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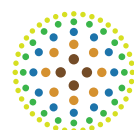


Delivery of Access to AgVet Chemicals Collaborative System - AgVet Collaborative Forum

By Rohan Rainbow

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Delivery of Access to AgVet Chemicals Collaborative System – AgVet Collaborative Forum

by Rohan Rainbow

Combined report - December 2016

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- Australian Pesticides and Veterinary Medicines Authority (APVMA)
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- Animal Health Australia (AHA)
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- Horticulture Innovation Australia (HIA)
- Ausveg
- Citrus Australia
- Growcom
- Protected Cropping Australia
- Summerfruit Australia
- Sugar Research Australia (SRA)
- Canegrowers
- Grains Research and Development Corporation (GRDC)
- Grain Producers Australia (GPA)
- Australian Grape and Wine Authority (AGWA)
- Wine Grape Growers Australia (WGGA)
- Cotton Research and Development Corporation (CRDC)
- Cotton Australia
- National Farmers Federation (NFF) Chemicals Committee
- CropLife Australia and member companies
- National Working Party on Pesticide Applications (NWPPA)
- Animal Medicines Australia
- Meat and Livestock Australia (MLA)
- Sheep Meat Council of Australia
- Goat industry Council of Australia (GICA)
- Cattle Council

- Red-Meat Council
- Australian Chicken Meat Federation
- Australian Egg Corporation Limited
- Australian Pork
- Dairy Australia
- Fisheries Research and Development Corporation (FRDC)
- National Aquaculture Council
- IR-4 USA
- Agriculture and Agri-Food Canada Minor Use Program
- Kevin Bodnaruk AKC Consulting Pty Ltd.

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- Andrew Weidemann - Grain Producers Australia
- Ken Young - Grains Research and Development Corporation
- Robert Hayes - Herbs and Spices/Protected Cropping Australia
- Scott Kwasny - Ausveg
- Jodie Pedrana - Horticulture Innovation Australia
- Bob Crouch - Goat Industry Council of Australia
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- Rural Industries Research & Development Corporation (RIRDC)
- Horticulture Innovation Australia Limited (HIAL)
- Grains Research and Development Corporation (GRDC)
- Cotton Research and Development Corporation (CRDC)
- Sugar Research Australia (SRA)
- Forestry and Wood Products Australia
- Wine Australia
- Dairy Australia
- Australian Wool Innovation
- CropLife Australia and member companies
- Animal Medicines Australia and member companies.

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Further information on RIRDC Projects PRJ-009981 - Delivery of Access to AgVet Chemicals Collaborative System and PRJ-010406 – AgVet Collaborative Forum is available at:

<http://www.rirdc.gov.au/AgVet>

Abbreviations

AAFC	Agriculture and Agri-Food Canada
ABARES	Australian Bureau of Agricultural & Resource Economics & Sciences
AgVet	Agricultural Chemicals and Veterinary Medicines
APVMA	Agricultural Pesticides and Veterinary Medicines Authority
CANMUP	Canada Minor Use Program
CANPMC	Agriculture and Agri-Food Canada Pest management Centre
GLP	Good Laboratory Practice
GRDC	Grains Research and Development Corporation
IR-4	Inter Regional Program #4 – USA Plant industry Minor Use Program
MRL	Maximum Residue Limit
NAFTA	North American Free Trade Agreement
NRSP-7	National Research Support Project #7 - USA Minor Use Animal Drug Program
RIRDC	Rural Industries Research and Development Corporation
USDA	United States Department of Agriculture

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Executive Summary

What the report is about

Agriculture is facing current productivity challenges in terms of managing pests and diseases, which will significantly increase within the next decade. With a general decline in productivity growth and changes to external factors in managing weed, pest and disease risk, Australia more than ever requires access to new and safer pesticide and veterinary medicines. The plant and animal industries are all facing significant emerging biosecurity threats and being impacted on by pesticide resistance. Australia is no longer on the global priority list for pesticide and veterinary medicine commercialisation as it was 20 years ago.

Australia more than ever requires access to new, safer pesticides and veterinary medicines. Australian agriculture is experiencing increasing market failure regarding investment in agricultural pesticides and veterinary medicines as the case for commercial investment is not always sufficient given the regulatory cost for chemical registration and the relatively small market size.

Some industries in Australia are currently missing out on up to 50% of the potential new technologies which key competitors in Europe and the USA have access to, putting those industries at a competitive disadvantage. Australian agriculture is experiencing increasing market failure regarding investment in agricultural pesticides and veterinary medicines as the case for commercial investment is not always sufficient given the current high level of regulatory cost for chemical registration and the relatively small market size.

Without significant change, Australian agricultural productivity will increasingly decline, as will the ability of new and emerging industries to deliver a more diverse range of foods due to increasing market failure, even though demand for these products continues to grow.

The RIRDC project PRJ-009981 Delivery of Access to AgVet Chemicals Collaborative System, was contracted to establish a forum to develop a sustainable approach for collaboration regarding AgVet chemicals, building on recent cross industry discussions on AgVet chemical access that were supported by industry and government stakeholders. It could include establishing a collaboration and co-investment framework to more efficiently improve AgVet technology access for agricultural industries at reduced cost.

The joint RDC funded project through PRJ-10406 – AgVet Collaborative Forum project has delivered the second phase of activity of the Forum established in 2014. This project has continued to deliver a sustainable approach for collaboration regarding improved access to AgVet chemicals. The project has continued to make further improvement to a collaboration and co-investment framework to more efficiently improve AgVet technology access for agricultural industries at reduced cost. The project has continued to demonstrate potential value of collaboration and cost savings from investment in the collaborative framework, delivering increased Agvet tools to Australian agriculture.

Who is the report targeted at?

This project establishes a sustainable approach for collaboration of all Australian plant and animal agricultural industries nationally regarding AgVet chemicals, building on recent cross industry discussions on AgVet chemical access that were supported by industry and government stakeholders. The project also establishes a collaboration and co-investment framework to more efficiently improve AgVet technology access for agricultural industries at reduced cost.

Where are the relevant industries located in Australia?

There is a continual threat of managing biosecurity threats, emerging pests and increasing pesticide resistance for all plant and animal agricultural industries in Australia. There have also been additional challenges with animal biosecurity preparedness with access to vaccines for exotic viruses. Minor use and emergency use permits have a very important role in delivering appropriate pest management options for Australian producers of crops and animals where market failure has resulted in a lack of registered label options. As the requests for these permits are always industry driven there is very rapid uptake of their use.

Background

Plant and animal industries are facing significant emerging biosecurity threats and impact from pesticide and veterinary medicines resistance. Australia is no longer on the global priority for pesticide and veterinary medicine commercialisation as it was 20 years ago. Some industries in Australia including grains are currently missing out on up to 50% of the potential new technologies which key competitors in Europe and the USA have access to. Australia strategically requires access to new and safer pesticide and veterinary medicines and is experiencing increasing market failure of investment in agricultural pesticides and veterinary medicines. Australia is also missing out from productivity improvement through commercial investment in a large number of potential emerging biological, biochemical and biotechnology based AgVet technologies.

Through facilitated discussions with most of the agricultural industry RDCs, peak industry bodies, both Plant and Animal Health Australia, Department of Agriculture, APVMA and key registrant groups CropLife Australia and Animal Medicines Australia identified the major factors resulting in declining investment in Australia. These major factors include:

- Australia is a small AgVet market in a global context < 1.5%
- Australia is experiencing difficulties with complex AgVet regulations, timeliness and costs relative to commercial return on investment
- Global multinational companies face a poor rate of return on commercialisation investment compared with major developing markets including Brazil and China.

There is clearly increasing market failure for investment in AgVet technologies in Australia. RDC, government and commercial priorities are now identified as an increasing grey area, well beyond the previously well-defined market failure areas of minor use and specialty crops programs.

Aims/objectives

The PRJ-009981 project delivered on the following objectives:

- Deliver a new formal system for collaborative cross industry AgVet investment, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet chemical needs and reducing current impacts of market failure. This system will:
- Promote information sharing and co-investment opportunities to better use resources for supporting applications to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for AgVet chemical uses.

- Inform chemical companies of potential market demand to assist in their decisions to register Australian uses.
- Provide a forum for producers and the chemical industry to interact with the department and the APVMA to discuss the most effective and efficient methods of improving access to chemicals. These may include combining the investment efforts of a few grower groups to the benefit of the wider group.
- Demonstrate the value of collaboration and cost savings from investment through the collaborative framework to delivering increased access to AgVet chemicals to Australian agriculture.

The PRJ-010406 project delivered on the following objectives:

- Delivery of a functional and self-sustaining system for growers to effectively share their priorities for chemical access needs with other growers, RDCs and chemical companies
- Deliver cost savings from investment and reduce current impacts of AgVet chemical market failure.
- Facilitate cross industry prioritisation and investment for improved access to uses of AgVet chemicals resulting in:
 - Improved priority setting and cross industry collaboration
 - Achieving agricultural industry and commercial co-investment in data generation supported through initial government incentive.
 - Achieving cost savings through cross industry efficiencies

The PRJ-009981 project in the 14 months from contracting has delivered on the following outcomes:

1. Deliver options for a new framework and functional collaborative AgVet investment program, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet needs reducing current impacts of market failure.
2. Demonstrate potential value of collaboration and cost savings from investment in the collaborative framework, delivering increased AgVet tools to Australian agriculture.
3. Deliver a new framework and functional collaborative AgVet investment program, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet needs reducing current impacts of market failure.
4. The system/framework will be negotiated between the Department of Agriculture, state and territory government departments, registrants and industry, and is expected to be managed with oversight by cross-industry RDCs resulting in:
 - Improved priority setting and cross industry collaboration
 - Achieving agricultural industry and commercial co-investment in data generation supported through initial government incentive
 - Achieving cost savings through cross industry efficiencies and national and international collaboration and co-investment
 - A sustainable program that is supported by all stakeholders

The PRJ-010406 project in the 8 months from contracting has delivered on the following outcomes:

1. Delivery of a functional and sustainable system for growers to effectively share their priorities for chemical access needs with other growers, RDCs and chemical companies
 - *The project has continued to deliver a functional and sustainable system with increased support from all stakeholders in 2016 compared with the 2015 Forums.*
2. Deliver cost savings from investment and reduce current impacts of AgVet chemical market failure.
 - *The project has continued to deliver additional cost savings to industry through identification of new solutions to emerging pest issues through an efficient and transparent process, enabling discussions with international programs on future collaborations to take place potentially delivering future cost savings and increased market access for produce.*
3. Facilitate cross industry prioritisation and investment for improved access to uses of AgVet chemicals.
 - *The project has delivered an improved priority setting and cross industry collaboration process in 2016, building on those established in 2015.*
 - *The project has achieved significant increased interest and activity in agricultural industry and commercial co-investment in data generation supported through initial government incentive, with grant applications increasing from less than 50 in 2015 to just under 90 in 2016.*
 - *The project has continued to deliver cost savings to industry, RDCs, registrants and government through cross industry efficiencies by bringing all stakeholders together in an efficient and structured program of discussion.*

Methods used

The project established with key stakeholders initial meetings that would eventually become the Forum for the collaborative AgVet collaboration system. This included facilitating the:

- Development and implementation of a sustainable governance structure for the forum with a focus of management and oversight by the cross-industry RDCs.
- Development of agreed processes for operation/administration of the system.
- Agreed industry indicators and measures of the success in increasing access to minor use, including the collaborative system, and documentation of baseline for indicator measures.

The project delivered proposed models and relevant information to the AgVet collaborative forum and the Department of Agriculture and Water Resources to allow stakeholders to consider using the collaborative forum to establish a functional AgVet investment program. Alignment of key international investment priorities with Australian industry priorities delivery was identified in a report to stakeholders of potential cost savings from collaboration including the value of international company partnership.

Reports were produced to demonstrate the functional approach and potential cost savings resulting from a collaborative AgVet prioritisation and investment program including existing national and international minor use programs. Deliver this report to RIRDC to be tabled to all industry stakeholders and the Department of Agriculture detailing options and benefits of increased international collaboration in minor use, potentially through IR-4 and other programs and deliver a prospectus to RIRDC for future joint RDC co-investment in this specific program.

The project consulted with all plant and animal industry stakeholders including peak industry bodies and their relevant RDC. The project maintained direct engagement through all meetings and workshops, by email and publications through to achieving consensus endorsement of outcomes at a

final consultation forum. Resulting industry AgVet prioritisation workshops and investment prospectus for the delivery of future outcomes of the Forum were presented to industry and their relevant RDC for endorsement and agreement for continued financial support.

Results/key findings

Through the stakeholder engagement in delivering this project, 82 grower and RDC organisations, 23 AgVet registrant companies and 5 GLP trial services providers have participated or been contacted in the delivery of the AgVet Collaborative Forum over the initial 14 months of delivery. There were consistently over 40 industry stakeholders involved in each meeting of the Forum.

The outcome for the plant industries from this workshop is particularly significant with the industry discussion of issues with registrants identifying solutions to 58%, or a third of the top five industry issues, which previously had no identified solution. This highlights the strategic value of this discussion and the AgVet Collaborative Forum. The outcomes of this process will have significant potential productivity benefits for these industries in the future.

The project has delivered on the planned objectives and outcomes resulting in the delivery of a new framework and functional collaborative AgVet investment program to deliver new AgVet tools to Australian agriculture.

This project has resulted in financial support for the ongoing delivery of the AgVet Collaborative Forum to industry with seven participating plant industry RDCs, which represent all plant industry RDCs in Australia, one animal industry RDC, three peak meat council organisations plus the peak registrant organisations CropLife Australia and Animal Medicines Australia.

Demonstrating potential cost savings achieved through cross industry efficiencies and national and international collaboration and co-investment for plant industries of up to \$567 million. The project has delivered a cost effective and sustainable program that is supported by all stakeholders, with participating industries and their RDCs in the future Forum accounting for over 95% of all AgVet use in Australia.

The PRJ-009981 project established with key stakeholders initial meetings that would eventually become the Forum for the collaborative AgVet collaboration system. This included facilitating the:

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The PRJ-009981 project consulted with all plant and animal industry stakeholders including peak industry bodies and their relevant RDC. The project maintained direct engagement through all meetings and workshops, by email and publications through to achieve consensus endorsement of outcomes at a final consultation forum. Resulting industry AgVet prioritisation workshops and investment prospectus for the delivery of future outcomes of the Forum were presented to industry and their relevant RDC for endorsement and agreement for continued financial support.

The planned approach to 2016 prioritisation for gaps workshops through PRJ-010406 was tabled and discussed with all RDCs and CropLife Australia registrants prior to the forum and delivered with approval of the plan and animal industries Forum steering committees. The outcomes of the prioritisation for gaps workshop and consultation process was an Excel pivot table spread sheet detailing all ranked industry top 5 priorities and technical solution options has been distributed by email to all plant and animal Forum participants and has been made available for download from the RIRDC AgVet website www.rirc.gov.au/agvet.

In 2015, 326 unique crop/pest issues, of which 319 solutions are technically supported by registrants. Of these industry issues, 135 had no identified solution for which 78 new potential solutions have been identified by registrants. An additional 90 new groups of solutions were identified by registrants adding to existing options proposed by industry.

In 2016, 500 unique crop/pest issues were identified for all Australian plant industries seeking solutions to registration gaps. Of these industry issues, 173 had no identified solution for which 90 new potential solutions have been identified by registrants. An additional 96 new solutions were identified by registrants adding to existing options proposed by industry. A total of 315 'A-L (Label) projects and 143 'A-P' (Permit) projects were identified. Additionally 24 solutions already on registration track that industry was not previously aware of were identified through discussions. Consideration of chemical modes of action and stewardship for resistance management were discussed during the Forum. These outcomes will improve pesticide resistance management by industry through access to a wider range of modes of actions.

In 2015, 98 unique animal pest issues, resulting in 68 solutions technically supported by registrants. Four additional groups of solutions to industry issues were identified by registrants.

In 2016, 69 unique animal pest issues, resulting in 36 solutions technically supported by registrants.

Implications for relevant stakeholders for:

Through the stakeholder engagement in delivering the PRJ-009981 project, 82 grower and RDC organisations, 23 AgVet registrant companies and 5 GLP trial services providers have participated or been contacted in the delivery of the AgVet Collaborative Forum over the 14 months of delivery. There were consistently over 40 industry stakeholders involved in each meeting of the Forum.

The outcome for the plant industries from the prioritisation workshops are particularly significant with the industry discussion of issues with registrants identifying solutions to 58%, or a third of the top five industry issues, which previously had no identified solution. This highlights the strategic value of this discussion and the AgVet Collaborative Forum. The outcomes of this process will have significant potential productivity benefits for these industries in the future.

The project has delivered on the planned objectives and outcomes resulting in the delivery of a new framework and functional collaborative AgVet investment program to deliver new AgVet tools to Australian agriculture.

This project has resulted in financial support for the ongoing delivery of the AgVet Collaborative Forum to industry with seven participating plant industry RDCs, which represent all plant industry

RDCs in Australia, one animal industry RDC, plus the peak registrant organisations CropLife Australia and Animal Medicines Australia. A decision by the peak red-meat councils is pending.

Potential cost savings achieved through cross industry efficiencies and national and international collaboration and co-investment for plant industries of up to \$567 million has been identified. The project has delivered a cost effective and sustainable program that is supported by all stakeholders, with participating industries and their RDCs in the future Forum accounting for over 90% of all AgVet use in Australia.

With survey feedback on the AgVet Collaborative Forum on motivation for involvement at the last Forum in the 89% range and confidence of success of the Forum currently in the 75% range, there is clearly opportunity to further boost industry confidence in the delivery of outcomes. Significant progress and industry consensus from a diverse group of stakeholders has been achieved in a relatively short time. While the Agvet Collaborative Forum is only the first step, there is every confidence based on survey results and feedback from registrants that the project will successfully deliver on providing improved AgVet technologies for producers.

There was considerable success in maintaining a cross industry culture of collaboration in the plant industries through the Phase II PRJ-010406 project. The exit survey from the Plant Industries prioritisation for gaps workshop has indicated that a high level of motivation (Mean Av score 81%) has been maintained and there is every confidence (Mean Av score 78%) that the project will deliver its planned outcomes. The recent survey has also indicated the recognised significant value of assembling a priorities list (Mean Av score 80%) The plant industries highlighted the continued significant value in discussing these priorities with registrants (mean Av score 79%). There continues to be significant alignment of motivation and confidence scores, even with a significant number of new participants to the Forum (STDDEV 16-19%).

There were a number challenges that impacted on the delivery of the PRJ-010406 project in delivery of the 2016 AgVet Collaborative Forum including:

- Delay in finalisation of financial commitment of some Plant Industry RDCs to the AgVet Collaborative Forum and delays in review of AgVet priorities by the RDC with their relevant peak industry body
- Delay of a public release of summary of projects supported by the Federal Government AgVet grants program
- Delay of finalisation of Animal Industry prioritisation due to limited Animal Industry RDC participation impacting on original plans

The lack of registrations for the Animal Industry prioritisation for gaps workshop was a significant issue for the project. While the project worked around this to deliver options for grant outcomes for the participating industries, several key issues were identified by registrants as a major contributing factor to a lack of a business case for participation:

- The absence of the red-meat industries lowering the commercial value of participation in the Forum
- The issues of existing off label use and resistance evolution to anthelmintics is a significant concern and it was suggested that RIRDC should develop a resistance management strategy and stewardship plan for the goat and Alpaca industries before commitment to investment and technical access to drench products would be considered.

A number of broader strategic cross industry AgVet issues would benefit from further workshops providing opportunity for further feedback to industry on leading into a potential annual review of

priorities beyond 2016. Plant industry workshops should potentially include further discussion on cross industry risks of fungicide resistance including *Botrytis cinerea* and insecticide resistance in Lepidoptera and aphids. Animal industry workshops should continue to focus on cross industry risks of anthelmintic resistance.

The exit surveys from the PRJ-010406 strategic meetings indicated that the facilitation ranking of the Forum had increased to a very high score of 88%. The combined plant and animal strategic meeting exits surveys also indicated reasonably high strategic value of these workshops of 77% and highlighted the continued significant value in discussing these priorities with registrants (mean Av score 87%). The exit survey indicated that there should be continue involvement of industries in both the plant and animal Forums with all but one animal industry suggesting the Forum should continue.

The outcome of PRJ-009981 was that all plant industry RDCs and three animal industry RDCs entered into a funding agreements with RIRDC, under the recommended governance model as identified in the investment prospectus in late 2015. A second round of AgVet prioritisation workshops were delivered in June 2016.

Following delivery of PRJ-010406, it is anticipated that the Plant industries will transition to the recommended investment, governance and delivery model identified in the investment prospectus September 2016. There is however significant concern that there appears to be inadequate interest from a broad range of animal industries in 2016 for transition to future investment in the Animal Industries AgVet Collaborative Forum.

Recommendations

The following key considerations are considered essential for the establishment and continued success of an Australian AgVet collaborative minor use program:

- Open discussion between industries and their priorities with companies on potential solutions
- Adopting a consensus approach to reaching agreement with stakeholders
- Effective financial and non-financial incentives program to maximise commercial investment support for the program
- Mechanism for effective engagement with the regulator to receive advice at key decision points in the prioritisation process
- Agreement by all stakeholders on the agreed program outcomes and success measures.

It is recommended that future investment consider measurement of impacts from the AgVet Collaborative Forum. Due to the long timeframes for resulting delivery of permit or label outcomes from the initial Forum program, estimated benefits will need to modelled forward based on the delivery of actual outputs. A commissioned impact assessment should report on the following:

- Profitability and productivity benefit
- Market access benefit
- Resulting industry growth potential
- Resistance and sustainability benefit
- OH&S and environment benefit

- Estimated cost savings and efficiency in delivery of projects

While the commissioned impact assessment approach is highly dependent on agreed assumptions, these can be well managed with industry and registrant stakeholder input. There should also be consideration of the economic measures and indicators used in the North American IR-4 impact studies. The costs of undertaking the review and reporting will need to be factored into program budgets.

It is recommended that further consideration be given by the Department of Agriculture and Water Resources for future discussion within the AgVet Collaborative Forum on the following;

- Utilising the plant and animal industry priorities identified including the list of plant industry priorities resulting from the workshop, give consideration to continued co-investment with industry and registrants in these priorities to incentivise continued engagement in the Agvet Collaborative Forum
- Engage in discussion with agricultural industry investors, particularly the RDCs and registrants on the effective financial and non-financial incentives program to maximise commercial investment support for the program, including funding for regulatory support of the priorities identified in the Forum
- Explore regulatory options to improve mechanisms for effective engagement with the regulator to receive advice at key decision points in the prioritisation process
- Establishment of an MOU agreement with IR-4/CANMUP to allow formal establishment of international collaboration including priority sharing and potential data sharing
- Discuss non-participation of key animal industries and options to increase the value of this program to these industries, including red-meat and aquaculture.

GLP residue laboratory capacity could be a potential trial bottleneck as a consequence of an increase in AgVet investment through the Department of Agriculture AgVet trial grants program. With a potential time lag of at least 6 months to order, commission equipment and train staff to increase GLP residue analysis. Combined with a maximum storage period of 6 months for GLP residue materials before processing, it will be critical for study directors to ensure GLP laboratories have adequate capacity on stream and commissioned to process a potential initial potential backlog of GLP field trial materials.

It is recommended that industries continue to co-invest and collaborate in the Agvet collaborative Forum. It is also recommended that RIRDC continues to take cross industry leadership in facilitating the management and delivery of the Forum. While the current model of delivery through consultants is a low cost and effective model for access to the necessary expertise during its establishment, the Forum should explore longer-term models where the Forum is delivered through larger multi-industry organisations facilitating currently facilitating stakeholder engagement on similar issues. Organisations such and plant Health Australia and Animal Health Australia should be considered as options.

1. Introduction

Agriculture is facing current productivity challenges in terms of managing pests and diseases, which will significantly increase within the next decade. With a general decline in productivity growth and changes to external factors in managing weed, pest and disease risk, Australia more than ever requires access to new and safer pesticide and veterinary medicines. The plant and animal industries are all facing significant emerging biosecurity threats and being impacted on by pesticide resistance. Australia is no longer on the global priority list for pesticide and veterinary medicine commercialisation as it was 20 years ago.

Australian agriculture is experiencing increasing market failure regarding investment in agricultural pesticides and veterinary medicines as the case for commercial investment is not always sufficient given the regulatory cost for chemical registration and the relatively small market size.

Some industries in Australia are currently missing out on up to 50% of the potential new technologies which key competitors in Europe and the USA have access to, putting those industries at a competitive disadvantage. Australian agriculture is experiencing increasing market failure regarding investment in agricultural pesticides and veterinary medicines as the case for commercial investment is not always sufficient given the current high level of regulatory burden for chemical registration and the relatively small market size.

Without significant change, Australian agricultural productivity will increasingly decline, as will the ability of new and emerging industries to deliver a more diverse range of foods due to increasing market failure, even though demand for these products continues to grow.

The RIRDC project PRJ-009981 Delivery of Access to AgVet Chemicals Collaborative System, was contracted to establish a forum to develop a sustainable approach for collaboration regarding AgVet chemicals, building on recent cross industry discussions on AgVet chemical access that were supported by industry and government stakeholders. It could include establishing a collaboration and co-investment framework to more efficiently improve AgVet technology access for agricultural industries at reduced cost.

This project establishes a sustainable approach for collaboration regarding AgVet chemicals, building on recent cross industry discussions on AgVet chemical access that were supported by industry and government stakeholders. The project also establishes a collaboration and co-investment framework to more efficiently improve AgVet technology access for agricultural industries at reduced cost.

