pesticides and maximum residue limits (MRL) violations.

The project has contributed to the improved security of Australian grain production by providing an increased range of pesticides approved for use in a number of crops. These approvals have primarily been through off-label permits but also

included research permits, emergency permits and label extensions.

In addition, the project has been effective in highlighting the issues faced by the grains industry to government at both the policy and operational level. The outcome is a greater awareness in government of the difficulties faced by minor and specialty grains industries. The project has also sought to increase awareness of regulatory requirements and procedures within the GRDC and grain industry bodies.

The purpose was to ensure that

- i. industries had an appreciation of the prerequisites for a successful permit application and
- ii. pesticides being evaluated have chemical industry agreement and are capable of being approved by the APVMA for use on that crop.

## Achievements/Benefits

The marketplace for manufacturers and suppliers of agricultural chemicals is highly competitive, and has resulted in significant consolidation by research and development companies. With increasing costs (now estimated at over US\$120 million/product) and uncertainty in success of commercialisation of new chemicals, manufacturers' development focus is increasingly on major earning opportunities (common pests and diseases, large hectare plantings and key crops). Less significant pests and diseases, smaller acreage crops and new and untried management innovations are less likely to attract any significant priority or support from these companies. In addition to the manufacturers limited resources, the ever more demanding regulatory and liability requirements have resulted in minor and specialty crops and minor uses being largely ignored.

This lack of focus from pesticide manufacturers has serious implications for affected grain growers and industries. Specifically, the application of unapproved pesticides can result in contravention of state based control of use legislation, non-compliance with quality assurance (QA) programs and violations of importing country MRLs. As a result, gaining access to new chemical solutions is of critical importance to grain growers.

The project team has sought to address this problem via the following process:

Firstly, the project team has collated a 'needs' list of minor uses for grains industries. This list was then assessed against regulatory requirements and prioritised on the basis of need and likelihood of success. Following the industry needs analysis, the project team approached manufacturers with regard to levels of possible support.

Upon completion of the above process, permit applications were prepared and submitted to the APVMA. During the life of the current project, over 30 permit approvals and one label extension (diuron<sup>#</sup> in pulses) were achieved. These permits have been communicated to the affected industries for circulation as well as a web-based listing via GRDC and industry websites. In addition, a number of preliminary co-operative projects have been initiated with chemical manufacturers.

The project team also sought to identify emerging issues for which current management options are unavailable or lack regulatory approvals. This involved seeking comprehensive permit approvals for new crops e.g oilseed mustard, new technologies, such as shielded spraying, and research including the use of plant growth regulators in high yielding cereal crops.

Secondly, from a communication perspective, the project team participated in a number of activities including GRDC Crop Updates, Agronomy workshops, and minor-use related workshops and conferences, such as the APVMA Minor Use Forum and Minor Use Operational Working group, IR4 Food Use Workshop. These activities sought to highlight the role of the project to the wider grains community with regard to input, as well as the difficulties faced by minor grains industries to government.

Thirdly, the project team sought to establish linkages internationally with minor use research programs in the USA and Canada. The intent was to identify opportunities for collaboration in the areas of data generation and sharing to support potential label extensions. This involved visits to the USDA IR4 Food Use Workshop, as well as field visits to grain producing regions of the US and Canada.

Lastly, the project team sought to link with GRDC funded research projects investigating the use of pesticide based management options to ensure data generated meets regulatory requirements and can be used to gain regulatory approvals. This activity is still at a preliminary level and requires further development.