The project also demonstrates potential value of collaboration and cost savings from investment in the collaborative framework, delivering increased AgVet tools to Australian agriculture. The project delivers on the Australian Government priority and \$8 million investment commitment - A Competitive Agriculture Sector - improved access to agricultural and veterinary chemicals.

Through this project, the Access to AgVet Chemicals Collaborative Forum has been funded through RIRDC by the Australian Government Department of Agriculture through the project GMS-2373 / Access to AgVet Chemicals Collaborative System.

This project investment also builds on the current RIRDC project delivering recommended options for cross industry AgVet prioritisation, PRJ-009454 - Improved access to AgVet chemicals for agricultural industries.

1.1 AgVet market failure and minor use

In addressing AgVet market failure by registrants, minor use permits are held by a number of agricultural industries including most horticultural industries, grains, cotton, sugarcane, grape and wine, rice, forestry, hay/fodder, non-crop uses, and a number of animal industries including fisheries, pork, poultry dairy, sheep cattle, goat, and alpaca. Horticulture currently represents the vast majority of minor use permits at nearly two thirds of all current permits. Minor use and emergency use permits have a very important role in delivering appropriate pest management options for Australian producers of crops and animals where market failure has resulted in a lack of registered label options.

Minor use permits are developed in response to urgent industry demand and therefore will result in a rapid rate and level of adoption. This has been clearly demonstrated in the Australian grains and horticulture industries. A study funded by the GRDC and HAL by Woods 2014, analysed economic studies in Australia that indicate benefits of minor use permits from 13:1 to 95:1. In the United States under a total economic impacts model, benefits from minor use permits has been shown to be as high as 462:1. The benefits applied to the 8.1 million expenditure by GRDC and HAL for the 3 years 2010-13 had a total economic impact at a minimum of \$113.5 million and potentially as high as \$3.565 billion. The combined benefit of a broader minor use program when applied to other industries would be significantly higher.

Public Benefits from an effective AgVet program addressing market failure include:

- Improving storage or shelf life for food products
- Meeting consumer expectations for safe residue free food, noting in 2008/09 the majority of MRLs established in Australia arose from minor use permits, highlighting the demand for minor uses.
- Maintaining a diversity of food types for an increasingly multi-cultural society
- Contributing to protection of the environment
- Managing Australia's international reputation for food production
- Reducing impediments to free trade
- Flow on effects to other industries such as the use in fodder and grain products for livestock and dairy product industries.

Market opportunity benefits from an effective minor use program with appropriate prioritisation include:

- Managing Australia's international reputation for food production
- Reducing impediments to free trade
- Flow on effects to other downstream animal industries such as for use in fodder and grain products for livestock and dairy product industries.

This report outlines the key rationale for cross industry collaboration, plus consideration and options for a collaborative approach in delivering new AgVet technology for industry and measuring the resulting benefits. Building on the experiences of overseas programs and their success, the key question for Australian industry is *"can we afford not to deliver a new sustainable collaborative AgVet program to remain internationally competitive"*.

1.2 Objectives

The PRJ-009981 project delivered on the following objectives:

- Deliver a new formal system for collaborative cross industry AgVet investment, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet chemical needs and reducing current impacts of market failure. This system will:
- Promote information sharing and co-investment opportunities to better use resources for supporting applications to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for AgVet chemical uses.
- Inform chemical companies of potential market demand to assist in their decisions to register Australian uses.
- Provide a forum for producers and the chemical industry to interact with the department and the APVMA to discuss the most effective and efficient methods of improving access to chemicals. These may include combining the investment efforts of a few grower groups to the benefit of the wider group.
- Demonstrate the value of collaboration and cost savings from investment through the collaborative framework to delivering increased access to AgVet chemicals to Australian agriculture.

This PRJ-009981 project in the 14 months from contracting has delivered on the following outcomes:

1. Deliver options for a new framework and functional collaborative AgVet investment program, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet needs reducing current impacts of market failure.
2. Demonstrate potential value of collaboration and cost savings from investment in the collaborative framework, delivering increased AgVet tools to Australian agriculture.
3. Deliver a new framework and functional collaborative AgVet investment program, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet needs reducing current impacts of market failure.
4. The system/framework will be negotiated between the Department of Agriculture, state and territory government departments, registrants and industry, and is expected to be managed with oversight by cross-industry RDCs resulting in:
 - Improved priority setting and cross industry collaboration
 - Achieving agricultural industry and commercial co-investment in data generation supported through initial government incentive
 - Achieving cost savings through cross industry efficiencies and national and international collaboration and co-investment
 - A sustainable program that is supported by all stakeholders

This PRJ-009981 project has delivered in 14 months since contracting, the following outputs:

1. Establish with key stakeholders the initial meetings that will eventually become the forum for the collaborative AgVet system. Delivery by 15 December 2014

2. Deliver proposed models and relevant information to the Forum stakeholders and the Department of Agriculture to consider using the collaborative Forum to establish a functional AgVet investment program. Delivery by 31 January 2015.
3. Deliver a functional and sustainable system for producers to effectively share their priorities for chemical access needs with other producers, RDCs and chemical companies, to deliver cost savings from investment and reduce current impacts of AgVet chemical market failure. Delivery by 31 October 2015.
4. Facilitate cross industry prioritisation and investment for improved access to uses of AgVet chemicals. Delivery by 31 October 2015.

Delivery of this project *PRJ-009981- Delivery of Access to AgVet Chemicals Collaborative System* supports RIRDC in its delivery by the Australian Government Department of Agriculture of the project GMS-2373 - Access to AgVet Chemicals Collaborative System. This includes establishing through the Forum, signed agreement for continued participation in the collaborative system including at least 4 plant and animal industry RDCs.

The PRJ-010406 project in the 8 months from contracting has delivered on the following outcomes:

1. Delivery of a functional and sustainable system for growers to effectively share their priorities for chemical access needs with other growers, RDCs and chemical companies
 - *The project has continued to deliver a functional and sustainable system with increased support from all stakeholders in 2016 compared with the 2015 Forums.*
2. Deliver cost savings from investment and reduce current impacts of AgVet chemical market failure.
 - *The project has continued to deliver additional cost savings to industry through identification of new solutions to emerging pest issues through an efficient and transparent process, enabling discussions with international programs on future collaborations to take place potentially delivering future cost savings and increased market access for produce.*
3. Facilitate cross industry prioritisation and investment for improved access to uses of AgVet chemicals.
 - *The project has delivered an improved priority setting and cross industry collaboration process in 2016, building on those established in 2015.*
 - *The project has achieved significant increased interest and activity in agricultural industry and commercial co-investment in data generation supported through initial government incentive, with grant applications increasing from less than 50 in 2015 to just under 90 in 2016.*
 - *The project has continued to deliver cost savings to industry, RDCs, registrants and government through cross industry efficiencies by bringing all stakeholders together in an efficient and structured program of discussion.*

1.3 Methodology

The PRJ-009981 project has delivered the following steps in delivery of milestones;

1. Conduct stakeholder consultation for AgVet investment identified in Proposed R&D Adoption/Commercial pathways. Engage through regular teleconference and face to face meetings with the Department of Agriculture and RDCs during the initial meeting phase, to refine the forum with the aim of delivering a system that is sustainable into the future. Delivery by 15 December 2014.

2. Meet individually with key industry investment stakeholders and potential investors to identify key deliverable outcomes and potential baseline indicator measures. Identify key industry priorities for Minor Use Global Joint Review Program. Delivery by 15 December 2014.
3. Consultation meetings with at least 11 CropLife Australia and Animal Medicines Australia member companies to identify investment incentives, which would deliver increased international AgVet investment into Australian agricultural crop protection and animal health programs and increased interest in investment partnership with federal government initiatives and Research and Development Corporation co-investment. Delivery by 15 December 2014.
4. Identify potential options for consideration of co-investment partners frameworks delivered in an options paper. Deliver proposed models and relevant information to the forum and the Department of Agriculture to allow stakeholders to consider using the collaborative forum to establish a functional AgVet investment program. Delivery by 15 December 2014.
5. Conduct stakeholder consultation on options for potential cost savings identified in Proposed R&D Adoption/Commercial pathways. Delivery by 15 December 2014.
6. Establish with key stakeholders initial meetings that will eventually become the forum for the collaborative AgVet collaboration system. This will include facilitating the:
 - Development and implementation of a sustainable governance structure for the forum with a focus of management and oversight by the cross-industry RDCs.
 - Development of agreed processes for operation/administration of the system.
 - Agreed industry indicators and measures of the success in increasing access to minor use, including the collaborative system, and documentation of baseline for indicator measures. Delivery by 15 December 2014
7. Facilitate by the 15 December 2014, the first AgVet collaborative forum, including:
 - Development of relevant discussion papers based on stakeholder consultation
 - In consultation with the Department of Agriculture receive input from all agricultural industries, RDCs and peak industry bodies and the APVMA, to be tabled at the initial AgVet collaborative forum. These will cover key matters for the effective delivery of the collaborative forum including a recommended approach for identifying and sharing each industry's priorities at the forums.
8. Deliver a report to RIRDC for consideration of the Department of Agriculture on the outcomes of the first forum (milestone 7) detailing success and any issues. Delivery by 20 January 2015.
9. Facilitate cross industry agreement on final priority lists for global joint review 20 January 2015.
10. Deliver an AgVet minor use capacity audit and capacity building implementation-plan to stakeholders and finalise a report delivered to RIRDC. Delivery by 30 June 2015.
11. Deliver proposed models and relevant information to the AgVet collaborative forum and the Department of Agriculture to allow stakeholders to consider using the collaborative forum to establish a functional AgVet investment program. Delivery by 31 January 2015.
12. Table a report to stakeholders on project 1 forum feedback and deliver a preliminary meeting with stakeholders to discuss the benefit and to discuss establishment of a collaborative investment forum potentially including formal international collaboration. Delivery by 31 March 2015.

13. Delivery of a prospectus to agricultural industry stakeholders on recommended project options for collaborative investment to deliver improved AgVet technology access. Delivery by 31 March 2015.
14. Consultation with at least 11 CropLife Australia and Animal Medicines Australia member companies to identify investment incentives, which would deliver increased international AgVet investment into Australian agricultural crop protection and animal health programs and increased interest in investment partnership with federal government initiatives and Research and Development Corporation co-investment. Delivery by 30 April 2015.
15. Attend meetings with AAFC Minor Use Pesticides Program Health Canada's Pest Management Regulatory Agency (PMRA), USDA Minor Use in animals program and IR-4 to identify potential opportunity for potential future data sharing and joint research collaboration. Delivery by 30 April 2015.
16. Meet individually with key investment stakeholders and potential investors and deliver a combined meeting with stakeholders to discuss clarity of roles and functional process for investment. Delivery by 30 April 2015.
17. Deliver report to the AgVet collaborative forum and the Department of Agriculture including; progress to date and possible future directions; plus potential new or additional tools to facilitate AgVet access including national and international data pools and possible system for funding application of these tools to gain access for the most critical use needs. Delivery by 30 June 2015
18. Workshop delivered in consultation with CropLife Australia, Animal Medicines Australia and department of Agriculture with at least 4 plant and animal RDCs to prioritise and achieve consensus on co-investment options. Delivery by 30 June 2015
19. Establish through the AgVet collaborative forum and the Department of Agriculture a signed agreement for continued participation in the collaborative system including at least 4 plant and animal industry RDCs. Including co-investment agreement, signing meeting and delivery of a finalised co-investment program report delivered to RIRDC and circulated to stakeholders and tabled to the Department of Agriculture. Delivery by 30 June 2015.
20. Identification and alignment of key international investment priorities (including at least IR-4) with Australian industry priorities identified in Project 1 and delivery of a report to RIRDC and tabled to stakeholders of potential cost savings from collaboration including the value of international company partnership. Delivery by 30 June 2015.
21. Meet individually with key investment RDC stakeholders and potential investors to discuss establishment of an AgVet collaborative investment program including international collaboration. Attend follow up collaboration options meetings based on AgVet collaborative forum discussion outcomes with AAFC, USDA and IR-4. Delivery by 30 June 2015.
22. Collaborate with Department of Agriculture and APVMA as a representative of cross industry RDCs to reach agreement for potential future international collaboration. Attend the Global Minor Use Summit, Minor Use Global Joint Review Prioritisation Meeting and IR-4 prioritisation and planning meeting. Delivery by 30 September 2015.
23. Produce a report to demonstrate the functional approach and potential cost savings resulting from a collaborative AgVet prioritisation and investment program including existing national and international minor use programs. Deliver this report to RIRDC to be tabled to all industry stakeholders and the Department of Agriculture detailing options and benefits of increased international collaboration in minor use, potentially through IR-4 and other

programs and deliver a prospectus to RIRDC for future joint RDC co-investment in this specific program. Delivery by 30 September 2015.

24. Delivery of an incentive options scoping document delivered to company, government and RDC stakeholders. Delivery by 30 September 2015.
25. Deliver an AgVet minor use capacity audit and capacity building implementation-plan to stakeholders and finalise a report delivered to RIRDC. Delivery by 30 September 2015.
26. Deliver a report to RIRDC to be tabled to all industry stakeholders and the Department of Agriculture detailing recommendations to establish a cross industry AgVet minor use prioritisation and investment program and conduct discussions and consultation of recommendations with national stakeholders for their endorsement/approval. Delivery by 31 October 2015.
27. Project activities concluded 31 October 2015 and final report submitted within 1 month. The delivery of a project final report to RIRDC will include all project outputs including a package of documents detailing the recommended AgVet collaborative forum framework. The final report will also detail the consensus and/or endorsement by industry stakeholders of the project findings and recommendations. Delivery by 1 December 2015.

The project consulted with all plant and animal industry stakeholders including peak industry bodies and their relevant RDC (all organisations detailed in Appendix 1). The project maintained direct engagement through all meetings and workshops, by email and publications through to achieve consensus endorsement of outcomes at a final consultation forum. Resulting industry AgVet prioritisation workshops and investment prospectus for the delivery of future outcomes of the Forum were presented to industry and their relevant RDC for endorsement and agreement for continued financial support.

The PRJ-010406 project has delivered the following steps in delivery of milestones;

1. Exchange of project contract. Delivery by 1 March 2016.
2. Provide industry stakeholder consultation in assembly and refinement of AgVet priorities. Delivery by 30 April 2016.
3. Assemble industry priorities for a prioritisation database. Delivery by 30 April 2016.
4. Consultation of draft industry priorities with CropLife and AMA members. Delivery by 30 April 2016.
5. Workshops delivered to prioritise and achieve consensus on co-investment options. Delivery by 30 June 2016.
6. Evaluate workshop outcomes and report submitted to RDCs and registrants. Delivery by 30 June 2016.
7. Deliver a 1-day animal and 1-day plant industry strategic discussion workshop. Delivery by 30 September 2016 – Variation approved for delivery 31 October 2016.
8. Support RIRDC in Delivering an annual update to the RIRDC AgVet website and communications program. Delivery by 30 September 2016 – Variation approved for delivery 31 October 2016.
9. Deliver a report to stakeholders to continue the operations of the AgVet Collaborative Forum. Delivery by 30 September 2016 – Variation approved for delivery 31 October 2016.

2. Strategic needs and opportunity for AgVet collaboration

2.1 Key issues impacting on agricultural productivity

Plant and animal industries are facing significant emerging biosecurity threats and impact from pesticide and veterinary medicines resistance. Australia is no longer on the global priority for pesticide and veterinary medicine commercialisation as it was 20 years ago. Some industries in Australia including grains are currently missing out on up to 50% of the potential new technologies which key competitors in Europe and the USA have access to. Australia strategically requires access to new and safer pesticide and veterinary medicines and is experiencing increasing market failure of investment in agricultural pesticides and veterinary medicines. Australia is also missing out from productivity improvement through commercial investment in a large number of potential emerging biological, biochemical and biotechnology based AgVet technologies.

Through facilitated discussions with most of the agricultural industry RDCs, peak industry bodies, both Plant and Animal Health Australia, Department of Agriculture, APVMA and key registrant groups CropLife Australia and the Animal Medicines Australia identified the major factors resulting in declining investment in Australia. These major factors include:

- Australia is a small AgVet market in a global context < 1.5%
- Australia is experiencing difficulties with complex AgVet regulations, timeliness and costs relative to commercial return on investment
- Global multinational companies face a poor rate of return on commercialisation investment compared with major developing markets including Brazil and China.

There is clearly increasing market failure for investment in AgVet technologies in Australia. RDC, government and commercial priorities are now identified as an increasing grey area, well beyond the previously well-defined market failure areas of minor use and specialty crops programs (Figure 1).

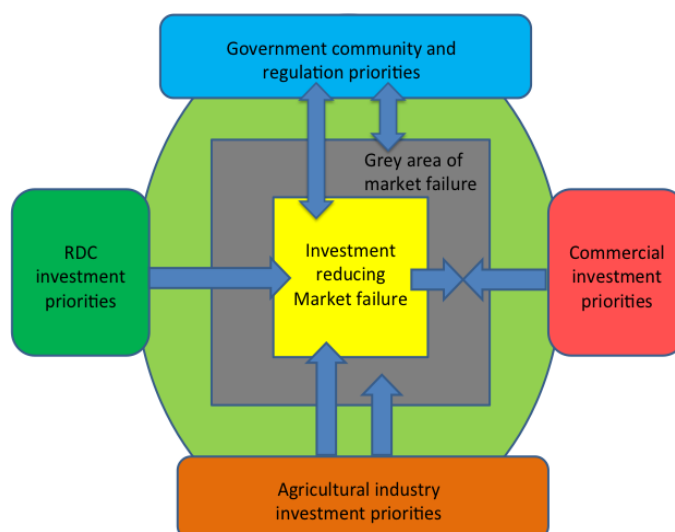


Figure 1. Model of investment priorities and commercial AgVet investment market failure

There is a need to increase multinational confidence for investment into Australia and also increase Australia's ranking on investment priority compared with competing investment opportunity in Asia and South America. To address investment market failure in the longer term, there is need for cross-agricultural industry discussion with government and commercial chemical companies on options to increase this confidence. Through industry consultation to date, the identified outcomes for community and industry that need to be achieved include:

- Increased National and foreign investment in Australia
- Increased agricultural profitability and sustainability
- Increased delivery of a diverse range of foods to a multicultural community
- Increase productivity and scale of industries contributing to GDP and balance of trade
- Improving safety to community, environment and trade.

Based on the experience of minor use programs in North America where there have been similar issues, there is clearly opportunity to deliver on these outcomes through a collaborative approach. Improved prioritisation of needs, identification of benefits of co-investment by industry, government and commercial registrants and establishment of investment incentive frameworks to support these programs has had a significant impact in delivering benefits to industry and the community.

2.2 Sustainable AgVet collaboration – Successful programs of international competitors

Market failure in AgVet investment in minor use, which is often been described as speciality crop programs, is not unique to Australia. There has been declining global investment in minor use, particularly since the global financial crisis began in 2002. Government supported minor use investment programs in North America have been expanded, such as the Inter-Regional Research Project Number 4 (IR-4 Project, also referred to as the Minor Crop Pest Management Program) and started such as the Canadian Agriculture and Agri-Food Canada Minor Use Program (CAN-MUP). The IR-4 Program has been significantly expanded with formal collaboration with Canada and Mexico under the North American Free Trade Agreement (NAFTA). More recently collaborations with IR-4 have been established with Brazil and Costa Rica. The US Minor Use Animal Drug Program, also known as the National Research Support Project #7 (NRSP-7) research focus is on drugs for minor species of agricultural importance, such as fish, sheep, and goats that make food or fibre products for people. With additional industry incentives and reduced data requirements for minor animal use, there has been a successful outcome for this program with a significant decline in investment market failure.

The IR-4 Project has provided the necessary field and residue data to account for approximately 20-25% of all submissions made to US EPA for new uses and account for approximately 50% of all new tolerances that are established. Over 80% of the IR-4 program is focused on new chemical actives or biologicals. At the 2014 IR-4 meeting in Atlanta, over 80% of the actives prioritised for investment are new technologies, most of which will not come to Australia unless there is additional investment incentive. The IR-4 program has delivered benefits to cost as high as 439:1 in the food crops program and 462:1 overall. The IR-4 programs and Canadian MUP have both highlighted their challenges in

the early establishment of these programs. Industry expectations of time to delivery of outcomes and early agreement and consensus on options and approaches required considerable patience and commitment of stakeholders

The New Zealand Ministry for Primary Industries Sustainable Farming Fund (SFF) has invested in a project ‘Registration of sustainable agrichemicals for minor crops’. The SFF project was set up to assist in developing and refining current policy to make registration of products more efficient, less costly and more achievable for growers of minor crops. This program has linked into IR-4. In facilitating minor use for animals, the NZ government has also established a pathway whereby, under certain circumstances, it will consider the decisions of the Australian APVMA, in lieu of data assessments, to support an application for registration of veterinary medicines.

There is a key challenge in being able to increase global AgVet investment to address Australian Agricultural industry needs. Clearly international minor use investment incentive programs have competed with Australian needs, but in addition to this additional incentive reforms such as reduced data requirements, increased data protection and conditional registration programs, have successfully increased investment in North American programs. If Australia is to remain globally competitive, the Australian AgVet Collaborative Forum will have to determine if it wants to press the button to hook into these international investment programs (Figure 2).

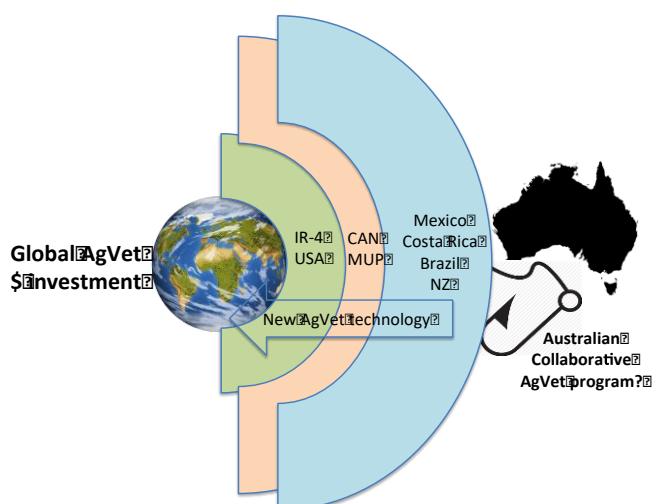


Figure 2. Opportunity for Australia to hook into the Global AgVet investment program, potentially building around IR-4

While these international programs have been clearly very successful, before Australian international collaboration and investment can be decided however, the Australian AgVet collaborative Forum must first determine if and how it wants to work together cross industry. The Forum must then determine how it wants to approach prioritisation issues; how it wants to interact in a global environment to hook into the global development opportunities; and how to capitalise on opportunity for early technology access to remain globally competitive.

2.3 Establishing a potential AgVet collaborative system in Australia

The first step in establishing a potential AgVet collaborative system in Australia is to ensure that all industries involved agree to take a long-term strategic approach to remaining profitable and internationally competitive. As discussed, a significant challenge in the early period of establishing both the USA IR-4 and Canadian MUP programs was the industry expectations of timeframes to

delivery of benefits to industry. Establishing what should be the agreed benefits and outcomes of a collaborative program are also important.

In establishing an internationally competitive collaborative AgVet system in Australia, it is important that the system delivers to stakeholder expectations and opportunities for all stakeholders with the right benefit-sharing models. The attributable benefits will need to be identified, KPIs and timeframes of delivery to industry agreed.

Key factors in successful collaboration include¹:

- Collaborations usually succeed where there is a solid foundation of identified need and opportunity. Success is also difficult where there are significant weaknesses in capacity to deliver and there are issues with a path to market
- Collaborations should turn win-lose situations into win-win situations and the benefits must be equitably shared
- Partnerships should be based on bringing needed skills, capability and strategic alignment to a program, not just the consideration of increased scale

To progress the discussion in establishing a potential AgVet collaborative system in Australia, it is proposed for the first step, that the existing positive solid foundations of AgVet programs are tabled cross industry and discussed. The following step would then potentially identify opportunity to address the needs of other industries by expanding these foundation strengths. Further steps may include exploring the benefits to all industries and the scale of interest in commercial investment through a broader program, as has been the experience of the IR-4 and CAN-MUP.

Based on a review of AgVet issues² and a cross industry workshop³ in early 2014, in establishing a cross industry AgVet program through the Forum, the following should be considered:

- There is a need for cross commodity project champions – possibly the industry that has most to gain from collaboration
- Representative crops/industry groupings are important – Noting that the current levy-funding model may create some challenges to cross industry collaboration. This potentially requires further industry discussion
- Commodities/industries wanting to have a seat with a cross industry prioritisation framework will need to consider some industry investment in the program.

What is evident from the review of the North American programs linked around IR-4 is the importance of the culture of collaboration, commercial engagement and producer patience in delivery of outcomes (often taking 5+ years). This culture has taken a considerable amount of time, negotiation and communication and goodwill to achieve.

This first meeting of the AgVet Forum enables stakeholders to identify what AgVet program success looks like for industry. It will also seek to explore mechanisms on how to collaborate and establish

¹ <http://www.supplychainquarterly.com/print/20120622-six-steps-to-successful-supply-chain-collaboration/>

² Rainbow, RW, Krause, M, (2014) National and international frameworks and methodology for determining priorities for industries seeking to access AgVet chemicals: RIRDC Draft milestone and industry stakeholder report.

RIRDC project PRJ-009454 - Improved access to AgVet chemicals for agricultural industries.

³ Rainbow, RW, Krause, M, (2014) RIRDC Cross agricultural industry AgVet investment prioritisation options workshop outcomes report. *RIRDC project PRJ-009454 - Improved access to AgVet chemicals for agricultural industries.*

industry indicators and measures of the success in increasing access to minor use, including through a collaborative system. Development and implementation of a sustainable governance structure for the forum will be established and the Forum will also identify key issues for detailed discussion and recommendation by industry stakeholders. It will also be a Forum for discussions with the Department of Agriculture in relation to the AgVet regulation reform agenda.

2.4 Sharing industry identified priorities at the forums – Options, risks and benefits

The objective of the AgVet collaborative forum is to discuss and explore the establishment of a sustainable cross-agricultural industry system for producers to effectively share their priorities for chemical access needs with other producers, RDCs and chemical companies and to deliver cost savings from investment and reduce current impacts of AgVet chemical market failure. A key role of the AgVet Forum is to enable producers and the chemical industry to formally engage ‘in discussion’ with the department and the APVMA to identify the most effective and efficient methods of improving access to chemicals.

The planned outcome of these discussions is to deliver a functional and sustainable system for producers to effectively share their priorities for chemical access needs with other producers, RDCs and chemical companies, to deliver cost savings from investment and reduce current impacts of AgVet chemical market failure. This will facilitate cross industry prioritisation and investment for improved access to uses of AgVet chemicals. The potential system will be negotiated between the Department of Agriculture, state and territory government departments, registrants and industry, and is expected to be managed with oversight by cross-industry RDCs resulting in:

- Improved priority setting and cross industry collaboration
- Achieving agricultural industry and commercial co-investment in data generation supported through initial government incentive.
- Achieving cost savings through cross industry efficiencies and national and international collaboration and co-investment
- A sustainable program that is supported by all stakeholders

It is planned that if the forum is successful, signed agreement for continued participation in the collaborative system will be achieved including at least four plant and animal industry RDCs.

AgVet Forum membership - It is intended that the AgVet forum is open to all industry stakeholders that have a need for the use of agricultural chemicals and veterinary medicines or contribute towards the regulation, investment or commercialisation of these products. While it is recognised that this could result in a large number of stakeholders, it is essential that the program deliver the long term strategic needs of all industries.

Following discussion of the desktop review of AgVet investment and pre-workshop stakeholder consultation, the AgVet prioritisation workshop held in April 2014 delivered through RIRDC Project PRJ-009454 concluded that, prioritisation starts at the commodity/industry level and each industry should be responsible for delivering this and commit to making some investment in delivering outcomes. Prioritisation should initially be based within each commodity, on pest and then product. Cross industry project prioritisation should then consider common pest and product needs for synergies, cost savings and increased scale of use. It was agreed by participants that outcomes should be focused on getting chemical minor use outcomes onto label, rather than using the permit program. AgVet prioritisation should however consider both new patented actives as well as generics. It is recognised however that greater focus on new, patented actives, will increase opportunity for

commercial registrant co-investment and lead to a broader number of uses and crops for these products especially when combined at the time of global development.

An AgVet prioritisation framework that addresses and manages real or perceived risks to industry, registrants and permit holders is required. It has been suggested that separate prioritisation between plants and animals should be considered. A consistent prioritisation framework should however be applied across all industries.

There are clearly some potential risks to agricultural industry if the market failure aspects of a collaborative program are not addressed. Market failure could in fact be made worse if the incentive for commercial investment is not understood, whether that be based on market scale, return on investment, regulatory challenges or investment risk. The same investment market failure risks could be applied for industry or RDC AgVet investment if the scale of benefit or impact is unknown or if there is limited intelligence of future industry needs. There is considerable concern from industry that the potential for investment from elsewhere ie via government or RDC programs itself creates an expectation for someone else to pay and contributes to market failure. Industry has clearly indicated that there needs to be a discussion around both regulatory commercial investment incentive to effectively support a program of industry investment. The department has indicated that incentive considerations and other potential reforms will be brought to the AgVet forum for stakeholder discussion.

It is clear that if there is sufficient information available on potential AgVet need and benefit and these priorities are clearly communicated, then the transparency of real market failure where it occurs is clear. If the benefits can also be more clearly attributed then the dialogue around which stakeholder pays and discussion around co-investment models can be approached more sensibly.

2.5 The need for AgVet industry access indicators and performance measures

In review of the successful programs that have been conducted over many years, both in Australia and overseas, the benefits of an effective minor use system are clearly evident. Programs to address investment market failure to deliver producers access to the best available AgVet technologies are critical and provide significant return on investment. The IR-4 Project and associated programs contribute US\$7.3 billion to annual gross US domestic product. There is an increasing level of global investment and interest in these minor use programs and an increasing momentum in international partnership in delivering joint global review programs. The precedence of successful collaborative cross industry approaches especially in the USA and Canada point to broad benefits, not only to industry production and sustainability, but to the broader community and economy as a whole. With an increasing global commitment by many governments to co-investment through appropriations to cross industry minor use programs, Australian industries should in the very least, explore what the potential benefits of similar approaches may deliver.

The review of AgVet prioritisation and investment programs³ identified benefits of a coordinated approach, including cross industry collaboration potentially including:

- Cost savings and efficiency in delivery of projects
- Improved identification of a broad number of cross-industry needs and efficiency in demonstrating benefit
- Improved export market access opportunities through establishment of cross-regional/international MRLs
- Opportunity to share underlying costs of managing permits

- Ability to demonstrate optimal value for investment of government appropriations.
- The challenges facing all programs whether collaborative or individual potentially are:
- Ensuring objectivity in prioritisation
- Having a broad number of objectives that address production, market and future risks
- Avoiding the ‘squeaky wheel’
- Have transparent systems to identify when market failure is real
- Demonstrating community value for government co-contribution to RDC investment.

Measures of benefit-cost, improvement in productivity and multi-factor productivity and return on investment based on net present value will be required. It is recognised that industry priorities will always be greater than the investment dollars available. Consensus from the workshop concluded that economic ranking of projects is important, but it must be transparent and simple.

The workshop participants gave clear consensus on the need for an assessment of ‘registerability’.

While it was agreed that outcomes should be focused on getting industry AgVet needs on label, it was also recognised that there will be a continued need for a permit program, particularly to support emergency permits. A new cross industry model to manage the real or perceived risks of holding these permits is required and options should be discussed further by industry.

Further cross-agricultural industry discussion is required on investment to deliver options for delivery of AgVet technology access. Significant efficiency gains and costs savings through a collaborative AgVet system leading to productivity gains are potentially possible. Different stakeholders do however require different economic performance criteria.

Based on the cross industry workshop outcomes, there is a strong rationale for objectivity in AgVet prioritisation and consistency of criteria for cross industry prioritisation. Government and industry priorities should be a continuous dialogue, particularly through joint government investment in RDCs. Based on the stakeholder dialogue, options should include:

- Profitability and productivity benefit
- Market access benefit
- Industry growth potential
- Resistance and sustainability benefit
- OH&S and environment benefit
- Registerability ranking options based on market requirements, MRL risks, efficacy and cost effective use by producers.

If industries are to successfully collaborate in a cross industry AgVet system, then consensus on the benchmarks, consistent assessment and prioritisation methodology and program KPIs must be agreed. Targets and KPIs for the options above would potentially be a useful starting point and should be SMART, ie specific, measurable, achievable, relevant and timely. KPIs for some of these measures have been worked through in competitors programs in North America. There is considerable opportunity to also learn from their experience in delivery of broader community benefits.

2.6 Getting the AgVet Forum input right – Industry governance and operation options

Through consultation with peak industry bodies and their RDCs, there is clearly a desire for any AgVet collaboration to be managed by industry rather than government. As an outcome of the RIRDC Cross agricultural industry AgVet investment prioritisation options workshop, it is clear that there is cross industry commitment to explore the opportunity and benefits of cross industry AgVet collaboration. Further cross-agricultural industry discussion is required on investment to deliver options for delivery of improved AgVet technology access to drive agricultural productivity. There is significant support from all industry stakeholders at the workshop to continue discussion on exploring such a program and a particular focus that this should be led by industries through collaboration of their respective RDCs. Significant efficiency gains and costs savings leading to productivity gains are potentially possible.

Key factors delivering successful collaboration identified include:

- Investment in the right structures, governance and infrastructure
- Joint management of performance and impact measurement
- Collaborate for the long term, focussing on strategic needs.

To deliver effective outcomes from a cross-agricultural industry program the following industry identified needs should be recognised:

- Effective communication between all cross industry stakeholders remains one of the greatest challenges to delivery of an effective program resolving AgVet technology access issues.
- Further discussion is required on methods to provide open and transparent communication, including identification of where investment market failure is real, to build a culture of effective collaboration.
- Need a mechanism for facilitated ‘horstrading’ behind closed doors - dealing with commercial in confidence issues which have impacts and outcomes for industry - talking about needs at commodity and related commodity level provides increased opportunity for this discussion
- The output from a cross industry prioritisation framework, which may be developed through a select expert/representative group, requires validation by the industry peak bodies and relevant RDC.

There are several models of how the AgVet Forum governance could be managed going forward;

1. Operation by open AgVet Forum consensus through the facilitated RIRDC project PRJ-009981 - The discussion agenda would be set by recommendation of RIRDC, the project facilitator and the Department of Agriculture - This could be an inefficient way to approach discussion and engagement.
2. Establishment of an AgVet Forum advisory committee comprising of nominee representative industry stakeholders to recommend key forum agenda issues for discussion and recommendation at the open AgVet Forums.
3. Establishment of working groups around each of the AgVet Forum agenda issues, including input into the development of discussion and options papers – This could be an efficient way

of developing concepts for wider discussion – working groups would be built around key skills and experience of nominee representatives and could vary based on the issue.

There is a need for industry and stakeholder dialogue on how to develop effective communication programs for negotiation, feedback and resolving differences in a culture of open and transparent collaboration. There are a number of options for communication within the AgVet Forum including;

- Negotiation, feedback and resolving differences in a culture of open and transparent collaboration will need to be managed within Forum meetings.
- Email based communications managed by RIRDC or Crop Protection Australia including distribution of discussion papers and agendas
- Email/weblink based outcomes from a subscriber based system managed by RIRDC including distribution of discussion papers and agenda – noting this will provide broad and transparent access to all industry and wider community stakeholders
- Meeting, phone and email access to the RIRDC AgVet forum facilitator
- Circulation of AgVet Forum sub-issue working group meetings and outcome documents.

The importance of a culture of collaboration, commercial engagement and producer patience in the delivery of outcomes will be critical for the success of the AgVet Forum. While the mechanics and frameworks of co-investment and prioritisation can be negotiated, agreed and developed across industries, the greatest challenge relates to open and transparent communication between stakeholders and ensuring that this is well resourced.

2.7 Next steps for the AgVet Forum.....

Through a GRDC and RIRDC funded workshop facilitated by Plant Health Australia (PHA) in Canberra in April 2012⁴, consensus of participants from plant industries currently engaged in minor use programs identified the potential key features of a new minor use system in Australia. These potential features include:

- A new Minor Use system should deliver a world class assessment system that contributes to the efficient production and delivery of safe food and fibre through the supply chain, provides appropriate protection of the environment and has the confidence of all stakeholders.
- Industry could work more co-operatively between sectors to determine cross-sectoral opportunities to better predict future needs and the research required. Costs and benefits would need to be demonstrated to decide the scope of collaboration and crop groupings (GRDC has already conducted a basic study of benefits).
- The system should be transparent, easily understood and provide incentives and rewards for registration of minor uses. It should be affordable to users, making it attractive to invest in registration and unattractive not to. The system should make it easy to move from permits to label registrations.
- The system should be user-driven, responsive and timely with a prioritisation process and ability to fast-track if necessary. It should also be flexible to be able to accommodate different crops, pests and use patterns, including new technologies and crops.

⁴ Woods, N, (2012). Workshop on pesticide minor use, 3 April 2012: Report on outcomes. Plant Health Australia

- There should be co-investment from all industry, registrants and governments. Communication channels should be clearly defined.
- The new system should make access to permits quicker because industry co-operation and co-ordination should result in longer-term planning to predict future uses and the use of one registration for multiple uses. The new system should support:
 - a diversity of responsible / sustainable production
 - biosecurity – the preparedness for incursions and ability to manage emergencies
 - appropriate environment protection, including the management of environmental weeds
 - industry initiatives, such as IPM and resistance management.
- The system should be enhanced by international connectivity and co-ordination. Regulatory approvals based on risk identification and management, legal use, and validated by residue testing, should facilitate market access and improve international competitiveness.

The PHA facilitated workshop in 2012 unanimously supported a proposal to work collaboratively together to progress the development of a revised and enhanced minor use system. It was proposed that this could be achieved through the *establishment of a formal cross-sector working group involving government and industry representatives*. It has taken 2.5 years for these actions to progress to what is now the AgVet collaboration forum.

It is planned that through this AgVet Forum that industry collaboratively delivers deliver the following outcomes:

- Demonstrate the value of collaboration and cost savings from investment through the collaborative framework to delivering increased access to AgVet chemicals to Australian agriculture
- Deliver a new formal system for collaborative cross industry AgVet investment, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet chemical needs and reducing current impacts of market failure. This system will:
 - Promote information sharing and co-investment opportunities to better use resources for supporting applications to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for AgVet chemical uses.
 - Inform chemical companies of potential market demand to assist in their decisions to register Australian uses.
 - Provide a forum for producers and the chemical industry to interact with the department and the APVMA to discuss the most effective and efficient methods of improving access to chemicals. These may include combining the investment efforts of a few grower groups to the benefit of the wider group.

The purpose of the AgVet Forum (see agenda in Appendices 2-4) is for industry to have the ability to drive the next steps in establishing a new system to support minor use needs and investment in Australian agriculture. The success of this will be completely dependent on industry engagement, support and commitment in working through a number of challenging issues. While government has indicated that this could potentially be supported through additional regulatory incentives, consideration of overseas data and regulatory decisions and other programs to incentivise commercial investment, most importantly this will provide a forum for producers and the chemical industry to interact with the Department of Agriculture and the APVMA to discuss the most effective and efficient methods of improving access to chemicals.

Establishing the AgVet Collaborative Forum agenda issues for discussion and delivery of background and options papers for industry consideration and recommendation are a key component of delivering consensus outcomes for future delivery of benefits to industry. The following chapters provide detail on the consensus from the Forum on each on these issues and agreed collaborative approach.

3. AgVet Collaborative Forum Terms of Reference and Operation

The following proposed AgVet Collaborative Forum Terms of Reference and Operation was agreed by consensus by Forum stakeholders on 26 February 2015 and formed the foundational approach to moving towards investing in the establishment of a collaborative program.

3.1 Purpose of the AgVet Collaborative Forum

The Forum stakeholders confirmed the Department of Agriculture and Waters key purpose and outcomes including; The AgVet Collaborative Forum will deliver options for a new system for collaborative cross industry AgVet investment, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet chemical needs and reducing current impacts of market failure. This system will:

- Promote information sharing and co-investment opportunities to better use resources for supporting applications to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for AgVet chemical uses.
- Inform chemical companies of potential market demand to assist in their decisions to register Australian uses.
- Provide a forum for producers and the chemical industry to interact with the department and the APVMA to discuss the most effective and efficient methods of improving access to chemicals. These may include combining the investment efforts of a few grower groups to the benefit of the wider group.
- Support a framework for government conditional co-investment with industry and registrants.
- Demonstrate the potential value of collaboration and cost savings from investment through the collaborative framework to delivering increased access to AgVet chemicals to Australian agriculture.

3.2 Principles that underpin the AgVet Collaborative Forum operations and processes

In dealing with industry prioritisation and investment, The AgVet Collaborative Forum:

1. Must deliver appropriate investment addressing minor use chemicals and veterinary medicines needs where investment market failure appears to have occurred in a cooperative, efficient, timely and fair manner;
2. Shall proceed with technical rigor addressing stewardship and resistance management risks through tests of registerability; and
3. Shall act in accordance with its confidentiality and privacy obligations.

3.3 Scope of the Terms of Reference

It is intended that the AgVet forum is open to all industry stakeholders that have a need for the use of agricultural chemicals and veterinary medicines or contribute towards the regulation, investment or

commercialisation of these products in the delivery of agricultural production. While it is recognised that this could result in a large number of stakeholders, it is essential that the program deliver the long term strategic needs of all industries.

3.4 AgVet Collaborative Forum Interim Steering Committee Structure

An interim structure of the AgVet Collaborative Forum has been established to allow nominee AgVet stakeholders including agriculture industry users, investors, manufacturers and registrants to develop an operational and self-sustaining business model

This interim structure for the AgVet Collaborative Forum detailed in figure 3 is intended to be in place until such a time an agreed organisation and functional structure is operational. The role of the AgVet Collaborative Forum Interim Steering Committee is to provide advice on the AgVet Forum agenda and initial feedback on proposed discussion papers before tabling and discussion with the broader forum. The Steering committee will also provide advice on the establishment of any working groups as required and nominate participants on these. It is proposed the role of the AgVet Collaborative Forum Interim Steering Committee will cease when an AgVet Collaborative Forum Advisory Board is established.

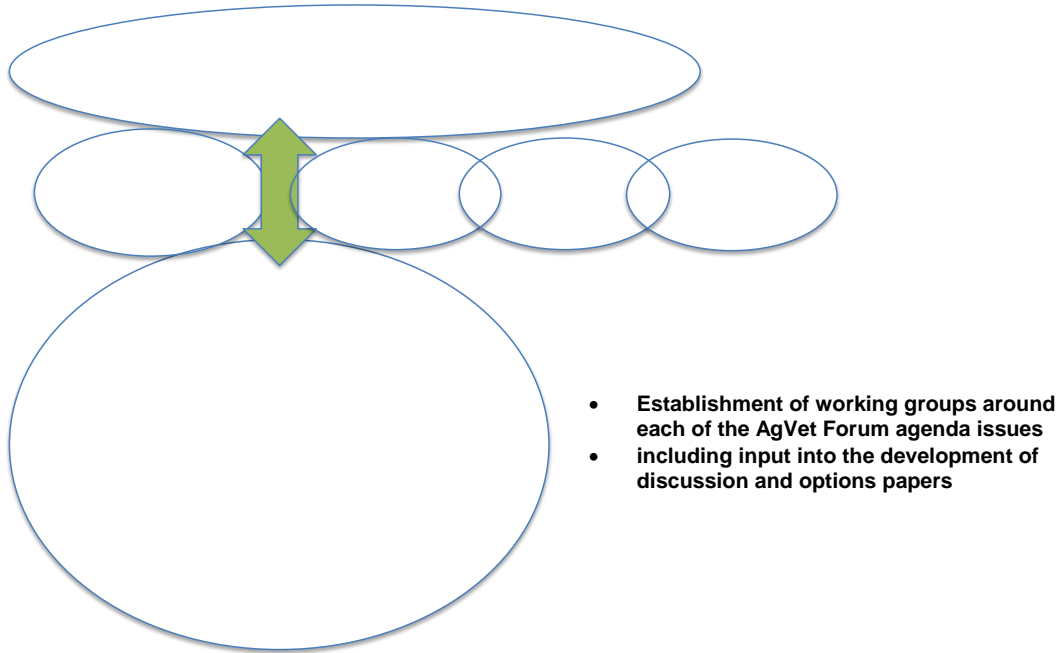


Figure 3. An Interim AgVet Collaborative Forum framework to provide advice for establishment of a long-term governance and operational structure

3.5 Proposed AgVet Collaborative Forum governance and operation

A proposed model for governance, implementation and operation of the AgVet Collaborative Forum from June 2015 is detailed in figure 4. It is proposed that a future adopted Forum governance and operations model would be passed for implementation under the terms of reference detailed by simple majority vote of more than 60% of stakeholder at a general Forum meeting. The Advisory Board would be responsible to the AgVet Collaborative Forum as shareholders.

The structure could operate either as a joint venture or as a not for profit incorporated company. If the later were to be determined then the AgVet Collaborative Forum Advisory Board would form the

basis of the incorporated entity and all other operational components would be contracted to it. The operational components could be one organisation or up to 4 separate individuals/organisations selected through limited/open tender based on the most suitable skillsets available. Benefits of a not for profit incorporated entity include;

- More identifiable contractual obligation with government, RDC and commercial co-investment
- Organisational structure will be more attractive for suitable contract candidates
- Indemnity insurance will be more compatible with governance arrangements of a traditional not-for profit incorporated structure

A joint venture arrangement will potentially be an easier operational structure to put in place and potentially be a cheaper model to implement and operate, building on the RDC capability already available.

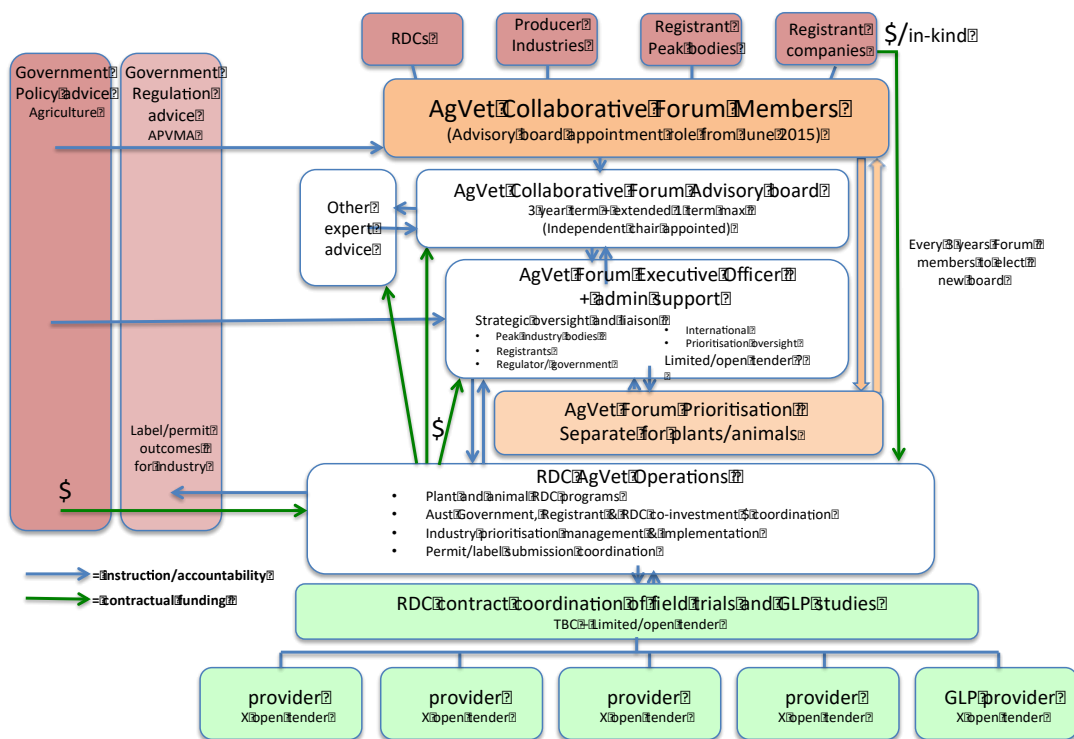


Figure 4. A proposed model for joint investment, management and operational structure through the AgVet Collaborative Forum

3.6 Appointment of AgVet Collaborative Form Advisory Board

It is proposed that the Appointment of up to 7 Forum Advisory Board members will be determined through nomination of AgVet Collaborative Forum Members and must include at least;

- 2 Plant industry nominees
- 1 Animal industry nominee
- 2 Registrant peak body nominees
- 1 Plant RDC and 1 Animal RDC nominee.

It is recommended that the board have a functional membership providing 7 votes. It is recommended that the advisory board appointed independent chair is non-voting. Voting of board members for each nominated position will be based on majority vote of each relevant stakeholder group.

3.7 Proposed powers and duties of the AgVet Collaborative Forum Advisory Board

The AgVet Collaborative Forum Advisory Board have the power to appoint the following contractors;

- Independent Advisory Board Chair
- Executive Officer and Administrative support
- External expert advice as required.

The AgVet Collaborative Forum Advisory Board has the authority to delegate the investment of funds including a trustee to hold funds to appoint the contractors above in the delivery of the AgVet Collaborative Forum including prioritisation, meetings, publications and communication. The Advisory board would provide advice to government and the RDCs on investment options based on cross industry collaborative AgVet priorities for RDCs to then contract field trials and GLP studies to deliver new AgVet data for label and permit registration.

3.8 AgVet Collaborative Forum Prioritisation

Prioritisation will start at the commodity/industry level and each relevant industry responsible for delivering and annually revised list of priorities including commitment to making some investment in delivering outcomes. Prioritisation will be based within each commodity, on pest and then product. Cross industry project prioritisation will then consider common pest and product needs for synergies, cost savings and increased scale of use.

Prioritisation outcomes will be focused on delivering minor use outcomes onto label in preference to the permit program. AgVet prioritisation will consider both new patented actives as well as generic actives. Separate prioritisation between plants and animals will occur. A consistent prioritisation framework will be applied across all industries. Any government investment will be conditional on both industry and commercial co-investment (Figure 5).

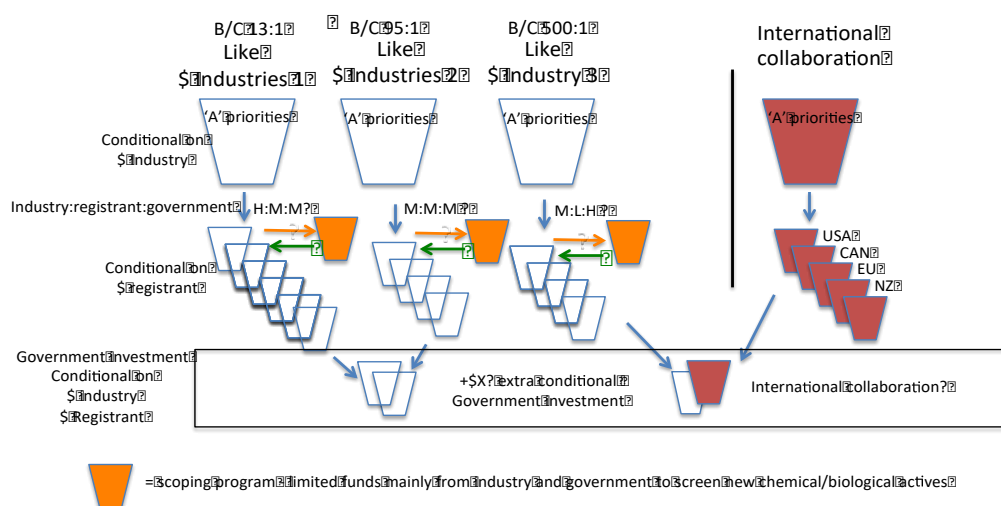


Figure 5. Co-investment model for the AgVet Collaborative Forum including separate plant and animal industry prioritisation.

3.9 Provision of reports

The AgVet Collaborative Forum will hold all data developed through the trial program or submitted to the Forum through collaboration to be considered as commercial in confidence until such a time that its status is considered a public document at the determination of guidelines approved the AgVet Collaborative Forum Advisory Board.

3.10 AgVet Forum Communication

Negotiation, feedback and resolving differences within Forum meetings will be managed in a culture of open and transparent collaboration through the independent Forum Chair. Email based communications including distribution of discussion papers and agendas and outcome documents will be managed the AgVet Collaborative Forum Executive at the direction of the Forum Advisory board. Communication to wider community stakeholders will be delivered through the direction of the AgVet Collaborative Forum Independent Chair.

3.11 Publication of data and reports

The AgVet Collaborative Forum will provide regular updated reports of operational activities and all financial reports on an email/weblink based vetted subscriber system with password protection including distribution of discussion papers and agendas and prioritisation outcomes to all stakeholders making financial or in-kind investment in the program.

3.12 Insurances

Members of the AgVet Collaborative Forum Advisory Board will at all times be covered by professional risk indemnity insurance or directors and officers liability insurance if the Forum becomes a not for profit incorporated company, funded by the AgVet Collaborative Forum program.

3.13 Changes to Terms of Reference

Changes to the Terms of Reference will require the Forum Advisory Board to move an amendment simple majority vote of greater than 60% of stakeholders present at an annual general meeting with 30 days prior written notice to the terms of reference.

3.14 Terms of Reference and Operations review

The AgVet Collaborative Forum Terms of Reference and Operation will be reviewed within 12 months of implementation.

4. AgVet Collaborative Forum operational prioritisation system

The following proposed AgVet Collaborative Forum operational prioritisation system was agreed by consensus by Forum stakeholders on 26 February 2015 and formed the foundational approach to moving towards investing in the establishment of a collaborative program.

4.1 Basis for the proposed AgVet Collaborative Forum minor use operational system

The proposed AgVet Collaborative Forum minor use operational system detailed in this paper is based on delivery under the consensus agreed governance detailed in chapter 3.

In dealing with industry prioritisation and investment, The AgVet Collaborative Forum has agreed through consensus that it:

- Must deliver appropriate investment addressing minor use chemicals and veterinary medicines needs where investment market failure appears to have occurred in a cooperative, efficient, timely and fair manner;
- Shall proceed with technical rigor addressing stewardship and resistance management risks through tests of registerability; and
- Shall act in accordance with its confidentiality and privacy obligations.

4.2 Acknowledgement and reference to existing successful IR-4 and Canadian programs

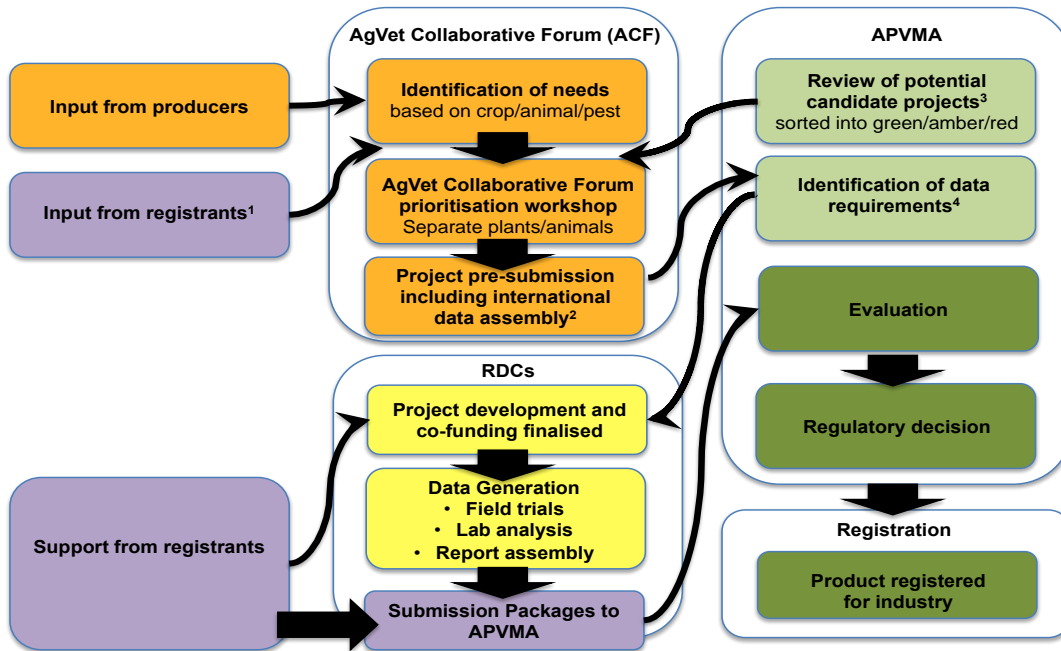
The proposed AgVet Collaborative Forum minor use operational system detailed in this paper is based on the delivery models combining both aspects of the North American IR-4 Program and Canadian Minor Use Programs. Particular reference and acknowledgement should be given to the Canadian Minor Use Pesticides Workshop Prioritisation Process detailed in documents supplied by Dr Manjeet Sethi Executive Director and Ms Shirley Archambault National and International Relations Officer Pest Management Centre Agriculture and Agri-Food Canada. Additional options detailed in this paper are currently used in the IR-4 Program supplied through discussions with the executive Dr Jerry Barron and Dr Dan Kunkel.

4.3 Proposed AgVet Collaborative Forum Workshop Prioritisation Process

A proposed model for how the AgVet Collaborative Forum and Workshop Prioritisation Process will interact with industry, registrants and regulators in the delivery of new AgVet technology registration is detailed in figure 6.

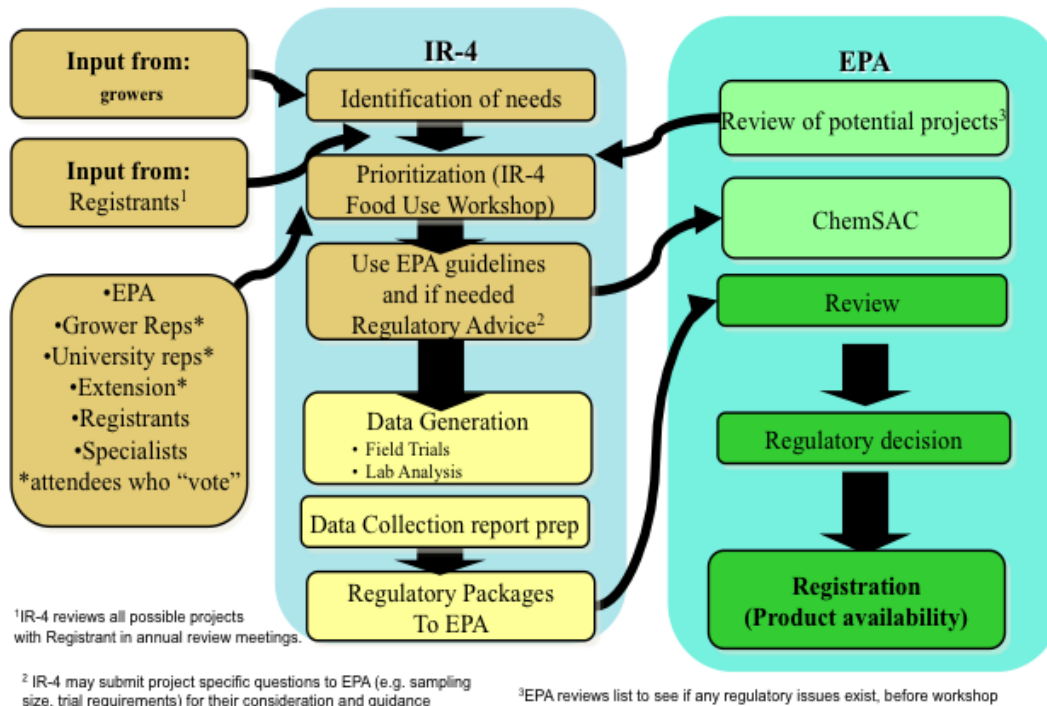
The AgVet Collaborative Forum (ACF) is essentially the first step in the process of delivering. Success of the program will be conditional on industry support and RDC investment with additional in-kind/cash investment by registrants and most importantly willingness to support the label submission process. The proposed operational model compares similarly with the USA IR-4 model detailed figure 7. The prioritisation workshop process is however modelled on the Canadian minor use program approach, which prioritises around crop and pest initially broken down into invertebrate

pest, disease and weeds, rather than around crop by chemical product prioritisation, which is the IR-4 approach.



¹ ACF reviews all possible projects with registrants in annual review meetings
² ACF may submit project specific questions to APVMA for their consideration and guidance
³ APVMA reviews lists to see if any regulatory issues exist before workshop
⁴ APVMA provides guidance on the potential acceptance of international data sets

Figure 6. Proposed model for AgVet Collaborative Forum and Workshop Prioritisation Process interaction with industry, registrants and regulators in the delivery of new AgVet product registration



¹ IR-4 reviews all possible projects with Registrant in annual review meetings.
² IR-4 may submit project specific questions to EPA (e.g. sampling size, trial requirements) for their consideration and guidance
³ EPA reviews list to see if any regulatory issues exist, before workshop

Figure 7. IR-4 program process

4.4 Proposal for a pilot operational process and review in 2015

It is proposed that the operational process described below is adopted for the first pilot of the AgVet Collaborative Forum under the governance of the AgVet Collaborative Forum Advisory Board. It is anticipated that both will be in place and operational by late May/early June 2015. Following this pilot Forum. It is proposed that there is a review of the process overseen by the Advisory Board by October 2015 and further amendments are recommended to the Forum and implemented for 2016.

4.5 Proposed AgVet Collaborative Forum and Workshop Prioritisation Process

The proposed AgVet Collaborative Forum and workshop prioritisation process is potentially delivered in 3 phases;

- Phase 1 - Identification of needs - based on crop/animal/pest
- Phase 2 - AgVet Collaborative Forum prioritisation workshop - separate plants/animals
- Phase 3 - Project pre-submission including international data assembly

Proposed steps in each phase are described below

Phase 1 - Identification of needs - based on crop/animal/pest

1. AgVet Collaborative Forum Coordinator (ACFC) and support staff through discussions with industry producer groups have assembled identified top priorities by crop/animal and pest. Priorities are ranked into at least top 5 and ideally top 10 by the respective industry.
2. These priorities are listed in an e-book/excel file by industry/crop/animal, discipline (entomology, pathology, weed/growth/regulators). Each discipline is divided into two sections; the top four priorities identified for each crop/animal/pest combination for each industry are in the first section and the remaining priorities are located in the second section.
[L]
[SEP]
3. Once the e-book/excel file industry priorities list is completed and published no later than February in any given year, the industry pest priorities ranking cannot be changed within that annual years prioritisation cycle. [L]
[SEP]
4. AgVet Collaborative Forum Coordinator (ACFC) and support staff will have individual discussions with registrant companies to identify AgVet technology solutions to industry priorities. With the support of the registrant company, viable options will be flagged for public industry discussions. Note however the chemical name will remain hidden in priority lists until the last round of prioritisation discussions.
5. AgVet Collaborative Forum Coordinator (ACFC) and support staff will forward a recommended list of issues and AgVet solutions to the APVMA for review of potential candidate projects prior to further industry consultation. Projects will be marked green/amber/red based on regulator feedback. The relevant registrant will meet jointly with the ACFC and APVMA to discuss red and amber projects. Red projects will not be considered in the final priority lists. Amber projects will be included in initial prioritisation.

The regulator will provide industry feedback on amber and red project concerns at the prioritisation workshop when chemical names are un-hidden.

6. A final e-book/excel file of potential candidate project priorities is distributed to industry stakeholders by email 1 month prior to the prioritisation workshop.

Phase 2 - AgVet Collaborative Forum prioritisation workshop

7. Separate plant and animal industry prioritisation meetings will be held between May-June annually with like industries assembled together for cross industry prioritisation at the determination of the Advisory Board.
8. Only the top five pest priorities identified in the first section of each discipline will be displayed and reviewed at the prioritisation meeting by discipline. The remaining industry pest priorities identified are included for reference only and will not be considered for further prioritisation. ^[L]_[SEP]
9. The industry ranking and rationales will be used, along with input from the participants in the room, to discuss the merits of each proposal for national priority ranking. Ranking will be as follows;
 - ‘A’ priority - Problem with solution and registrant support = Industry commitment for investment in a project – All Go! ‘A’ vote identifies that this is a high priority for industry and there is a commitment to:
 - invest \$
 - Invest time in working with relevant RDC in developing a project
 - Invest time in negotiation with registrants
 - ‘A’ projects must have registrant support
 - ‘P’ priority - Problem with solution BUT...no registrant support
 - ‘P’ or Permit projects are an option if there is no registrant support
 - Most likely a generic chemical
 - Industry/RDC will bear most of the cost
 - B’ priority - Problem with solution but registrant support unclear = Industry commitment for formal discussions with a registrant. ‘B’ vote identifies that this is a high priority for industry and there is a commitment to:
 - invest \$
 - Invest time in discussion with registrants
 - Registrants strongly encouraged to identify if there is commitment for support at this point
 - An outcome would be:
 - no project yet, but planned meetings with registrants would occur over the next 12 months

- Limited trial work to answer key questions eg residue risks
 - ‘C’ priority - Problem with no known solution = Industry request for registrant help
 - □ ‘C’ vote identifies that this is a priority for industry and there is a commitment to invest \$
 - Registrants strongly encouraged to identify if a potential solution exists – Note there is no commitment for support at this point
 - An outcome is that an efficacy trial may need to be initiated
10. Each pest priority will be ranked nationally with the final decision made by consensus.
 11. All participants will respect the rights of others (i.e., no one will dominate or take undue time in the process). ^[1]_{SEP}
 12. If participants are in dispute on a decision and consensus cannot be reached, a nominated industry representative with concerns can use up to 2 challenges (similar to that in tennis line calls) over the course of a prioritisation workshop to have a science-based debate around the merits of the project.
 13. To facilitate consensus and a spirit of collaboration if a nominated industry representative changes and already agreed “A” priority to a “B” priority, that industry will get the first pick of an “A” priority in the following years prioritisation (similar to that of draft pick trades in football)
 14. Tank mix options should not be suggested as each product tested is one project. If a tank mix is selected, then more than one priority will be used. ^[1]_{SEP}
 15. For each pest/solution combination, the commodity group representative(s) with the pesticide company representative(s), the APVMA, and ACFC staff will be asked for input to assist in reaching a final determination. ^[1]_{SEP}
 16. Whenever possible, potential joint registration candidate products with IR-4 and Canadian Minor Use Program should be chosen, all other factors being equal. ^[1]_{SEP}
 17. The pest priorities identified as As, Bs, or Cs or Ps will all be considered by the ACF as potential selections for IR-4/Canadian MUP joint projects, technology gap projects and other joint projects. ^[1]_{SEP}
 18. Wherever possible, regional and special crop needs will be considered, as well as national coverage and net benefit to Australian agriculture, in reaching final decisions on researchable projects. ^[1]_{SEP}
 19. Final decisions for each entry will be displayed to let all participants know the outcome.
 20. Participants will recognise the importance of keeping the process moving forward at ALL times
 21. A final list of national project priorities will be published in an e-book and emailed to industry and registrant stakeholders

Phase 3 - Project pre-submission including international data assembly

22. The final list of priorities will be shared with both the IR-4 and CAN MUP for potential alignment of research data needs and data sharing under an MOU.
23. Outcomes of international collaboration discussions will be incorporated in to the final priority list, which is forwarded to the APVMA for further review.
24. The APVMA provides advice to the RDCs on data requirements based on the review of priority lists and international data available.

Roles of Minor Use Priority Setting Meeting Participants producers/industry representatives

Prior to the AgVet Collaborative Forum prioritisation workshop, producers or their representatives are expected to:

- interact with the AgVet Collaborative Forum Staff to ensure that the most important pest problems are identified;
- to network with the crop/pest specialists to determine the best possible corrective measures, including identifying the preferred use pattern (keeping pesticide resistant managements strategies in mind);
- network with registrants to determine their willingness to support the use of their pesticide to control the pest of concern.

During the AgVet Collaborative Forum prioritisation workshop, producers or their representatives are expected to:

- interact with their respective RDC representative, relative to the selection of priorities;
- actively participate in the identification and selection the year's top priorities;
- network with crop specialist and registrants to discuss potential solutions (including new technology).

After the AgVet Collaborative Forum prioritisation workshop, producers or their representatives are expected to:

- Draft a letter of support for the project, detailing a description of the pest problem and the preferred use pattern;
- Work with their commodity associations to recommend when the pest should be controlled according to pest biology, crop growth stage, thresholds, etc.
- Work with the relevant RDC, registrants and APVMA staff to facilitate the successful completion of the project/priority;
- Responding to APVMA inquiries in a timely manner.

Registrant representatives:

Prior to the AgVet Collaborative Forum prioritisation workshop, the registrants are expected to:

- review the top 4 pest priorities for each crop, in each industry, in order to confirm support;
- communicate with grower reps, in order to confirm support;
- During the AgVet Collaborative Forum prioritisation workshop, the registrants are expected to:
 - registrants who have agreed to co-invest or are the primary registrant should be available for grower consultations during the meeting (i.e., at specified times and locations and during the breaks);
 - provide input if conflict resolution is required

After the AgVet Collaborative Forum prioritisation workshop, the registrants involved with the selected priorities are expected to:

- to provide their letter of support and label when applicable to the APVMA within the timeframe established;
- Work with the relevant RDC and APVMA to facilitate the successful completion of the project/priority.

RDC representatives:

Prior to AgVet Collaborative Forum prioritisation workshop, the RDC reps are expected to:

- meet with Grower Reps to identify and review their top pest/crop priorities for the year
- prepare the list of priorities according to the agreed format and forward that list to the AgVet Collaborative Forum Staff by the end of January.

During AgVet Collaborative Forum prioritisation workshop, the RDC reps are expected to:

- work with the grower reps to identify the year's top priorities;
- network with crop specialist and registrants to discuss potential solutions (including new technology);
- assist the AgVet Collaborative Forum staff in resolving any conflicts that may arise.
- After the AgVet Collaborative Forum prioritisation workshop, the RDC reps are expected to:
 - follow-up with grower representatives from their industry if and when appropriate
 - work with the grower representatives, registrants, and AgVet Collaborative Forum staff to facilitate the successful development of the project/priority investment contracts;
 - respond to AgVet Collaborative Forum staff inquiries in a timely manner.

APVMA representatives:

1. Prior to the AgVet Collaborative Forum prioritisation workshop, staff at the APVMA is expected to review the list of industry priorities and proposed solutions in order to advise AgVet Collaborative Forum staff, prior to the meeting, of potential problems.

2. During the AgVet Collaborative Forum prioritisation workshop, staff at the APVMA is expected to provide ongoing regulatory advice and identify any potential problems. [SEP]
3. After the AgVet Collaborative Forum prioritisation workshop, staff at the APVMA are expected to work closely with ACF staff to facilitate the Minor Use Program. [SEP]

AgVet Collaborative Forum (ACF) staff:

Prior to the AgVet Collaborative Forum prioritisation workshop, staff of the ACF are expected to:

- review the list of industry priorities and proposed solutions in order to [SEP] identify potential overlaps with previous projects or overseas projects; [SEP]
- respond to all producer rep, registrant, and APVMA inquiries in a timely [SEP] manner; [SEP]
- know the status of the on-going projects. [SEP]

During the AgVet Collaborative Forum prioritisation workshop, staff of the ACF are expected to:

- provide ongoing advice/information to grower reps, registrants, and RDCs;
- know the status of the on-going projects; [SEP]
- intervene and interact during the course of the discussion on projects listed on the books and during the prioritization process;
- participate in conflict resolution if required. [SEP]

3. After the AgVet Collaborative Forum prioritisation workshop, staff of the ACF is expected to:

- work closely with the producer reps, registrants, and APVMA to identify the pest use pattern for the crop/animal/pest/product priorities selected; [SEP]
- respond to all inquiries in a timely manner.

4.6 Post AgVet Collaborative Forum delivery of registration outcomes

Next steps for delivery of project development and co-funding by industry, government and registrants will be managed by the respective industry RDC as detailed in figure 1. Where projects are supported by one or more RDC, then the industry contributing the most significant component of the funding will take overall leadership responsibility. The relevant RDC will be responsible for contracting data generation including field trials and laboratory analysis. The RDC will also be responsible for liaison with the relevant registrant for report assembly for submission of data packages to the regulator APVMA.

4.7 AgVet Collaborative Forum prioritisation for gaps workshop process for 2016

Following significant discussion with both the plant and animal Industries AgVet Collaborative Forum Steering Committees, the 2016 Forum prioritisation for gaps process was modified from that used in 2015. There was significant interest from CropLife Australia registrants in the 2016 Forums with increased staff resources being provided to the 2016 Forum.

The AgVet Collaborative Forum workshop prioritisation process was delivered in 2 phases:

Phase 1 – Industry facilitation and identification of needs - based on crop/pest. Each industry sector was invited to submit its priorities through its RDC prior to the workshop

Phase 2 - AgVet Collaborative Forum prioritisation for gaps workshop – a 2016 workshop, run separately for plant industries plus a workshop was planned for animals but was unfortunately cancelled.

In discussions with RIRDC, AWI and Animal Medicines Australia, due to a lack of registrations for the planned Forum prioritisation for gaps workshop, it was agreed that registrant feedback for the industry pest priorities would be facilitated through one-on-one meetings with individual companies. This task was completed by mid July 2016 enabling this updated list to be also populated onto the RIRDC website as a revised file in mid August. The outcomes of this process were however communicated to participating animal industry RDCs by the 30 June 2016. While this change in plan was unfortunate, the re-worked process did enable revised animal industries priorities list to be finalised to support animal industry RDC eligibility for applications to the Department of Agriculture and water Resources AgVet grant process.

The inputs for the process include:

- A target number of ‘A’ projects nominated by the Department of Agriculture and Water Resources
- Industry priorities with at least the ‘top 5’ being identified

Preparation:

- All industries submit draft priority lists – Identify top 1-5 priorities based on animal/pest – potential solutions identified. Any registrant support is noted
- Plant and animal prioritisation will be run as a separate funded Forum.
- Industry/registrant discussions on identified issues prior to the workshop will be an advantage to those industries (Figure 8).

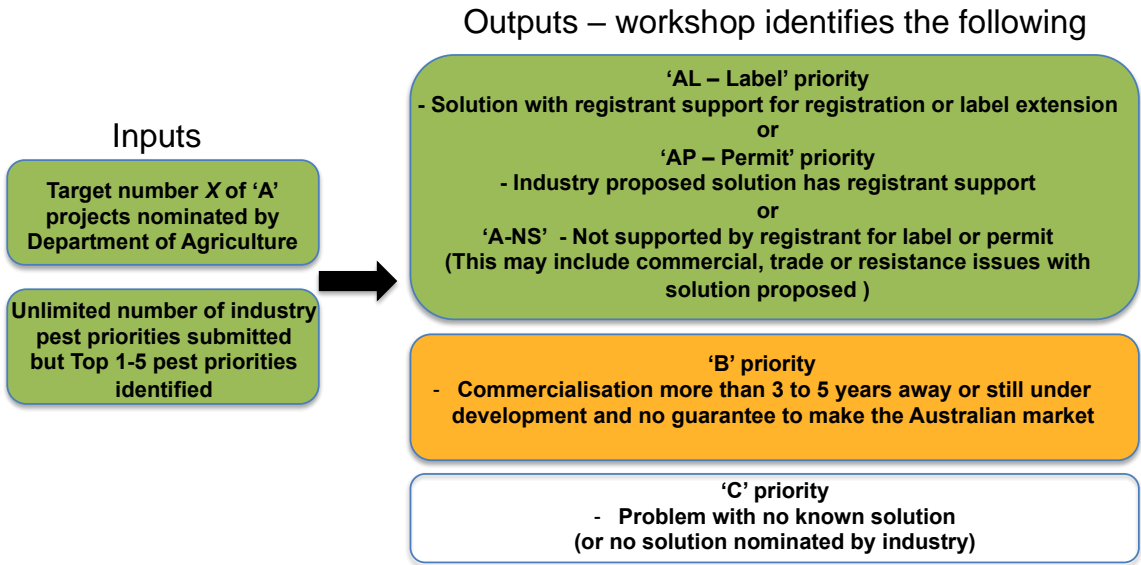


Figure 8. AgVet Collaborative Forum inputs and outputs for prioritisation

The plant industries Forum prioritisation for gaps workshop incorporated three key steps. Voting of ‘A-P’ or ‘A-L’ priorities by industries is a key step to identify the high priority needs. Interaction of industries with registrants during the workshop is an important component, which resulted in

registrants providing ‘in principle’ support for potential solutions for ‘A-P and A-L’ priorities, which can be developed into projects for investment. It is however recognised that industries which nominate for ‘A-P’ or permit projects, will likely result in industries bearing most of the project cost (Figure 9).

Although outside the scope of this Forum coordination project, the next steps for delivery of project development and co-funding by industry, government and registrants have been managed by the respective industry RDC as detailed in figure 10. Where projects are supported by one or more RDC, then the industry contributing the most significant component of the funding will take overall leadership responsibility. The relevant RDC is responsible for contracting data generation including field trials and laboratory analysis. The RDC is also responsible for liaison with the relevant registrant for report assembly for submission of data packages to the regulator APVMA.

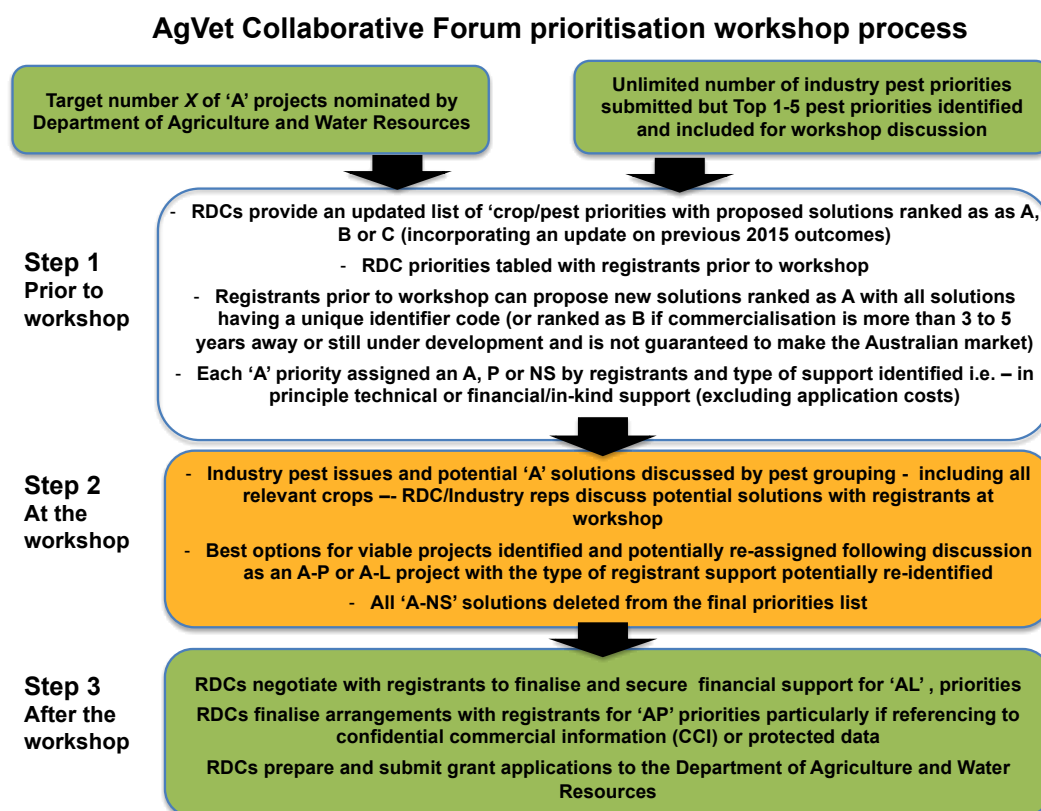


Figure 9. AgVet Collaborative Forum prioritisation workshop process

5. Options for international AgVet data collaboration for cross industry use

The following proposed options for international AgVet data collaboration for cross industry use were discussed with stakeholders and incorporated into AgVet Collaborative Forum planning.

5.1 International AgVet collaboration opportunities and benefits

The use of international AgVet data provides a number of opportunities for Australian agriculture. It should be recognised that Australian producers in general have access to less registered technologies than overseas competitors, particularly compared with North America. There are also some potential advantages to increased collaboration with New Zealand due to this countries proximity as a trading partner and also sharing the same food safety regulator. The scope for international collaboration with EU countries would appear to be more limited. There are a number of reasons for pursuing international AgVet data generation collaboration:

- Reduced timelines for Australian producers getting access to products sooner across a broader range of crops/animals
- Reduced costs in delivering new registered chemical products if based on agro-ecological co-equivalence and cost sharing of data generation
- Increased government and consumer confidence in regulatory decisions if there is bi-partisan agreement across a number of jurisdictions through global joint reviews
- Improved market access and acceptance of international residue data
- Maintaining an internationally competitive production capability through accessing new AgVet technologies at the same time.
- Ensuring that impacts of local, regional and national pesticide resistance do not impact more significantly compared with overseas competitors with greater options for pesticide resistance management for common pests with Australia
- Improved preparedness for managing exotic pest incursions

To access international data however there needs to be two-way bilateral benefits rather than a data grab by one country. Advantages of North America collaborating with Australia potentially include;

- Potential increase in the number of data points in a registration submission with an argument of broader opportunity of product use across a range of environments.
- Increased government and consumer confidence in regulatory decisions if there is bi-partisan agreement across a number of jurisdictions through global joint reviews
- acceptance of international residue data and Improved market access and potential expansion of the global market opportunity and business returns to the registrant for a new active
- A significant benefit would be at CODEX plus having MRLs in place in more countries particularly when trade is concerned.

It should be recognised that international collaboration does not guarantee outcomes for Australian producers, but is more likely to provide earlier access if successful.

5.2 Mechanisms to support international AgVet collaboration

There has been considerable discussion by the APVMA in potentially increasing acceptance and greater recognition of international data in regulatory assessment. The APVMA has in fact accepted the use of international data for some time, particularly in minor and emergency use permits. There is potential for greater use of international data in chemical label submission. It is clear that industry must deliver a clear scientific case for the use of international data based on independent agro-ecological co-equivalence studies. To more broadly justify a data claim for the use of international data, there must be evidence-based grounds for submission to the regulator by industry. While this can be sought on a case by case basis and is already used by registrants in Australian registrations, the grains industry is in the process of developing and presenting an evidence-based study to potentially provide a scientific basis for broader acceptance of international data, particularly for efficacy and residues. Other industries should be actively pursuing similar studies to exercise this opportunity.

Meetings took place in 2014 with the executive of the North American IR-4 program and the Canadian minor use program (CANMUP) to gain insight into the key steps and recommendations for the establishment of an effective and functional collaborative Australian minor use program. IR-4 and CANMUP have expressed significant support and goodwill towards the establishment of an Australian minor use program with offers of potential collaboration. This would potentially include participation in joint prioritisation and data sharing. Both the IR-4 program and Canadian Minor Use Program executive have recommended the following key considerations, which are essential for the establishment and success of an Australian AgVet collaborative minor use program;

- a) Open discussion between industries and their priorities with companies on potential solutions
- b) Adopting a consensus approach to reaching agreement with stakeholders
- c) Effective financial and non-financial incentives program to maximise commercial investment support for the program
- d) Mechanism for effective engagement with the regulator to receive advice at key decision points in the prioritisation process
- e) Agreement by all stakeholders on the agreed program outcomes and success measures

Items a), b) and e) have been agreed to and recommended for implementation within the AgVet Collaborative Forum. There is clearly a need for Government proposals for incentives to be tabled to the AgVet Collaborative Forum as detailed in item c) above. In discussions with CANMUP and IR-4 it has been indicated that the Australian AgVet Collaborative program would potentially fail without effective incentives. It would also make commercial company interest in international collaboration with Australia more difficult.

The legislative or regulatory framework is currently unclear for engagement of the regulator APVMA with the AgVet Collaborative Forum to receive advice at key decision points in the prioritisation process as adopted by IR-4 and CAN MUP as detailed in item d) above. This includes early vetting of proposed priorities for amber and red flags in regard to environment, human health and trade. This will require discussion with the government and APVMA to ensure there is an effective mechanism for this to occur. Without this mechanism both IR-4 and CAN MUP have indicated that there will be significant wastage of prioritisation time and costs in trying to reach agreement on final recommended

priorities. It would be important that the APVMA also have intergovernmental agreements in place to discuss priority options with the US EPA and Canadian PMRA regulators to effectively support the Australian prioritisation process.

5.3 Proposed mechanisms for access to international AgVet data for cross industry use

For Australian industry driven minor use programs to receive benefits and effective engagement from an international collaboration, several principals would need to be accepted by the AgVet Collaborative Forum;

1. There needs to be a mutual need for the chemical product solution for similar crop types/groupings/animals for similar target pests in both countries based on industry prioritisation with all inter-country regulatory issues addressed to the satisfaction of the registrant
2. Priority projects should ideally be delivered in reference crops/animals to maximise the broader benefit
3. Projects would need to be developed where the same registrant has the rights to the active or primary (pioneer) registration in both countries in both countries
4. Commercial in-confidence and data protection rights on overseas data would need to be maintained
5. Potential AgVet solution projects should have been passed 'green' by the APVMA⁵ as well as the other countries in the collaboration
6. Preference new AgVet products which will enable more effective commercial investment and support for stewardship communication
7. Database access to international collaborators and acceptance by industry for mutual sharing of existing data sets; subject to maintaining commercial in-confidence, data protection rights or other joint investment agreement conditions.

Based on the current progress of the AgVet Collaborative Forum discussion and consensus, it is anticipated that the forum will transition to the recommended governance model by May 2015. This would allow the first pilot of cross industry prioritisation for separate plant and animal industry priority lists to be developed in recommended investment priority order by late May or early June 2015. A number of broader strategic cross industry AgVet issues would benefit from workshops later in 2015 providing opportunity for further feedback to industry on leading into a potential annual review of priorities again in 2016. There would be significant benefit in Australia having memorandum of understanding (MOU) agreements in place with IR-4 and CAN MUP to table Australian potential priorities at the North American prioritisation meetings later in September 2015.

To facilitate timely progress of these outcomes, and facilitate opportunity to establish the mechanisms for international collaboration, it is recommended that consideration be given for future discussion within the AgVet Collaborative Forum on the following points. This will assist with achieving agreement for industry support and sign-off by the Department of Agriculture for funds through the proposed AgVet access grants program:

⁵ See recommended process in the AgVet Collaborative Forum operational prioritisation system discussion paper

- Consensus agreement of the 7 potential key principles for international collaboration noted above
- Establishment of an intergovernmental MOU agreement with IR-4/CANMUP to allow formal establishment of international collaboration including priority sharing and potential data sharing
- Explore regulatory options to support a mechanism for effective engagement with the APVMA to receive advice at key decision points in the prioritisation process both nationally and internationally

6. AgVet Collaborative Forum stewardship for resistance management

The following proposed options for stewardship for resistance management were discussed with stakeholders and incorporated into AgVet Collaborative Forum planning.

6.1 What is product stewardship?

Stewardship is the responsible overseeing and protection of something considered valuable and preserving i.e. such as pesticides. Resistance management stewardship is to decrease the likelihood of resistance through application of resistance management strategies (use patterns etc) to prolong the life of the product. CropLife Australia have developed a number of pesticide resistance management strategies however there are still a number of gaps across a wide range of industries. Key principles of these pesticide resistance management strategies could be aggregated and applied to potential AgVet Collaborative Forum prioritisation programs.

A definition of product stewardship by the Department of Environment⁶ is an approach to managing the impacts of different products and materials. It acknowledges that those involved in producing, selling, using and disposing of products have a shared responsibility to ensure that those products or materials are managed in a way that reduces their impact, throughout their lifecycle, on the environment and on human health and safety.

National product stewardship legislation

The *Product Stewardship Act 2011*⁷ provides the framework to effectively manage the environmental, health and safety impacts of products, and in particular those impacts associated with the disposal of products. The framework includes voluntary, co-regulatory and mandatory product stewardship. This ensures that environmental standards are met including legal, ethical and moral obligations. This is to ensure products and technologies are safe and environmentally responsible over the product life cycle, both pre and post market.

In Australia, before an agrochemical product can be sold or used, the APVMA must first register it. In order for a manufacturer to register a product they are required to submit a comprehensive data package to the APVMA. The costs for generating and collating such data are high and unfortunately many crop and animal industries are too small individually for agrochemical manufacturers to bear the high cost of registering products for use. As a result, producers are often placed in situations where they risk severe losses from invertebrate pests, parasites, weeds and diseases. On the other hand, they risk buyers rejecting their produce and other penalties if they are detected using products that are not registered.

The need for stewardship focus in prioritisation

The need to gain minor-use permits and new registrations has come about due to emergence of new pests, pesticide resistance development and loss of some agrochemicals and/or uses due to chemical reviews and product rationalisation. Agricultural produce must meet minimum standards relating to quality, safety and consumer expectation. Quality Assurance programs, dealing with the whole

⁶ <http://www.environment.gov.au/protection/national-waste-policy/product-stewardship/voluntary-product-stewardship>

⁷ <http://www.environment.gov.au/protection/national-waste-policy/product-stewardship/legislation>

production process including agrochemical use demand that producers only exercise Best Management Practices (BMP).

The selective use of pesticides to control agricultural pests plays an important role in increasing production, improving the quality of Australia's agricultural production and enabling producers to earn reasonable returns on their investments. At the same time, today's health conscious society is extremely sensitive to issues relating to chemical use and it is essential that consumers be protected by adequate regulations governing the use of agrochemicals.

The APVMA's National Permit System adds some flexibility to the lengthy registration process and legalises the availability of products for minor-use purposes, not specified on the product label. However, off-label permits issued by the APVMA still must be applied for with associated information and data that verify the proposed permit use pattern will be effective and will not have any harmful effects on humans, the crops or the environment. An IPM compatible approach improves the scope for resistance management, sound biological profile, and residue and trade acceptance for domestic and export markets.

Delivering stewardship messages

To deliver an AgVet product stewardship program it is essential that clear and well-understood messages be delivered to producers, markets, end users, government and the community. When a new AgVet technology is developed, commercialised and released, communication of stewardship needs to address these factors described above are carefully managed by the registrant.

Delivering stewardship messages for new uses and changes to use management for generic chemicals and pesticides are somewhat more difficult, but not impossible. There are challenges in that chemical labels will often differ and lines of communication between the registrant and end user are often less clear as the cost of stewardship communication by the registrant is difficult to justify commercially. Communication of stewardship in these situations often in practice falls back on the broader industry or the regulator. This is particularly true for managing resistance management and confidence to consumers and markets, however it is important that permits and labels are adhered to by producers.

It should be recognised that pesticide residue breaches and industry stewardship issues are usually the result of a problem without a solution. Many minor industries are often boxed into a corner with no viable registered solutions, which could eventually result in business failure. There is clearly a role for the AgVet collaborative forum to provide systems and solutions delivering in the short, medium and long term. It should also be recognised that there is a common good for all industries in working together to particularly deliver on improved resistance management to ensure product longevity is maintained.

There is value for agricultural industries collaboratively working towards improving industry stewardship messages which will underpin success in delivering industry, market and consumer confidence. This discussion paper proposes mechanisms to address these needs through the cross industry prioritisation processes.

6.2 Options to address stewardship issues and priorities

The AgVet Collaborative Forum through consensus has agreed to deliver a new system for collaborative cross industry AgVet investment, which will increase current industry and commercial registrant participation and investment in addressing Australian AgVet chemical needs and reducing current impacts of market failure. This system will:

- Promote information sharing and co-investment opportunities to better use resources for supporting applications to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for AgVet chemical uses.
- Inform chemical companies of potential market demand to assist in their decisions to register Australian uses.
- Provide a forum for producers and the chemical industry to interact with the department and the APVMA to discuss the most effective and efficient methods of improving access to chemicals. These may include combining the investment efforts of a few grower groups to the benefit of the wider group.
- Support a framework for government conditional co-investment with industry and registrants.

In dealing with industry prioritisation and investment, the AgVet Collaborative Forum has agreed through consensus that it:

- must deliver appropriate investment addressing minor use chemicals and veterinary medicines needs where investment market failure appears to have occurred in a cooperative, efficient, timely and fair manner;
- shall proceed with technical rigor addressing stewardship and resistance management risks through tests of registerability; and
- shall act in accordance with its confidentiality and privacy obligations.

The aim of the AgVet Collaborative Forum prioritisation program in addressing market failure needs, is to ensure that minor use system and adequately reflects the unique and changing crop protection needs of industries. The AgVet Collaborative Forum program aims to establish an effective process for prioritising industries AgVet requirements.

Proposed outcomes for the AgVet Collaborative Forum in addressing stewardship include;

- Improve grower productivity and quality
- Optimise the performance and efficacy of the product
- Ensuring longevity of the technology through resistance management
- Deliver alternative solutions to pest problems
- Improve access to the same chemicals as overseas competitors
- Deliver access to new, softer, IPM compatible chemistry
- Deliver enhanced environmentally friendly pest management practices
- Providing confidence in sustainable BMP practices to industry, consumers and markets.

Possible justification for new AgVet products could be based on:

- New disease, insect or weed identified as a cropping issue
- No pesticide approved for the problem

- Insufficient options for resistance management
- Current pesticides ineffective due to resistance
- Trade risk - current pesticides unsuitable where crop commodities will be exported
- IPM, environment or OH&S issues
- Loss of pesticides due to removal from market or chemical review restrictions
- Opportunity to extrapolate a use pattern when a new, effective pesticide is registered in another crop
- Alternate pesticide has overseas registration or minor use permit
- Market failure – insufficient return on investment for registrant.

Based on this AgVet Forum agreement the key principals in addressing stewardship and priorities could potentially include;

1. There must be an industry issue with no ‘viable’ registered solution. Establish and implement an effective prioritisation process through identification with producers where there are no or limited products registered for effective control of pests including where current pesticides are:
 - Ineffective due to resistance
 - Incompatible with IPM systems, or
 - Unsuitable for trade / market access
2. Establish data generation projects to support registration and permit approvals demonstrating that new uses sought would;
 - Not pose unacceptable risks to the environment, users or the crop.
 - Not result in unacceptable residues
 - Be effective, and
 - Not adversely affect Australia’s trade
3. AgVet products selected should take into consideration of active currently under Australian Priority 1-4 review⁸.

In determining if a ‘viable’ solution already exists, cost considerations in regards to viability would rarely be a case as it would be unlikely that a registrant would deliver a new commercial AgVet technology beyond that the industry would bare. It would be very difficult to argue for new investment in an AgVet product if a registered solution already exists. It should also be recognised that in time as patents and data protection expire that international competition for AgVet sales would deliver the most cost effective solutions.

⁸ <http://apvma.gov.au/node/10876>

It is proposed that the Australian AgVet collaborative Forum adopt the same principles as the North American IR-4 and Canadian Minor use programs in that while generic AgVet technology solution options should be potentially considered as an option, preference to seeking suitable new ‘viable’ AgVet products will often provide greater scope for managing resistance and IPM compatible use. This principle has stood the test of time for these programs and has been considered a long-term strategic program delivering viable long-term solutions addressing resistance management and stewardship needs.

6.3 Potential mechanisms to deliver stewardship principles into the AgVet Forum priorities

The AgVet forum is open to all industry stakeholders that have a need for the use of agricultural chemicals and veterinary medicines or contribute towards the regulation, investment or Commercialisation of these products in the delivery of agricultural production.

It is recommended that the AgVet Collaborative Forum consider all of the 3 key principles in addressing stewardship through the industry pre-meeting priority needs list development. Consultation around these principles with the relevant industry would potentially be required. When ‘like industries’ come together through a workshop of the AgVet Collaborative Forum to prioritise AgVet options, potential projects would have already been assessed against these criteria.

7. AgVet Collaborative Forum measurement of success

7.1 Benefits of measures of success

In review of the successful programs that have been conducted over many years, both in Australia and overseas, the benefits of an effective minor use system are clearly evident. Programs to address investment market failure to deliver producers access to the best available AgVet technologies are critical and provide significant return on investment. The IR-4 Project and associated programs contribute US\$7.3 billion to annual gross US domestic product. There is an increasing level of global investment and interest in these minor use programs and an increasing momentum in international partnership in delivering joint global review programs. The precedence of successful collaborative cross industry approaches especially in the USA and Canada point to broad benefits, not only to industry production and sustainability, but to the broader community and economy as a whole. With an increasing global commitment by many governments to co-investment through appropriations to cross industry minor use programs, Australian industries should in the very least, explore what the potential benefits of similar approaches may deliver.

The review of AgVet prioritisation and investment programs⁹ identified benefits of a coordinated approach, including cross industry collaboration potentially including:

- Cost savings and efficiency in delivery of projects
- Improved identification of a broad number of cross-industry needs and efficiency in demonstrating benefit
- Improved export market access opportunities through establishment of cross-regional/international MRLs
- Opportunity to share underlying costs of managing permits
- Ability to demonstrate optimal value for investment of government appropriations.

The challenges facing all programs whether collaborative or individual potentially are:

- Ensuring objectivity in prioritisation
- Having a broad number of objectives that address production, market and future risks
- Avoiding the ‘squeaky wheel’
- Have transparent systems to identify when market failure is real
- Demonstrating community value for government co-contribution to RDC investment.

Measures of benefit-cost, improvement in productivity and multi-factor productivity and return on investment based on net present value will be required. It is recognised that industry priorities will

⁹ Rainbow, RW, Krause, M, (2014) RIRDC Cross agricultural industry AgVet investment prioritisation options workshop outcomes report. RIRDC project PRJ-009454 - Improved access to AgVet chemicals for agricultural industries.

always be greater than the investment dollars available. Consensus from the workshop concluded that economic ranking of projects is important, but it must be transparent and simple.

Based on the cross industry workshop outcomes, there is a strong rationale for objectivity in AgVet prioritisation and consistency of criteria for cross industry prioritisation. Government and industry priorities should be a continuous dialogue, particularly through joint government investment in RDCs. Based on the stakeholder dialogue, options should include:

- Profitability and productivity benefit
- Market access benefit
- Industry growth potential
- Resistance and sustainability benefit
- OH&S and environment benefit
- Registerability ranking options based on market requirements, MRL risks, efficacy and cost effective use by producers.

If industries are to successfully collaborate in a cross industry AgVet system, then consensus on the benchmarks, consistent assessment and prioritisation methodology and program KPIs must be agreed. Targets and KPIs for the options above would potentially be a useful starting point and should be SMART, ie specific, measurable, achievable, relevant and timely. KPIs for some of these measures have been worked through in competitors programs in North America. There is considerable opportunity to also learn from their experience in delivery of broader community benefits.

7.2 Measure of success options

From a review of existing RDC strategies, surveys, current measures of government and industry, the following measures detailed in table 1 have been considered and the benefits and risks and complexities of the various options have been detailed. These measures of success were endorsed by the AgVet Collaborative Forum on the 26 February 2015.

7.3 Recommended measures of success options

Based on the options in table 1, it is recommended the AgVet Collaborative Forum adopt the following measures of success;

1. Industry registered permit/label priority gap reduction
2. Percentage (%) minor use permits to registration
3. Average number of crops per new label registration
4. Number of new permits/labels for minor uses for each industry including support for international MRLs
5. Confidence in industry's ability to respond to emerging endemic crop protection and animal health threats – recognising that this measure is highly seasonally dependent
6. Industries see value of the AgVet Forum Collaboration
7. Commissioned impact assessment reports

Table 1. Potential options for measures of AgVet Collaborative Forum success.

Performance measure	Existing RDC/industry source	Benefits	Risks	Complexities
Industry total factor productivity improvement	ABARES	Gives a real measure of economic benefit	Attribution of benefits is almost impossible to define	The studies and reports driving estimates are not undertaken every year and highly dependent now on industry funding
Agricultural chemical input costs	ABARES	Gives a real measure of cost	The cost estimates are too coarse for practical use in defining short to medium term benefits (eg 3-5 years)	The studies and reports driving estimates are not undertaken every year and highly dependent now on industry funding
Impact Assessment reports	GRDC Impact assessment report - An Economic Analysis of GRDC Investment in Minor Use Chemicals 2011	An accepted methodology has been established – attribution of benefits can be more accurately described – estimated benefits can be modeled forward	Highly dependent on agreed assumptions	Costs of undertaking the review and reporting
Confidence in industry's ability to respond to emerging endemic crop protection and animal health threats.	GRDC Grower Survey – currently around 65% (2012) HIA Stakeholder survey (2013)	Gives a real measure of industry confidence and preparedness	Highly dependent on the most recent seasonal experience	Will rely on continued industry survey
GRDC Practice change strategy – Growers/producers use a combination of new genetic, biological, cultural and chemical tools to reduce crop loses and minimise control costs	GRDC Grower Survey – currently questions are not specifically targeted on new chemical tools	Gives a real measure of industry practice change and adoption of outcomes		Costs of inserting new questions
HIA strategy - Provide growers/producers with knowledge and tools to quickly recover from natural disasters/unplanned events.	HIA stakeholder survey – currently questions are not specifically targeted on new chemical tools	Gives a real measure of industry confidence and preparedness	Highly dependent on the most recent seasonal experience	Costs of inserting new questions
Industry registered permit/label priority gap reduction	Industry priority lists	Gives a real measure of reduced label gaps		
% minor use permits to registration	APVMA	Gives a real measure of program output		
Average number of crops per new label registration	APVMA	Gives a real measure of program output		
Number of new permits/labels for minor uses for each industry including support for international MRLs	APVMA/RDCs	Gives a real measure of program output		
Industries see value of the AgVet Forum Collaboration	AgVet Forum stakeholder survey	Gives a measure of confidence in the process and outcomes		
Producer practice change survey - % on label use	None available	Gives a real measure of producer practice change	Creates significant consumer and market concern on risks that may have no scientific grounds	Producers may have concerns around privacy and liability with this type of survey

Amber = some concern with approach

Red = significant concern with approach

Recommendation 5 is a particularly important option for the AgVet collaborative Forum. An accepted methodology has been established and adopted by the council of RDCs for this type of cross industry study. The major strength of this approach is that benefits can be more accurately described. Importantly due to the timeframes to delivery of the initial 4 year AgVet Collaborative Forum program, estimated benefits can be modelled forward based on the delivery of actual outputs. The commissioned impact assessment should report on the following;

- Profitability and productivity benefit
- Market access benefit
- Resulting industry growth potential
- Resistance and sustainability benefit
- OH&S and environment benefit
- Estimated cost savings and efficiency in delivery of projects

While the commissioned impact assessment approach is highly dependent on agreed assumptions, these can be well managed with industry and registrant stakeholder input. There should also be consideration of the economic measures and indicators used in the North American IR-4 impact studies. The costs of undertaking the review and reporting will need to be factored into program budgets.

8. Incentive options to support AgVet Collaborative Forum outcomes

The role of incentives in AgVet investment, being financial or non-financial, less tangible benefit such as accelerated decision outcome delivery or extended data protection has been widely discussed by agricultural industries and registrants over the last decade. Market failure in AgVet investment clearly still exists today and there is considerable discussion in regards to achieving a preferred three-way partnership of investment between registrants, agricultural industries and government. There has been considerable concern that government investment intervention could potentially increase investment market failure, not only by registrants, but also by industries themselves through their relevant research and development corporation (RDC).

Through recent discussion with industry stakeholders and registrants through completed RIRDC project PRJ009454 -Improved access to AgVet chemicals for agricultural industries¹⁰, there are 4 key categories that registerable AgVet investment falls into;

1. Project has very good registerability and sound commercial business case – commercially viable and no industry or government investment is required
2. Project has very good registerability and a commercial business case – commercially viable but investment is often deferred potentially delaying access by a broader number of industries (Noting that the deferred commercial investment by companies is becoming less common) - industry or government investment may accelerate technology access; incentives may bring forward deferred commercial investment.
3. Project has good registerability but difficult business case – and usually fall below the available commercial investment line – This is where industry or government investment incentives are beneficial to achieve technology access.
4. Project has registerability but poor business case – classic minor use/market failure example - Industry or government investment is required for technology access.

The role of RDCs and government in facilitating investment in market failure is clearly in scenarios 3 and 4. The challenge is what incentives will facilitate commercial co-investment discussions?

This review explores some of the key incentive options put forward by registrants, industry and OECD governments. This section provides an assessment of how these may impact on the role and opportunities for AgVet Collaborative Forum with some recommended options for consideration. Input into this section from the following people is gratefully acknowledged:

- Alastair James, CropLife Australia
- Michael Wright, Animal Health Australia
- Alan Norden, APVMA
- Jodie Pedrana, Horticulture Innovation Limited
- Kevin Bodnaruk, AKC Consulting Pty Ltd

¹⁰ http://www.rirdc.gov.au/research-project-details/custr10_NRI/PRJ-009454

- Manjeet Seethi, Agriculture & Agri-Food Canada Pest Management Centre
- Jerry Baron and Dan Kunkel, IR-4 USA
- Nikki Johnson, Market Access Solutionz (NZ)

8.1 Potential role of incentives in the AgVet Collaborative Forum

Following the completion of the first AgVet Collaborative Forum prioritisation workshop, there has been considerable discussion with the RDCs and contracting/consulting minor use program managers in regards to the impact of both the prioritisation workshop and the combination of government investment through the AgVet grants program¹¹ on registrant interest in minor use investment. While it will take time for discussions and decisions to transpire, there is already some concern that a number of collaborative RDC/registrant projects have had the registrant support withdrawn.

There is concern that there is inadequate incentive for registrants to invest in the low gross value, minor industries compounded by the fact that registrant data supplied for minor use permits would lose data protection under current AgVet regulations.

While there are considerable benefits of the AgVet Collaborative Forum in drawing out registrant supported technical options for new AgVet technologies to support industry issues, there is still the considerable challenge of achieving increased registrant investment in AgVet technologies in Australia, particularly new mode of action chemicals. There is clearly a need for consideration of new incentives to assist with these registrant investment decisions. At this time, there is considerable concern by the RDC crop protection and animal health managers that the Forum will deliver the planned outcome of increased AgVet investment by registrants without access to new investment incentive programs.

IR-4 and CAN PMC have expressed significant support and goodwill towards the establishment of an Australian minor use program with offers of potential collaboration. This would potentially include participation in joint prioritisation and data sharing. Both the IR-4 program and Canadian Minor Use Program executive have recommended the following key considerations, which are essential for the establishment and success of an Australian AgVet collaborative minor use program:

- Open discussion between industries and their priorities with companies on potential solutions
- Adopting a consensus approach to reaching agreement with stakeholders
- Effective financial and non-financial incentives program to maximise commercial investment support for the program
- Mechanism for effective engagement with the regulator to receive advice at key decision points in the prioritisation process
- Agreement by all stakeholders on the agreed program outcomes and success measures.

In discussions with the Canadian Pest Management Centre Minor Use Program (CAN PMC) and IR-4 it has been indicated that the Australian AgVet Collaborative program would potentially fail without effective incentives.

¹¹ <http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/improved-access-AgVet-chemicals/AgVet-assistance-grants>

8.2 Incentives sought by registrants to drive investment in minor use and AgVet market failure

CropLife International conducted a global survey¹² of members to identify what factors would present attractive minor use investment incentives for industry. The survey also looked at different types of regulatory incentives to identify what incentives are most likely to attract companies to decide in favour of registering for minor uses. The two most frequently mentioned incentives are extension of the period of protection of regulatory data, and lower fees; followed by fast authorisation or shorter review time, and reduced data requirements or support for data generation.

The top priority quite clearly is extension of the data protection period, during which secondary applicants will have to provide their own registration data for market entry. In discussion with Australian registrants, this scenario only provides opportunity on new actives, not older generic actives that dominate the minor use sector.

It should be noted that these provisions do exist in the Australian AgVet current legislation but have been removed from the new legislation that commenced in August 2014. The IR-4 and CAN PMC programs have stated that the data protection incentive is readily utilised and assists in getting registrant investment support. The current Australian data protection legislation is similar, however in practice the extension period has been of less commercial value, except for perhaps near to end of patent life actives. Australian data protection has been 8 years initial protection with up to 11 years for addition of minor uses. For each year up to the max of three years (8-11 years) you require 5 minor uses (or 15 in total). This will change to a flat 10 years data protection from the 1 July 2014 when the new AgVet regulations are implemented. In the United States, data protection is 10 years upfront increasing up to 13 years for minor use additions. Only three minor uses are required for each year. In Canada, data protection is 11 years the upfront with ability to extend up to 15 years for minor uses. Again only 3 additional uses are required for each additional year of data protection. The recent complete removal of additional data protection for adding minor uses in Australia would seem to be at odds with international standards. Compounding this is that registrants are reluctant to consider support of minor use permits in Australia as in doing this they lose data protection on data supplied with the permit application.

The other key priority identified in the CropLife analysis was lower registration fees or altogether waiving registration fees for label extensions. This would appear to be an effective way of increasing the number of minor uses onto a label. The current permit to label program being developed by the Australian government and APVMA would appear to address some of these opportunities. Table 2 reflects a wish list of CropLife International incentives that make a decision to register a minor use more attractive. The CropLife International analysis of the survey answers also revealed the potential for more minor use registrations if:

- Mutual recognition were applied (EU). Attractiveness increases if mutual acceptance is added to data protection (see the USA and Canada)
- Waivers were applied to tackle specific national data requests
- Registration were made easier, i.e. by harmonised regulatory requests like extended extrapolation schemes and crop grouping
- Registration timelines were shortened.

¹² Vassilia Sgouri V. and Keller S. (2012) CropLife International - Minor use incentive schemes globally industry perspective of success. *Proceedings FAO Global Minor Use Summit 2 - Pathways to Pesticide Registrations and MRLs for Minor Uses. Rome, 21–23 February 2012. Pp109-114*

Table 2. Factors making a decision to register a minor use more attractive (Number of respondents)

• Data protection extensions	7
• Lower fees or no-cost label extensions	7
• Attractive market or market share	5
• Funding available for data generation	5
• Simplicity of scheme, reduced data requirements or accept foreign data and crop groups	5
• Time or priority review	5
• Enforce legal use or cut down on counterfeit products	4
• Beyond the MRLs set by regulators, regional or local decisions to register for minor uses, were:	4
• Dedicated contact person for minor uses, or facilitation to manage stakeholders	3
• The general market of that country	

- International trade in that (minor) crop
- Market share of manufacturer
- Infrastructure to market or deliver product to minor use producers
- Cultivation techniques and likelihood of farmers implementing new cultivation techniques
- Individual company strategies. ^[11]_{SEP}

The CropLife International survey also showed that raising awareness about existing minor use schemes is important. Following discussion of the desktop review of AgVet investment and pre-workshop stakeholder consultation, the workshop concluded that prioritisation starts at the commodity/industry level and each industry should be responsible for delivering this and commit to making some investment in delivering outcomes. Prioritisation should initially be based within each commodity, on pest and then product. Cross industry project prioritisation should then consider common pest and product needs for synergies, cost savings and increased scale of use.

An excellent example of how AgVet incentive programs can deliver effective outcomes for increased registrant investment is the United States animal minor use program. The US Food and Drug Administration (FDA) established the Minor Use and Minor Species Animal Health Act in 2004 to establish programs to provide incentives to sponsors to encourage approval of new animal drugs for minor uses in major species and for minor species. It established Conditional Approval to allow sponsors to recover some development costs through earlier access to the market. It also established an alternate legal marketing status for some minor species through the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species. Minor use refers to disease conditions that are rare in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats). Minor species encompasses all other animal species and includes pet animals such as ornamental fish, parrots, ferrets, guinea pigs, and iguanas; zoo animals; and species of agricultural importance, such as sheep, goats, commercially-produced fish such as salmon, catfish and tilapia, and honey bees.

The provisions of the Act accommodate a range of needs for a variety of species and those uses that have not been supported through approvals because of a lack of economic incentive. The incentive provisions include designation and conditional approval options and these have been significantly exploited through NRSP-. In discussions with the US Animal Health Institute (The peak industry

body for animal medicines manufacturers in the USA), the incentive program described above with the additional incentives of reduced data requirements for minor use species and additional data protection benefits, resulted in a significant improvement in commercial AgVet co-investment in minor animal species and it was stated that the need to the NRSP-7 program has reduced. This is testament to the potential role of incentive programs in addressing industry minor use needs.

8.3 Incentives sought by agricultural industry to address AgVet market failure

There has been considerable agricultural industry peak body discussion in regards to the opportunities and needs of incentives to drive investment in minor chemical use in Australian agriculture. There have been a number of submissions to the Department of Agriculture in response to AgVet policy reform¹³ and also to the Agriculture Competitiveness White Paper¹⁴. It has been proposed that these initiatives, supported through further reform to the AgVet Act and regulations code, when combined with programs such as the AgVet Collaborative Forum would allow delivery of a well-managed cross industry RDC led minor use program. Proposed options have included:

- Establish provisional registration system with fee payment deferral options based on agro-ecological co-equivalence and same use in crops/animals overseas:
 - Delivering technology to agricultural industries faster
 - Increasing incentive to commercialise technology in Australia
 - Provisional review self-funded through sale of product.
- Establish a points credit system for registrants who put minor use onto label being rewarded with acceleration of an alternate registrations evaluation priority to incentivise commercial investment in industry priorities where market failure exists. These credits could then be used to accelerate other applications being assessed perhaps even at a later time eg. 6-12 months later allowing the build up of credits:
 - Would be a self-funding program by registrants
 - Delivering minor use and new technology onto label to industry faster
 - Encourages parity with international labels for agriculture.
- Adopt in new AgVet legislation and regulations improved data protection for emergency and minor use permits to improve the value proposition and incentive for commercial investment, encouraging contribution of exiting Australian and International data to these programs. In addition provide data protection incentives on existing registered labels encouraging investment in minor use through adopting a USA based system of 1 extra year for 3 minor use label extensions would:
 - be self funding program by registrants
 - potentially provide incentives for additional label registration of minor uses
 - improve product stewardship through company label communication.

Agricultural industry peak bodies believe that there is scope for a suite of regulatory incentives for the registration of minor use chemicals. It is likely that many of these incentives would be of little or no

¹³ Grain Producers Australia, Submission in response to Department of Agriculture Proposed Agricultural & Veterinary Chemicals Legislation Amendments Consultation Paper (7 March 2014).

¹⁴ Grain Producers Australia, Submission in response to the Australian Government Agricultural Competitiveness Issues Paper (17 April 2014).

cost to government and the regulator. Clearly consideration of data protection provisions and potential transfer of data protection benefits or other regulation assessment cost credits from investment in minor use label registrations would drive increased interest by registrants in participating in the AgVet Collaborative Forum prioritisation process and potential increased investment in resulting collaborative projects.

8.4 OECD AgVet incentive discussions and recommendations

The Organization for Economic Cooperation and Development (OECD) released three documents in 2011 on pesticide minor uses. Although these surveys were conducted in 2009, the results were only released in July 2011:

1. OECD Survey on Regulatory Incentives for the Registration of Pesticide Minor Uses: Survey Results¹⁵
2. OECD Survey on Efficacy & Crop Safety Data Requirements & Guidelines for the Registration of Pesticide Minor Uses: Survey Results¹⁶.
3. Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses¹⁷

Also in 2009, the OECD published a Guidance Document on Defining Minor Uses of Pesticides¹⁸ to provide guidance on defining minor uses of pesticides at local or regional levels with the aim of enhancing the consistency between countries in the methods used for defining minor uses. The documents were limited to guidance for defining minor uses of pesticides only and do not provide an OECD definition. As there is no one internationally or OECD accepted definition for minor uses, the criteria and guidelines for determining what constitutes a minor use varies amongst member countries.

The third Guidance Document on Regulatory Incentives document listed above which was derived from these surveys, provides guidance to national regulatory authorities in providing greater incentives to encourage manufacturers and registrants to register agricultural pesticides for minor uses. The document lists existing regulatory incentives available in a number of countries and suggests additional possible new incentives that could be explored to encourage the registration of specialty crop or minor use needs including:

- Economic incentives (or increased ‘value’) for registrants - Data protection; Expedited reviews; and Fee reductions or waivers
- Technical arrangements based on sound science - Extrapolation and mutually accepted data; and Number of trials
- Authorisation process arrangements - Third party registrations; and Temporary approvals (off-label & emergency schemes)
- Research investment - Data generation assisted schemes
- Promotion of safer alternatives - Reduced risk incentives

¹⁵<http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282011%2914&doclanguage=en>

¹⁶<http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282011%2913&doclanguage=en>

¹⁷<http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282011%2916&doclanguage=en>

¹⁸<http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono%282009%2939&doclanguage=en>

The OECD survey reports that most of the member countries that participated in the survey have waivers or reductions as an economic incentive for pesticide minor use registrations. With regard to data protection, the member countries that participated in the surveys noted that while extended data protection may not be currently available, when the new European Commission regulations for biocides (i.e., pesticides) are in place, these countries expect to have provisions extending by three years protection for data supporting minor use registrations.

Areas of potential incentives discussed in the Minor Use Guidance and surveys to be explored include:

- a ‘fast track’ registration review for minor uses, data waivers to be provided for minor use registrations (noting that there have been instances where registrant support of minor uses has extended regulatory assessment times in Australia).
- greater flexibility in allowing "mutually acceptable data (perhaps data from another country) or through the use of data extrapolations (or crop and pest groupings),
- and the development or expansion of government-funded programs for minor uses (e.g. IR-4).

The OECD Survey on Efficacy & Crop Safety Data Requirements & Guidelines for the Registration of Pesticide Minor Uses: Survey Results, for example, indicates it is possible to exchange data and reviews to support registrations across jurisdictions. Specifically, the report states: "Based on the results of the survey, it appears possible to exchange data and reviews to support the registration of minor uses across jurisdictions. The amount and type of data required are similar enough to support or at least facilitate minor use registration across jurisdictions." To enhance data sharing opportunities, the OECD survey includes recommendations for European Union countries to develop efficacy and residue data requirements and guidelines for minor uses that are harmonized with other countries and to examine expanding information data sharing agreements and consideration of foreign data and reviews across all OECD member countries.

The OECD Minor Use Guidance document concludes with a recommendation for regulators and industry to continue to "progress and maintain dialogue and information exchange on the successful implementation of regulatory incentives, and in doing so continually... review existing incentives, explore improvements in existing incentives and opportunities for new incentives." The Guidance also states as one of the "conclusions/key objectives": *“whilst a number of commonly accepted approaches are utilised in several countries, such as data protection, fee waivers and data extrapolation, these alone may not provide sufficient incentive for the registration of minor uses. Countries should also consider developing new and/or complementary approaches to raise the 'value' a registrant may associate from the registration of minor uses. For example many countries have or are considering the establishment of national programmes that work directly with affected producers to prioritise needs, generate data and make regulatory submissions”*.

Minor use incentives that have been identified by the OECD that have not yet been integrated into the Australian APVMA national registration program include:

- Economic incentives:
- data protection
- expedited reviews
- fee reduction or waivers
- Technical arrangements based on sound science:

- extrapolation and mutually accepted data
- reduced requirement for trials
- Promotion of safer alternatives:
- reduced risk incentives
- Liability:
- liability waivers and disclaimers.

In addition to the establishment of these programmes it is recognised by the OECD that; *“complementary regulatory incentives can enhance the registration of minor uses from those programmes/schemes. Where a registrant may still not associate economic value with a minor use to justify registration, countries should have in place regulatory mechanisms that allow for third party and/or temporary authorisations to be considered and where the liability from such uses are clearly outlined”*.

8.5 Recommendations for success of the AgVet Collaborative Forum

There are clearly some potential risks to agricultural industry if the market failure aspects of a collaborative program are not addressed. Market failure could in fact be made worse if the incentive for commercial investment is not understood, whether that be based on market scale, return on investment, regulatory challenges or investment risk. The same investment market failure risks could be applied for industry or RDC AgVet investment if the scale of benefit or impact is unknown or if there is limited intelligence of future industry needs. There is considerable concern from industry that the potential for investment from elsewhere *i.e.* via government or RDC programs itself creates an expectation for someone else to pay and contributes to market failure. Industry has clearly indicated that there needs to be a discussion around both regulatory commercial investment incentive to effectively support a program of industry investment.

The recommendations of the RIRDC PRJ009454 final report have contributed to the discussions and papers of the AgVet Collaborative Forum. Key points relevant to incentive options that would impact on the effectiveness and delivery of the Forum include:

- Industry off-label pesticide use highlights that market failure at an industry level is real and immediate
- Market failure could in fact be made worse if the incentives for commercial investment is not understood, whether that be based on market scale, return on investment, regulatory challenges or investment risk.
- Recognise the risks of increasing investment market failure for industry as there is no conditional commercial co-investment requirement
- Communication of transparent priority setting and cross industry collaboration will achieve potential cost savings through cross industry efficiencies and national and international collaboration and co-investment
- Improved communication of the business case for cross industry AgVet needs will increase awareness of industry needs and investment opportunity from an aggregated program of projects with increased NPV benefits.

- There is considerable concern from industry that the potential for investment from elsewhere ie via government or RDC programs itself creates an expectation for someone else to pay and contributes to market failure
- Industry has clearly indicated that there needs to be a discussion around both regulatory commercial investment incentive to effectively support a program of industry investment
- If there is sufficient information/economic data available on potential AgVet need and benefit and this is clearly communicated, then the transparency of real market failure where it occurs is clear.

Both the IR-4 program and CAN PMC executive have recommended the following key considerations, which are essential for the establishment and success of an Australian AgVet collaborative minor use program:

- Open discussion between industries and their priorities with companies on potential solutions
- Adopting a consensus approach to reaching agreement with stakeholders
- Effective financial and non-financial incentives program to maximise commercial investment support for the program
- Mechanism for effective engagement with the regulator to receive advice at key decision points in the prioritisation process
- Agreement by all stakeholders on the agreed program outcomes and success measures.

There is clearly a need for Government proposals for incentives to be tabled to industry. In discussions with CAN PMC and IR-4 it has been indicated that an Australian AgVet collaborative program would potentially fail without effective incentives. It would also make commercial company interest in international collaboration with Australia more difficult.

Based on the premise that industry RDCs in Australia will commit towards financially resourcing the continued delivery of a cross-agricultural industry minor use program through the AgVet Collaborative Forum, there is both opportunity and need for consideration of additional incentives, particularly those focussing on no or low cost incentives, which are less likely to distort investment decisions and potentially contribute to market failure. While direct investment by industry and government in data generation would support companies in filling regulatory gaps, there is a clear pattern that this can contribute to increasing investment market failure if investment drivers are not carefully managed. There is clear consistency in the incentive options put forward from registrants, industry and OECD members. In addition to direct funding and investment in minor use data generation, a combination of low cost minor use AgVet investment incentives that would underwrite the benefit of investment in time, energy and transaction cost and improved the delivery of outcomes from the AgVet Collaborative Forum include:

- Improved data protection for emergency and minor use permits to improve the value proposition and incentive for commercial investment, encouraging contribution of exiting Australian and international data to these programs.
- Provide data protection incentives on existing registered labels encouraging investment in minor use through adopting a USA based system of 1 extra year for 3 minor use label extensions which would;
 - be self funding program by registrants
 - potentially provide incentives for additional label registration of minor uses

- improve product stewardship through company label communication.
- Focus economic cash incentives (or increased ‘value’) for registrants on fee reductions or waivers for minor use industry priorities or provide a priority registration review ‘fast track’ for minor uses, plus label data waivers (less trials) for additional minor use registrations.
- Provide greater flexibility in technical arrangements allowing greater data extrapolation flexibility based on sound science including; reduced data requirements or acceptance of foreign data and crop groups – Including extrapolation and mutually accepted data based on agro-ecological co-equivalence.
- Consider further improvement to the current Australian Permit systems; ie through establishing a provisional label registration system with fee payment deferral options based on agro-ecological co-equivalence and same use in crops/animals overseas. This low cost to government approach would;
 - Deliver technology to agricultural industries faster
 - Increase incentive to commercialise technology in Australia
 - Self fund provisional review through sale of product.
- Allow registrant flexibility to transfer benefit to where value can be captured from investment in minor use, including allowing additional data protection benefits to be transferable to another chemical label. This would;
 - be a self-funding program by registrants
 - deliver minor use and new technology onto label to industry faster
 - encourage parity with international labels for agriculture.
- An increased focus on incentives for reduced risk chemicals or biological control options would provide a strategic increase in investment, which would benefit industry, the community and environment in the long term. Incentives supporting increased investment into biological control options have been a particular new focus of the IR-4 and CAN PMC programs. It is clear that Australia is missing out on many of these potential control options compared with North American competitors through lack of registrant interest and equivalent incentive programs.

The potential incentive options detailed in this report would provide further investment support from registrants for both national and international collaboration in AgVet data submission to the APVMA. A key outcome for industry is to insure that incentive preferences go towards the introduction of new and improved AgVet technologies to ensure improved stewardship, market access and resistance management.

9. AgVet trial delivery capacity

The role of the AgVet trial delivery service sector is an essential component for industry achieving chemical technology access and meeting both national and international regulatory requirements, particularly satisfying confidence in managing maximum residue limits (MRLs) for trade and food safety.

To deliver community confidence and compliance against international food, human and environmental safety, government regulators require a demonstration of the quality of test data from clinical, laboratory and field studies of AgVet chemicals. This would include accreditation of a laboratory to ISO/IEC 17025 or equivalent. In Australia, this can be demonstrated by the testing laboratory's National Association of Testing Authorities¹⁹ (NATA) accreditation²⁰ for medicine and chemical testing. The basis for the development of GLP was to provide assurance regarding test

data related to the hazard assessment of chemicals (pharmaceuticals, veterinary and agricultural chemicals, industrial chemicals) when manufacturers are seeking to register products for use. In Australia the relevant registration authorities are TGA (pharmaceuticals), APVMA (veterinary and agricultural chemicals), and NICNAS (industrial chemicals).

The principles of GLP are applied to the conduct of non clinical health and environmental safety studies of test items contained in various chemical products. A study covers work done in a laboratory, in animal houses, in greenhouses, and in the field. The Principles of GLP do not apply to clinical studies. Non-clinical studies include physico-chemical testing, toxicity, mutagenicity, environmental toxicity, bioaccumulation and residue studies; studies of effect on mesocosms and ecosystems, and the analytical chemistry associated with such studies.

The OECD Principles of Good Laboratory Practice (GLP)²¹ ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations. The principles have been created in the context of harmonising testing procedures for the Mutual Acceptance of Data (MAD).

With the new Federal Government investment in delivering improved AgVet technology access to industry through the proposed grants program, there is likely to be a significant increase in AgVet trial investment in Australia over the next 3 years. This is likely to be an increase of at least 50% of the current investment by research and development corporations (RDCs). This section identifies unforeseen issues with capacity to deliver on this increased investment and identify options to reduce the impacts of these risks.

Input in developing this section from the following people is gratefully acknowledged:

- Alastair James, CropLife Australia
- Andrew Bradbury and Atilla Tottszer, Advanced Analytical
- Andrew Keats, AgriSolutions Australia Pty Ltd
- Dale Griffin, Crop Protection Research

¹⁹ <http://www.nata.com.au>

²⁰ http://www.nata.com.au/nata/phocadownload/publications/General_information/What-is-GLP.pdf

²¹ <http://www.oecd.org/chemicalsafety/testing/goodlaboratorypracticeglp.htm>

- Ian Macleod and Belinda Rawnsley, Peracto
- Jodie Pedrana, Horticulture Innovation Limited
- Kevin Bodnaruk, AKC Consulting Pty Ltd
- Martin Collette and Kathryn Adams, Eurofins

9.1 AgVet GLP providers in Australia

In developing a regulatory package of data for submission, all the following skilled providers would contribute to the process of delivery of an AgVet registration outcome for industry:

1. Investment manager or study sponsor (may be a consultant coordinator or chemical company)
2. Regulatory Manager or consultant
3. Study Director
4. Field study provider (crop safety studies)
5. GLP field study provider (residue studies)
6. GLP laboratory study provider (residue studies)

The commercial companies, RDCs and their consultant providers are the key investment stakeholder that drives the quantum of GLP activity. Both the regulatory manager (or consultant) and the study directors have a key role in managing the planning and coordination of any GLP study. The study director in particular has a key role in coordinating the various aspects of the trial delivery, both in the field and the laboratory. While a number of chemical companies have the entire capability 'in-house', a number of GLP providers also deliver services for all items 2-6 above, while others provide only provide specific field or laboratory services. While there are a number of providers of GLP services for the plant industry and laboratory analytics, there is a duopoly of only two animal GLP study providers. The requirements for animal studies are technically more difficult and expensive to maintain both expertise and infrastructure, meeting both human and animal ethics requirements.

Providers can be listed into the following groups;

1. Commercial company GLP capability

- Many of the multinational companies have GLP Field study and laboratory analytics capacity in Australia

2. Field study providers (non GLP)

- There are numerous providers in the commercial consulting services, universities and state departments of agriculture

3. Field study providers (GLP) include;

- AgriSolutions Australia Pty Ltd
- Crop Protection Research
- Eurofins

- Kalyx
- Peracto
- SGS

4. Animal study providers (GLP) include;

- Eurofins
- Veterinary Health Research

5. Laboratory analytical providers (GLP) include;

- Advanced Analytical
- AgriSolutions Australia Pty Ltd
- Australian Wine Research Institute
- Eurofins
- Hill Laboratories (NZ)
- SGS

9.2 GLP provider and study director capacity

The consultation with RDCs and their consulting providers indicated that while there was some concern with initial demand for GLP services may create some initial bottlenecks in development of studies, particularly in planning by GLP service provider study directors and meetings with the APVMA around study requirements. The planning stage for GLP studies requires a significant amount of skilled human resource. There was however a view that there was adequate capacity to service an increase of investment. This confidence could be confirmed in that a number of GLP field study providers have recently made new investment in both equipment infrastructure and human resources to service an increase in investment in field study delivery.

There was seen to be potential capacity to deliver the associated increased activity in GLP laboratory studies, required mainly for residues. GLP laboratory studies usually account for a third to half of the total trail costs. A recurrent concern was that there might be a lag of 6-9 months in necessary growth of GLP laboratory capacity due to the time required in purchase, commissioning of new equipment and training of staff. A couple of GLP field providers noted that GLP laboratory services used are only just delivering currently with a 6 month timeframe required, based on the maximum storage time of 6 months for residue samples. A number of organisations noted that this initial delivery lag could be offset through the use of overseas GLP laboratory services if required.

A number of providers noted the limited number of GLP animal study providers in Australia. There have previously been other providers, however the significant infrastructure costs and sporadic work opportunity in recent years has led to a number of organisations withdrawing their services. It was suggested that if demand outstripped capacity, investment in new infrastructure for GLP animal studies would be a very difficult investment decision. There is currently no specific service provider expertise for GLP residue studies in aquaculture in Australia. It was suggested that options should be developed to address these concerns.

Other issues identified which require discussion on management options include:

- GLP residue studies with new chemical products to Australia can be potentially delayed if the standards and protocols for residue analysis are not provided with sufficient lead-time to Australian GLP laboratories. Supplies of chemical standards are contingent of company support for these studies and often subject to approval from overseas. Metabolite standards can sometimes be even more difficult to obtain.
- There was an element of caution noted in taking on GLP laboratory studies for new chemical compounds in terms of unforeseen time and cost, especially for review and validation of protocols that also are required to be completed under GLP.
- There is often less knowledge of how new chemical products react, therefore more time is often required in establishing the protocols which is new to a GLP laboratory. This includes determining the stability of a metabolite in a particular matrix
- Further investment commitment in GLP studies beyond the proposed 3 years would be important for consideration of increased investment in GLP laboratory capacity
- It was suggested that GLP field trials would need to be delivered over at least 4+ years rather than within 3 years to address delivery bottlenecks.
- With limited specific expertise in Australia to deliver GLP aquaculture studies, options to provide regulatory certainty around trial outcomes may be required.

9.3 Recommendations to address AgVet trial delivery capacity

While it is envisaged that there is potentially adequate resources and capacity to deliver an increased number of GLP field trials for plant industries, there appears to be more limited capacity for additional animal trials with only two Australian providers of GLP animal studies. While this is not a critical concern, there may be a potential time lag of capacity for both human and physical infrastructure in delivery of these studies. To potentially reduce these impacts it is suggested that investment projects should consider collaboration with North America in delivery of these animal studies, particularly in controlled environment industries. This would potentially increase relevant animal GLP capacity and also increase competition to the existing duopoly of animal service providers.

GLP residue laboratory capacity could be a potential trial bottleneck as a consequence of an increase in AgVet investment through the Department of Agriculture AgVet trial grants program. With a potential time lag of at least 6 months to order, commission equipment and train staff to increase GLP residue analysis, combined with a maximum storage period of 6 months for GLP residue materials before processing, it will be critical for study directors to ensure GLP laboratories have adequate capacity on stream and commissioned to process a potential initial potential backlog of GLP field trial materials.

To reduce the impact of these issues to the delivery of the outcomes from increased Federal Government grant and RDC investment, it is recommended that:

- Consideration and encouragement be given to increased international collaboration of RDC funded programs, based on principles of agro-ecological co-equivalence, especially for animal studies, to reduce unnecessary duplication of trials and increase the use of international field and laboratory GLP capacity

- Regulatory options or temporary exemptions to allow for the lack of aquaculture specific GLP expertise in Australia should be considered
- Utilisation by RDCs of the commercial company GLP capacity for animal studies with companies such as Bayer and Elanco should be considered
- Encourage utilisation of GLP field service providers, especially in the first 12 months with access to international GLP laboratory analytics to reduce any initial backlog of field trial samples
- A survey of RDCs within the first 12 months of the Federal Government grant program is implemented to determine timeliness of delivery of both field and laboratory GLP services to determine if adjustment to investment timeframes is warranted.

10. Potential function and cost savings from a collaborative AgVet program

There has been considerable industry discussion within the AgVet Collaborative Forum in regards to the potential use of existing international data and potential collaboration and data sharing opportunities with international minor use programs, in particular the US IR-4 and Canadian Pest Management Centre (CAN PMC) minor use programs. As detailed in a previous discussion paper presented to the AgVet Collaborative Forum, the use of international AgVet data provides a number of opportunities for Australian agriculture. It should be recognised that Australian producers in general have access to less registered technologies than overseas competitors, particularly compared with North America. There are also some potential advantages to increased collaboration with New Zealand due to this countries proximity as a trading partner and also sharing the same food safety regulator. The scope for international collaboration with EU countries would appear to be more limited. There are a number of reasons for pursuing international AgVet data generation collaboration:

- Reduced timelines for Australian producers getting access to products sooner across a broader range of crops/animals
- Reduced costs in delivering new registered chemical products if based on agro-ecological co-equivalence and cost sharing of data generation
- Increased government and consumer confidence in regulatory decisions if there is bi-partisan agreement across a number of jurisdictions through global joint reviews
- Improved market access and acceptance of international residue data
- Maintaining an internationally competitive production capability through accessing new AgVet technologies at the same time.
- Ensuring that impacts of local, regional and national pesticide resistance do not impact more significantly compared with overseas competitors with greater options for pesticide resistance management for common pests with Australia
- Improved preparedness for managing exotic pest incursions

This chapter details the potential costs savings and benefits from the use of international data in minor use permits and registration. It should be recognised that some companies undertake this task in using international data sets through the normal course of their research and development, however more often than not; research and development corporations (RDCs) undertake this role due to commercial investment market failure. This section details the potential cost savings and estimated benefits from an international approach to a collaborative AgVet program. The potential function and coordination role of the AgVet Collaborative Forum in facilitation this process is also discussed. Input into this section from the following people and sources is gratefully acknowledged:

- Manjeet Seethi and Shirley Archambault, Agriculture & Agri-Food Canada Pest Management Centre - Excel database supplied plus <http://www.agr.gc.ca/eng/?id=1298923934733>
- Jerry Baron and Dan Kunkel, IR-4 USA - <http://ir4app.rutgers.edu/ir4FoodPub/fullSearch.aspx>
- Nikki Johnson, Market Access Solutionz (NZ) - Registration of sustainable agrichemicals for minor crops Final Report SFF Project 11-053

- NRSP-7 database <http://www.nrsp-7.org/mumsrx/>

10.1 Cost saving estimate methodology and data sources

The cross agricultural industries, animal and plant AgVet priorities²² from the AgVet Collaborative Forum prioritisation workshops held in June 2015 has been mapped against the following international databases:

- IR-4 USA - <http://ir4app.rutgers.edu/ir4FoodPub/fullSearch.aspx>
- Agriculture & Agri-Food Canada Pest Management Centre - Excel database supplied plus <http://www.agr.gc.ca/eng/?id=1298923934733>
- Nikki Johnson, Market Access Solutionz (NZ) - Registration of sustainable agrichemicals for minor crops Final Report SFF Project 11-053
- NRSP-7 database <http://www.nrsp-7.org/mumsrx/>

Review of international AgVet data sources from North America, mapped against the 566 Australian AgVet priorities and options was completed. The outcomes of this data mapping process have been compiled in an Excel file detailed in References. This includes analysis of all IR-4, NRSP-7 databases from the USA and mapping against current and previous CAN PMC projects. The review of international AgVet data sources from North America has identified 193 Australian plant industry priorities with useful relevant IR-4/PMC/NRSP-7 project data that is also supported by companies. This review also identified 15 solutions to Australian priorities, which have not been supported by manufacturers in North America for a range of reasons. In addition there is data available from a recently completed New Zealand minor use project for an additional 6 priorities and supporting data with IR-4 for another 2.

Unfortunately the NRSP-7 database elicited only 29 project options for animal industries, all being for aquaculture. This brings to a total of 199 potential Australian plant industry projects and 29 aquaculture industry projects which contain potentially relevant data which could be used in a permit or label registration.

In calculating the benefit from potential use of this international data, the following assumptions have been used:

- All data would be used in a minor use permit application, rather than label registration
- Average cost per trial based on calculations from RIRDC project PRJ-009454²³ is estimated at \$15,000 for crops and \$90,000 for aquaculture;
- That at least 2 international trials would be considered available and appropriate based on agro-ecological co-equivalence;
- That benefit/cost attributed to every trial would average at least 95:1. A review of Horticulture industry minor use investment benefit has proposed a benefit/cost of of 95:1²⁴. While other studies have indicated benefit/cost from investment in minor use could be as low as 14:1²⁵, long- term experience from investment in North America through IR-4 has indicated

²² <http://www.rirdc.gov.au/AgVet>

²³ http://www.rirdc.gov.au/research-project-details/custr10_NRI/PRJ-009454

²⁴ Horticulture Australia Limited, 2010, MT10029, Managing pesticide access in horticulture through the Pesticides Minor Use Coordinator.

²⁵ Grains Research and Development Corporation, 2011, An Economic Analysis of GRDC Investment in Minor Use Chemicals. www.grdc.com.au/uploads/documents/MINOR_USE_CHEMICALS_FINAL_30JUNE1.pdf

benefit could be as high as 462:1²⁶. A conservative approach to benefit cost has been used in the calculations.

10.2 Cost savings from a collaborative AgVet program

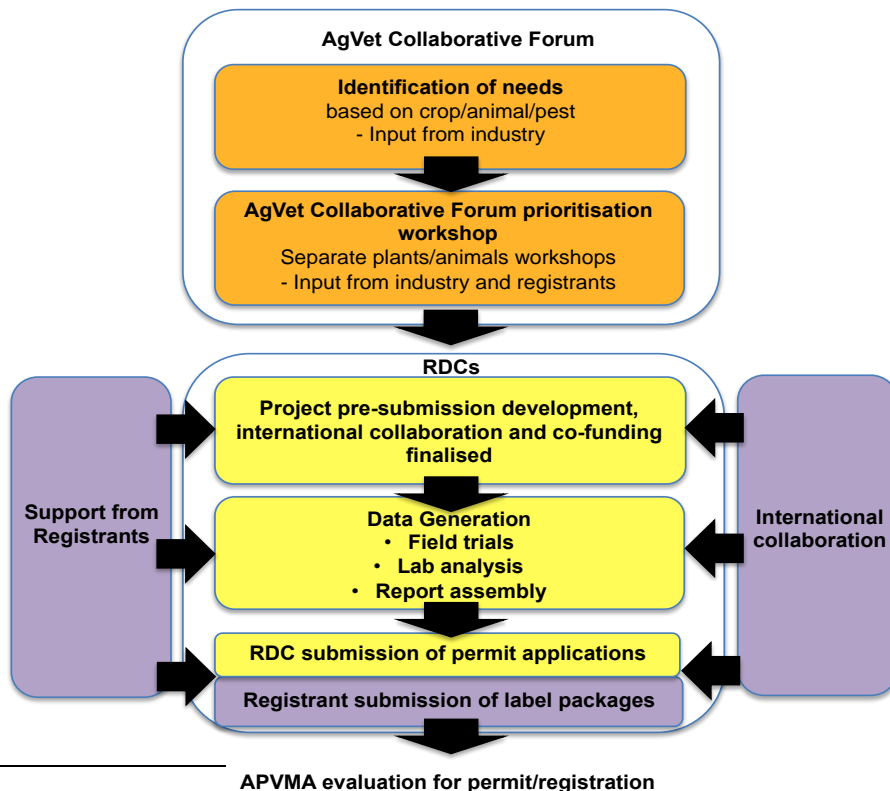
Based on the 199 Australian plant industry priorities which have potential supporting overseas data, based on the assumption of 2 trials @\$15,000 each would value the data at \$5.97 million @B/C of 95:1, this provides a total benefit to Australian plant industries of \$567 million

Based on the 29 Australian aquaculture industry priorities which have potential supporting overseas data, based on the assumption of 2 trials @\$90,000 each would value the data at \$5.2 million, @B/C of 95:1, this provides a total benefit to Australian aquaculture industries of \$496 million

Based on the data review, assumptions and benefit/cost calculations, it is estimated that the direct cost saving to Australian industries from the combined plant and aquaculture industry use of existing overseas data sets is \$11.17 million with a resulting benefit/cost from potential international collaboration of more than \$1 billion. Success in capturing benefit from this opportunity is subject to the Australian Government signing of an MOU agreement with IR-4/CAN PMC to allow formal establishment of international collaboration including priority sharing and data sharing.

10.3 Potential function and coordination role of the AgVet Collaborative Forum

The investment prospectus delivered to RDCs for continued investment for the delivery of the AgVet Collaborative Forum details that the role of international collaboration for accessing data would be the role of the RDCs. There is however a potential need for some cross-industry coordination to ensure efficiency and parity in negotiation of data access and sharing with programs such as IR-4. The currently proposed future delivery framework for the Forum is detailed in figure 10.



²⁶ Miller S.R. and Leschewski A. (2011) Economic Impacts of the IR-4 Project and IR-4 Project Programs. <http://ir4.rutgers.edu/Other/IR4EconomicImpact.pdf>

Figure 10. AgVet Collaborative Forum prioritisation process next steps for RDCs delivering industry access to AgVet technologies

As detailed previously in a review document presented to the AgVet Collaborative Forum, for Australian industry driven minor use programs to receive benefits and effective engagement from an international collaboration, several principals would need to be accepted by the AgVet Collaborative Forum;

1. There needs to be a mutual need for the chemical product solution for similar crop types/groupings/animals for similar target pests in both countries based on industry prioritisation with all inter-country regulatory issues addressed to the satisfaction of the registrant
2. Priority projects should ideally be delivered in reference crops/animals to maximise the broader benefit
3. Projects would need to be developed where the same registrant has the rights to the active or primary (pioneer) registration in both countries in both countries
4. Commercial in-confidence and data protection rights on overseas data would need to be maintained
5. Potential AgVet solution projects should have been passed 'green' by the APVMA²⁷ as well as the other countries in the collaboration
6. Preference new AgVet products which will enable more effective commercial investment and support for stewardship communication
7. Database access to international collaborators and acceptance by industry for mutual sharing of existing data sets; subject to maintaining commercial in-confidence, data protection rights or other joint investment agreement conditions.

At this time, the role of the AgVet Collaborative Forum in coordinating access to international data would be limited to achieving agreement on a consistent approach for RDCs accessing data from international sources, both in terms of approach to data sharing and maintaining commercial in-confidence and data protection rights of data owners. The AgVet Collaborative Forum may also potentially provide efficiencies to identify potential international data sources against Forum priorities. It is not proposed that the Forum has a role in coordinating data sharing negotiations with IR-4, CAN PMC or NRSP-7. However, RDCs may wish to pursue a consultant contractor, which could jointly fulfil the role for a number of industries. This would reduce transaction costs and frustration for IR-4/PMC programs of dealing with multiple Australian RDC contacts.

²⁷ See recommended process in the AgVet Collaborative Forum minor use operational system discussion paper

10.4. Benefits from a collaborative AgVet program

Additional review of international AgVet data sources from North America, mapped against the 566 Australian AgVet priorities and options has been completed. This includes analysis of all IR-4, NRSP-7 databases from the USA and mapping against current and previous Canadian Pest Management Centre (PMC) Minor Use Program projects. The review of international AgVet data sources from North America has identified 193 Australian plant industry priorities with useful relevant IR-4/PMC/NRSP-7 project data that is also supported by companies. In addition there is data available from a recently completed New Zealand minor use project for an additional 6 priorities and supporting data for another 2 priorities for which IR-4 data also exists. This review also identified 15 solutions to Australian priorities, which have not been supported by manufacturers in North America for a range of reasons. The review identified 29 relevant aquaculture NRSP-7 projects with supporting data for Australian priorities.

It is estimated that the direct cost saving to Australian industries is \$11.17 million with a resulting benefit/cost from potential international collaboration of more than \$1 billion. Success in capturing benefit from this opportunity is subject to the Australian Government signing of an MOU agreement with IR-4/CAN PMC to allow formal establishment of international collaboration including priority sharing and data sharing. It will be important that the Australian government provides timely focus on considering signing these MOUs to ensure maximum benefit from this opportunity is captured in combination with the AgVet Collaborative Forum prioritisation process and the AgVet grants program. The role of the AgVet Collaborative Forum should be restricted to achieving agreement on a consistent approach for RDCs accessing data from international sources, plus potentially identifying potential data sources against Forum priorities, rather than having a role in coordinating RDC access to international data.

11. Results

PRJ-009981

There have been three discussion meetings of the AgVet Chemicals Collaborative Forum (abbreviated to the AgVet Collaborative Forum) and both a plant and animal industry prioritisation workshop up until 30 June 2015. Forums were facilitated by Dr Rohan Rainbow and chaired by project sub-contractor Mr Cameron Begley. Each AgVet Collaborative Forum has had in excess of 40 cross industry stakeholders attending, it was agreed to establish an AgVet Collaborative Forum Interim Steering Committee. Since its establishment, the interim steering committee has assisted with the development of discussion papers including terms of reference and operation for the forum into the longer term, measures of success and mechanisms for registrant and industry priority sharing. Consensus on options for the implementation of these foundational components has been reached.

Considering the Forum was in effective operation for only seven months, there was considerable progress in achieving the project outcomes to establish a functional system leading to the first pilot prioritisation workshop in 2015. While there was an initial lack of engagement of animal industries in the Forums, additional meetings with NFF and Animal Health Australia members has led to significantly increased participation of animal industries in the AgVet Collaborative Forum. The strategy to increase engagement through a practical mechanism of development of a cross industry animal priority list appears to be effective.

The project outcomes from the AgVet Collaborative Forum prioritisation workshops held in June 2015 were widely publicised in rural press releases by RIRDC. The project has fielded a number of enquiries from peak industry bodies, RDCs and registrants on next steps. The updated RIRDC website project also holds the official link to AgVet Collaborative Forum priorities list which has been used as a criteria by the Department of Agriculture Assistance Grants – Access to Industry Priority Uses of AgVet Chemicals Grants Program. The project has also assisted with follow-up discussions in relation to RDC commitment to financially support the continuation of the AgVet Collaborative Forum.

Additional review of international AgVet data sources from North America, mapped against the 566 Australian AgVet priorities and options has been completed. This includes analysis of all IR-4, NRSP-7 databases from the USA and mapping against current and previous Canadian Pest Management Centre (PMC) Minor Use Program projects. This has provided opportunity to identify potential cost savings and benefits from prioritisation and collaboration. Building relationships with these international programs is imperative if data sharing arrangements are to be of bipartisan benefit and deliver true collaboration and cost saving benefits. This project has been instrumental in providing a framework to deliver a list of priority needs for discussion and allow a potential relationship to support the yet unsigned MOU between the Australian government and the USA IR-4 and NRSP-7 programs and also the Canadian Pest Management Centre (PMC) Minor use Program.

Considerable progress made on developing a new cross industry culture of collaboration and survey has indicated that a high level of motivation (Mean Av score 84%, animals 81%, plants 85%) has been achieved and there is every confidence (Mean Av score 77%, animals 71%, plants 80%) from stakeholders that the project will deliver its planned outcomes. The most recent of 3 stakeholder surveys, has also indicated the recognised significant value of assembling a priorities list (Mean Av score 71%, animals 65%, plants 76%). The value of the plant industries noted greater value of the process (Mean Av score 71%, animals 65%, plants 76%) and there was significant value in discussing these priorities with registrants (mean Av score 79%, animals 71%, plants 84%). There continues to be significant alignment of motivation and confidence scores, even with a significant number of new participants to the Forum (STDDEV 14-15%).

The following milestone activities and delivery details results from the project;

Milestone 1. Conduct stakeholder consultation for AgVet investment identified in Proposed R&D Adoption/Commercial pathways. Engage through regular teleconference and face to face meetings with the Department of Agriculture and RDCs during the initial meeting phase, to refine the forum with the aim of delivering a system that is sustainable into the future. Delivery by 15 December 2014.

Milestone 1 delivered 15 December 2014 – The project has conducted extensive stakeholder consultation both prior to and following the AgVet Collaborative Forum agendas detailed in Appendices 8.1 and 8.2. Stakeholders have been identified and consulted through the AgVet forum with a complete list tabled in Appendix 8.3. Through the Forum, an Interim Steering Committee has been formed to provide advice and feedback in the development of discussion paper, the Forum agenda and strategic advice to the Forum facilitator. The AgVet Collaborative Forum Interim Steering Committee has met 3 times by teleconference plus addition sub-committee working groups have been formed for development of key discussion papers. The project has met monthly face to face with the Department of Agriculture to discuss options for engaging with industry stakeholders and coordinating options for the Department of Agriculture to present on opportunities to deliver underlying policy and regulatory support including potential financial investment and other incentives to the program.

Milestone 2. Meet individually with key industry investment stakeholders and potential investors to identify key deliverable outcomes and potential baseline indicator measures. Identify key industry priorities for Minor Use Global Joint Review Program. Delivery by 15 December 2014.

Milestone 2 delivered 8 December 2014. A cross plant industry Global plant minor use priority list has been developed in collaboration with GRDC, Horticulture Innovation Australia and RIRDC. This included 2 formal cross plant industry RDC meetings to discuss options to discuss and reach consensus on prioritisation and baseline measure options. Three Excel based priority lists for fungicides, insecticides/nematicides, herbicides that are still in development detail industry needs, by pest, crop and product opportunity. These preliminary lists have already been forwarded to the Department of Agriculture at their request on the 8 December 2014. This priority options list should be finalised in January 2015 and will be detailed to key industry groups and registrants prior to forwarding a recommend final list in late January 2015 of 25 Australia priorities to the Global Plant Minor Use Priority program via the Department of Agriculture

The development of a combined animal industry AgVet minor use need priority list has been strongly encouraged at the forum and mechanisms to develop such a list are currently being discussed. Animal industries have been encouraged in the first instance to discuss this within their own industry groups and also as a potential coordinated response through Animal Health Australia.

A request was communicated to all plant and animal industries that did not have a strategic agrochemical review process (SARP) that has been coordinated by Horticulture Innovation Australia, GRDC, RIRDC, MLA or FRDC. These industries were strongly encouraged to develop and table their AgVet needs priority list based on crop/animal/pest/chemical to the AgVet Forum project for further cross industry discussion.

Milestone 3. Consultation meetings with at least 11 CropLife Australia and Animal Medicines Australia member companies to identify investment incentives, which would deliver increased international AgVet investment into Australian agricultural crop protection and animal health programs and increased interest in investment partnership with federal government initiatives and Research and Development Corporation co-investment. Delivery by 15 December 2014.

Milestone 3 delivered 5 December 2014 – Consultation has taken place with CropLife Australia and Animal Medicines Australia two times each since the project began, plus presentation as an invited speaker at the CropLife Australia Members Forum speaking with all plus attendance at the Animal

Medicines Australia Annual Members Dinner Function. One on one discussion has also taken place with the following companies:

- AgNova Technologies
- Assenci
- Adama
- BASF
- Bayer Crop Science
- Dow Agrosiences
- Sumitomo
- Syngenta
- Bayer Animal Sciences
- Elanco Animal Health
- Merial
- MSD

Milestone 4. Identify potential options for consideration of co-investment partners frameworks delivered in an options paper. Deliver proposed models and relevant information to the forum and the Department of Agriculture to allow stakeholders to consider using the collaborative forum to establish a functional AgVet investment program. Delivery by 15 December 2014.

Milestone 4 delivered 5 December 2014 – A series of discussion papers presenting options for establishment of an AgVet Collaborative Forum were developed in consultation with stakeholders and also through the AgVet Collaborative Forum Interim Steering Committee. These discussion papers detailed options for the initial establishment of a collaborative forum and its initial function, terms of reference and operation, measures of success and a mechanism for industry and registrant priority sharing. A complete list of discussion papers is detailed in section 7.

Milestone 5. Conduct stakeholder consultation on options for potential cost savings identified in Proposed R&D Adoption/Commercial pathways. Delivery by 15 December 2014.

Milestone 5 delivered 5 December 2014 - In developing the series of discussion papers for the first 2 meetings of the AgVet Collaborative Forum to deliver potential cost saving outcomes for industry as detailed in Section 5, the following stakeholders were specifically consulted including:

- Department of Agriculture
- Australian Pesticides and Veterinary Medicines Authority (APVMA)
- Plant Health Australia (PHA)
- Animal Health Australia (AHA)
- Australian Pork
- Dairy Australia
- Fisheries Research and Development Corporation (FRDC)
- National Aquaculture Council
- Meat and Livestock Corporation (MLA)
- Sheep Meat Council of Australia
- Cattle Council of Australia
- Goat Industry Council of Australia (GICA)
- Australian Chicken Meat Federation
- Rural Industries Research & Development Corporation (RIRDC)
- Ricegrowers Association of Australia (RGA)
- Horticulture Innovation Australia (HIA)
- Protected Cropping Australia
- Growcom

- Ausveg
- Citrus Australia
- Summerfruit Australia
- Canegrowers
- Sugar Research Australia (SRA)
- Cotton Research and Development Corporation (CRDC)
- Australian Grape and Wine Authority (AGWA)
- Wine Grape Growers Australia (WGGA)
- Grains Research and Development Corporation (GRDC)
- Grain Producers Australia (GPA)
- National Farmers Federation (NFF) - AgVet Chemicals Taskforce
- CropLife Australia and member companies
- Animal Medicines Australia and member companies
- National Working Party on Pesticide Applications (NWPPA)
- IR-4 USA
- Agriculture and Agri-Food Canada Minor Use Pesticides Program
- Kevin Bodnaruk AKC Consulting Pty Ltd

Milestone 6. Establish with key stakeholders initial meetings that will eventually become the forum for the collaborative AgVet collaboration system. This will include facilitating the:

- Development and implementation of a sustainable governance structure for the forum with a focus of management and oversight by the cross-industry RDCs.
- Development of agreed processes for operation/administration of the system.
- Agreed industry indicators and measures of the success in increasing access to minor use, including the collaborative system, and documentation of baseline for indicator measures. Delivery by 15 December 2014

Milestone 6 delivered 7 November 2014 and 5 December 2014 - At the first AgVet Collaborative Forum with 42 cross industry stakeholders attending, it was agreed to establish an AgVet Collaborative Forum Interim Steering Committee as an interim governance structure mechanism to:

- Provide input into the development of discussion and options papers for the AgVet Collaborative Forum
- Establishment of working groups around each of the AgVet Forum agenda issues
- Provide advice to the RIRDC PRJ-009981 project facilitator in establishing a new formal system for collaborative cross industry AgVet investment

While it is recognised that this could result in a large number of stakeholders, it is essential that the program deliver the long term strategic needs of all industries. The Forum consensus was that the AgVet Collaborative Forum is:

- Open to all industry stakeholders that have a need for the use of agricultural chemicals and veterinary medicines
- Will contribute towards collaborative discussion on the regulation, investment and commercialisation of these products

Development and implementation of a sustainable longer term governance structure for the Forum was discussed to enable transition from an interim structure to the establishment of a longer-term

sustainable cross industry structure for the Forum. The AgVet Collaborative Forum Interim Steering Committee have recommended that the following revised documents represent the Forum consensus discussion outcomes of the 5 December 2014 for a long-term sustainable system:

- AgVet Collaborative Forum Terms of Reference and Operation (to establish a formal system for the AgVet Collaborative Forum)
- AgVet Collaborative Forum measurement of success

Milestone 7. Facilitate by the 15 December 2014, the first AgVet collaborative forum, including:

- Development of relevant discussion papers based on stakeholder consultation
- In consultation with the Department of Agriculture receive input from all agricultural industries, RDCs and peak industry bodies and the APVMA, to be tabled at the initial AgVet collaboration forum. These will cover key matters for the effective delivery of the collaborative forum including a recommended approach for identifying and sharing each industry's priorities at the forums.

Milestone 7 delivered 7 November 2014 and 5 December 2014 - It was tabled and consensus was reached that the Interim AgVet Collaborative Forum Steering Committee nominees would establish a working group to discuss and develop each AgVet Forum topic as required. Working group options and recommendations would be brought back to the AgVet Forum for discussion and decision. This included development of a new system or structure to deliver long-term outcomes for the AgVet Collaborative Forum. There has been consensus agreement for an AgVet Collaborative Forum mechanism for industry and registrant priority sharing. The survey of stakeholder findings from the second workshop were encouraging, in particular the motivation of stakeholders to engage in the AgVet Collaborative Forum had significantly increased.

Milestone 8. Provide strategic and technical support to RIRDC to ensure suitable contractor expertise is in place and contracted with RIRDC for Delivery of Access to AgVet Chemicals Collaborative System - Part 2. Delivery by 15 December 2014.

Milestone 8 delivered 5 December 2014 - There was signed agreement as a contract variation to PRJ-009981 on the 5 December 2014 between RIRDC and Rainbow and Associates Pty Ltd trading as Crop Protection Australia to deliver Part 2 - RIRDC for Delivery of Access to AgVet Chemicals Collaborative System.

Milestone 9. Deliver a report to RIRDC to be forwarded to Department of Agriculture on the outcomes of milestone 7 (discussion paper based on stakeholder consultation, and first Agvet forum). Delivery by 27 February 2015.

Milestone 9 delivered 20th January 2015 - A detailed report around the outcomes of milestone 7 was delivered to RIRDC (see attachment) tabled on 20th January 2015 was forwarded to the Department of Agriculture and also presented on the 4th February 2015.

Milestone10. Facilitate cross industry agreement on final priority lists for global joint review by 20 January 2015.

Milestone 10 delivered 14 February 2015 - Following industry, RDC and registrant discussions, a final recommended priority list for OECD global joint review was forwarded to the Department of Agriculture on the 14 February 2015. (see attached Excel file). A summary of all identified cross industry plant and animal priorities to April 2015 is contained in this file.

Milestone 11. Deliver an AgVet minor use capacity audit and capacity building implementation plan to stakeholders and finalise a report delivered to RIRDC. Delivery by 30 June 2015.

Milestone 11 delivered 22 July 2015 – An AgVet trial delivery capacity report was delivered to RIRDC. While the report indicates that there is potentially adequate resources and capacity to deliver an increased number of GLP field trials for plant industries, there appears to be more limited capacity for additional animal trials with only two Australian providers of GLP animal studies. While this is not a critical concern, there may be a potential time lag of capacity for both human and physical infrastructure in delivery of these studies. To potentially reduce these impacts it is suggested that investment projects should consider collaboration with North America in delivery of these animal studies, particularly in controlled environment industries. This would potentially increase relevant animal GLP capacity and also increase competition to the existing duopoly of animal service providers.

GLP residue laboratory capacity could be a potential trial bottleneck as a consequence of an increase in AgVet investment through the Department of Agriculture AgVet trial grants program. With a potential time lag of at least 6 months to order, commission equipment and train staff to increase GLP residue analysis, combined with a maximum storage period of 6 months for GLP residue materials before processing, it will be critical for study directors to ensure GLP laboratories have adequate capacity on stream and commissioned to process a potential initial potential backlog of GLP field trial materials.

To reduce the impact of these issues to the delivery of the outcomes from increased Federal Government grant and RDC investment, it is recommended that;

- Consideration and encouragement be given to increased international collaboration of RDC funded programs, based on principles of agro-ecological co-equivalence, especially for animal studies, to reduce unnecessary duplication of trials and increase the use of international field and laboratory GLP capacity
- Regulatory options or temporary exemptions to allow for the lack of aquaculture specific GLP expertise in Australia should be considered
- Utilisation by RDCs of the commercial company GLP capacity for animal studies with companies such as Bayer and Elanco should be considered
- Encourage utilisation of GLP field service providers, especially in the first 12 months with access to international GLP laboratory analytics to reduce any initial backlog of field trial samples
- A survey of RDCs within the first 12 months of the Federal Government grant program is implemented to determine timeliness of delivery of both field and laboratory GLP services to determine if adjustment to investment timeframes is warranted.

Milestone 12. Deliver proposed models to establish a functional Agvet investment program including collaboration with IR-4

Milestone12. Deliver proposed models and relevant information to the AgVet collaborative forum and the Department of Agriculture to allow stakeholders to consider using the collaborative forum to establish a functional AgVet investment program. Delivery by 31 March 2015.

Milestone 12 delivered on 26 February 2015 - Following stakeholder consultation, a revised functional model for the AgVet Collaborative Forum investment prioritisation was developed and detailed in a report distributed to stakeholders.

Milestone 13. Table a report to stakeholders on project 1 forum feedback and deliver a preliminary meeting with stakeholders to discuss the benefit and to discuss establishment of a collaborative investment forum potentially including formal international collaboration. Delivery by 31 March 2015.

Milestone 13 delivered on 26 February 2015 - A report to Forum stakeholders detailing 'Mechanisms for access to international AgVet data for cross industry use' (see attached) including collaboration with CANMUP, IR-4 and NRSP-7 was discussed and distributed to Forum stakeholders on 26 February 2015.

Milestone 14. Delivery of a prospectus to agricultural industry stakeholders on recommended project options for collaborative investment to deliver improved AgVet technology access. Delivery by 31 March 2015.

Milestone 14 delivered on 22 July 2015 - Delivery of an investment prospectus based on agreed governance structures through RIRDC has been developed and was distributed to investor stakeholders by RIRDC on 27 July 2015. Delivery of this milestone was delayed by variation agreement with RIRDC to enable RIRDC to manage investor discussions to avoid any conflicts of interest with the project provider.

Milestone 15. 4. Consultation with at least 11 CropLife Australia and Animal Medicines Australia member companies to identify investment incentives, which would deliver increased international AgVet investment into Australian agricultural crop protection and animal health programs and increased interest in investment partnership with federal government initiatives and Research and Development Corporation co-investment. Delivery by 30 April 2015

Milestone 15 delivered 25 May 2015 – Consultation has taken place with CropLife Australia and Animal Medicines Australia two times each since April 2015, plus presentation as an invited speaker at the CropLife Australia Members technical Forum and presentation to the Animal Medicines Australia Board. The outcome of these meeting contributed significantly to the participation of companies in the AgVet Collaborative Forum prioritisation workshops with 12 crop protection registrants and 8 veterinary medicine registrants attending the workshops. The participation of these companies was an essential element to the success of the prioritisation workshops.

Milestone 16. Attend meetings with AAFC MUP/ IR-4 and NRSP-7. Delivery by 30 April 2015

Milestone 16 delivered 31 March 2015 – The Canadian Minor Use Program prioritisation workshops were attended where observations of the prioritisation process used and case studies were incorporated into the delivery of the AgVet Collaborative Forum prioritisation workshops.

Formal meetings have continued face to face with the executive of the North American IR-4 program and the Canadian minor use program (CANMUP) to gain further insight into the key steps and recommendations for the establishment of an effective and functional collaborative Australian minor use program. IR-4 and CANMUP have continued to express significant support and goodwill towards the establishment of an Australian minor use program with offers of potential collaboration. This would potentially include participation in joint prioritisation and data sharing.

While the NRSP-7 program in the USA while continues to provide a database of veterinary medicine project outcomes for minor industries, its funding has been terminated and the program is now in a wind down phase. Discussions with Agriculture and Agri-Food Canada have highlighted their intention to fund a pilot program focused on animal minor use needs, initially focussed on sheep, goats and aquaculture industries. At this point it would appear that future active collaboration with AAFC would be the best option for Australia to pursue when the pilot program plans are finalised later in 2015. AAFC have indicated that they are open to discussion on collaboration with Australia. Further discussion by the Department of Agriculture with AAFC on this opportunity is encouraged.

Milestone 17. Meet with investor stakeholders and delivery of investors WS Deliver by 30 April 2015

Milestone 17 delivered 31 May 2015 – Meetings have taken place in April and May 2015 with the following RDCs and peak industry bodies to specifically ensure continued support and investment in the AgVet Collaborative Forum:

- Australian Pork
- Dairy Australia
- Fisheries Research and Development Corporation (FRDC)
- Meat and Livestock Corporation (MLA)
- Sheep Meat Council of Australia
- Cattle Council of Australia
- Goat Industry Council of Australia (GICA)
- Australian Chicken Meat Federation
- Rural Industries Research & Development Corporation (RIRDC)
- Horticulture Innovation Australia (HIA)
- Ausveg
- Canegrowers
- Sugar Research Australia (SRA)
- Cotton Research and Development Corporation (CRDC)
- Cotton Australia
- Australian Grape and Wine Authority (AGWA)
- Wine Grape Growers Australia (WGGA)
- Grains Research and Development Corporation (GRDC)
- Grain Producers Australia (GPA)
- CropLife Australia and member companies
- Animal Medicines Australia and member companies

A revised AgVet Collaborative Forum investment prospectus building on the prospectus submitted in April 2015 has been developed and delivered to RIRDC on the 15 July 2015 (See Appendix 7). A final version for distribution to investors including RDCs is now being developed by RIRDC. In agreement with Simon Winter, the delivery of an investor's workshop/meeting has been handed back to RIRDC responsibility to avoid investment conflict of interest issues with Crop Protection Australia.

Milestone 18. Deliver report to AgVet forum and Department of Agriculture. Delivery by 30 June 2015.

Milestone 18 delivered 22 July 2015. Written report submitted to RIRDC and Department of Agriculture on 22 July 2015 and presented in a meeting to the Department on 3 September 2015.

Milestone 19. Workshop delivered to prioritise and achieve consensus on co-investment options. Delivery by 30 June 2015.

Milestone 19 delivered on 12 June 2015 - AgVet Collaborative Forum Prioritisation Workshops held in Canberra (see workshop agenda Appendix 5 and 6) on the 9-10 June 2015 (plant industries) and 12 June 2015 (animal industries). The workshops were well attended on the three days with over 100 participants including industry representatives, RDCs, state and federal government, APVMA and 20 registrant companies. The workshops delivered a completed priorities list for plant and animal industries, identifying where there is technical support of the registrants. Outcomes of prioritisation workshops have been posted on the RIRDC website and communicated to stakeholders on 20 July 2015. (see www.rirdc.gov.au/agvet)

The outcome for the plant industries from this workshop is particularly significant with the industry discussion of issues with registrants identifying solutions to 58% of a third of the top five industry issues, which previously had no identified solution. This highlights the strategic value of this discussion and the AgVet Collaborative Forum. The outcomes of this process will have significant potential productivity benefits for these industries in the future. This discussion may not have occurred, or it may have taken much longer to identify solutions for these gaps.

The prioritisation needs of animal industries highlighted the high priority for almost all animal industries for access to local anesthetic technology for improving animal welfare. The workshop highlighted the opportunity for industries to work together on needs to address common issues.

Plant industries priorities outcomes - 319 A's (Solutions with technical support of registrants) and 94 P's (Solutions sought by industry permit):

- 326 unique top 5 crop/pest priorities submitted (total of 384 priorities submitted including lower ranking priorities)
- 135 top 5 crop/pest priorities had no identified solution (41% of top 5 submissions)
- 78 new potential solutions were identified by registrants (addressing 58% of priorities with no solution)
- At least 1 additional new solution was identified by registrants for 90 of the 191 priorities already with a solution identified by industry (47% of all top 5 identified solution priorities) potentially improving resistance stewardship

Animal industries priorities outcomes - 68 A's (Solutions with technical support of registrants) and 8 P's (Solutions sought by industry permit):

- 98 unique top 5 animal/pest priorities submitted (total of 183 priorities submitted including lower ranking priorities)
- At least 1 additional new solution was identified by registrants for four of the 98 priorities already with a solution identified by industry (4% of all top 5 identified solution priorities) potentially improving resistance stewardship

Milestone 20. Establish the collaborative system including at least four plant and animal industry RDCs Delivery by 30 September 2015. Delivered by 12 June 20

Milestone 20 delivered 12 June 2015 - The initial three AgVet Collaborative Forum meetings included participation of the following nine RDCs:

- Australian Pork (AP)
- Fisheries Research and Development Corporation (FRDC)
- Meat and Livestock Corporation (MLA)
- Australian Wool Innovation (AWI)
- Rural Industries Research & Development Corporation (RIRDC)
- Horticulture Innovation Australia (HIA)
- Sugar Research Australia (SRA)
- Cotton Research and Development Corporation (CRDC)
- Grains Research and Development Corporation (GRDC)

The AgVet Collaborative Forum prioritisation workshop included participation of the following six RDCs and peak industry bodies of other relevant industries (RDCs which attended are abbreviated in brackets):

- Australian Pork (AP)
- Dairy Australia (DA)
- National Aquaculture Council
- Meat and Livestock Corporation (MLA)
- Rural Industries Research & Development Corporation (RIRDC)
- Horticulture Innovation Australia (HIA)
- Cotton Australia
- Wine Grape Growers Australia
- Grains Research and Development Corporation (GRDC)

Milestone 21. Identification of alignment of national and international IR-4 priorities and cost savings. Delivery by 30 June 2015.

Milestone 21 delivered 16 June 2015 - Building on the original agchem priorities 35 submitted in February 2015, a revised list of 566 Australian plant industry agchem priorities, have been submitted to the OECD Global Joint Review Program. This list was submitted as agreed as an outcome of the AgVet Collaborative Forum prioritisation meeting including all crop/pest priorities plus a nominated potential chemical solution if classified as an A priority. (see attachment 5)

While there may be future requests for changes to this priorities list, this submission marks a major milestone for Australia in bringing together for the first time a combined cross plant industry agchem priority list for which Australian priorities and potential solutions can be directly compared to other OECD nations. This list to be released in final form in August 2015 clearly identifies potential opportunity for collaboration with other OECD nations and potential cost savings in delivery of trial data.

The list of 566 Australian priorities have now been mapped against current and previous IR-4, NRSP-7 and Canadian PMC Minor Use Program projects to identify data sharing and collaboration opportunity (See details Excel data files). This list has been distributed to the relevant RDCs.

Milestone 22. Establishment of AgVet collaborative investment program including collaboration with IR-4. Delivery by 30 June 2015

Milestone 22 delivered 30 June 2015 - There has however been considerable success in establishing a cross industry culture of collaboration and there is every confidence that this will continue. There has been significant success in establishing and delivering the first cross industry AgVet prioritisation workshops for both plant and animal industries. Collaboration has been established with the IR-4 and AAFC MUP programs with invited participation in preparation for the OECD Global Minor Use Workshop Planning meeting in Chicago in September 2015 plus engagement in discussion on formatting, analysis and prioritisation methodology for consideration of the global priorities list.

Investment prospectus (See Appendix 7) delivered by the project and distributed by RIRDC to all RDCs. By the 30 September 2015, a total of 7 plant and animal industry RDCs plus 3 meat industry peak bodies and registrant organisations CropLife Australia and Animal Medicines Australia, had confirmed continued financial support for the Forum. This well exceeded the project targets. By the 4th November 2015, a total of 7 plant industry RDCs, plus 1 animal industry RDC, plus 3 red-meat council members plus CropLife Australia and Animal Medicines Australia have provided written commitment to both support the continuation of the AgVet Collaborative Forum as detailed in the prospectus. There were a number of caveats however requesting that RIRDC place provisions in place to ensure any later stakeholder groups, including non-aligned commercial companies and non

RDC aligned industries wanting to participate at a later date to make appropriate financial contribution to the Forum.

Milestone 23. As a representative of cross industry RDCs to reach agreement for potential future international collaboration - Attend the Global Minor Use Summit, Minor Use Global Joint Review Prioritisation Meeting and IR-4 prioritisation and planning meeting. Delivery by 30 September 2015.

Milestone 23 delivered 24 September 2015. Attended the Global Minor Use Workshop and IR-4 prioritisation workshops as a representative of Australia, GRDC, RIRDC and in support of HIA to deliver potential collaboration. The project also supported the Australian participation in the Global Minor Use Workshop delivering 3 potential and 6 reserve projects relevant to Australia. This workshop had participation of over 35 countries. The outcome of prioritisation is shown in the following table 3. While all priorities are relevant to an Australian industry, it should be noted that for Australia Greenhouse fruiting vegetables/whiteflies and Tropical fruit – inedible peel/Anthracnose ranked as a higher priority.

Table 3. Global Minor Use Workshop prioritisation outcomes 2015 Chicago

Crop group name	Pest rank 1 (votes)	Pest rank 2 (votes)	Pest rank 3 (votes)
greenhouse	Aphids (A), lettuce Flonicamid, Pymetrozine, Cyantraniliprole, Sulfoxaflor	Thrips (B), fruiting veg, other than cucurbits, Cyantraniliprole, Novaluran	Whiteflies (B), fruiting veg, other than cucurbits, Flupyradifurone, Cyantraniliprole, Novaluron
temperate	Downy mildew (A), leafy veg, Zoxamide, Ametoctradin + Dimethomorph, Acibenzolar, Fluopicolide + Propamocarb, Cyazofamid, Oxathiapiprolin	Aphids (B), legumes Flonicamid, Pymetrozine, Cyantraniliprole, Sulfoxaflor, Dinotefuran, Spirotetramat, Flupyradifurone	Weeds (B), leafy veg
tropical	Fruit flies (A), inedible peel, Spinosad, Cyantraniliprole, Kaolin	Anthracnose (B), inedible peel, Isofenamid, Trifloxystrobin + Fluopyram, Pyraclostrobin + Metiram, Mandistrobin, Azoxystrobin + Difenconazol, Cyprodinil + Fludioxonil, Penthiopyrad	Psyllids (B), Citrus, Diflubenzuron, Flonicamid, Sulfoxaflor, Buprofezin

Following discussions with HIA, it was agreed that Australia would lead the temperate program for the global minor use collaboration project. This was confirmed to the Global minor use coordinating committee at a meeting on the 13 November 2015.

Milestone 24. Delivery of an incentive options scoping document. Delivery by 30 September 2015.

Milestone 24 delivered 30 September 2015. See attached report - Incentive Options to support AgVet Collaborative Forum Outcomes. The project has detailed in a report, potential incentive options, which would provide even further benefits and investment support from registrants for both national and international collaboration in AgVet data submission to the APVMA. A key for industry benefit is to insure that incentive preferences go towards the introduction of new modes of action to ensure stewardship and resistance management.

Milestone 25. Produce a report to demonstrate the function and cost savings resulting from a collaborative AgVet program. Delivery by 30 September 2015.

Milestone 25 delivered 30 September 2015. Potential function and cost savings from a collaborative AgVet program. Additional review of international AgVet data sources from North America, mapped against the 566 Australian AgVet priorities and options has been completed. This includes analysis of all IR-4, NRSP-7 databases from the USA and mapping against current and previous Canadian Pest Management Centre (PMC) Minor Use Program projects. An additional project from New Zealand was also reviewed. The review of international AgVet data sources from North America and New Zealand has identified 199 Australian plant industry priorities with useful relevant IR-4/PMC/NZ/NRSP-7 project data that is also supported by companies. This review also identified 15

solutions to Australian priorities, which have not been supported by manufacturers in North America for a range of reasons. The review identified 29 relevant aquaculture NRSP-7 projects with supporting data for Australian priorities.

It is estimated that the direct cost saving to Australian industries from accessing existing international data would total \$11.17 million with a resulting benefit/cost to industry productivity from potential international collaboration of over \$1 billion. Success in capturing benefit from this opportunity is subject to the Australian Government signing of an MOU agreement with IR-4/CAN PMC to allow formal establishment of international collaboration including priority sharing and data sharing.

Milestone 26. Deliver a report to establish a cross industry AgVet minor use investment program. Due 31 October 2015 - Completed with the submission of the this PRJ-009981 final report - submitted on 1 December 2015

PRJ-010406

Milestone 1. Exchange of project contract. Delivery by 1 March 2016.

Milestone 1 delivered 24 March 2016. This was later than anticipated than the 2016 AgVet Collaborative Forum prospectus and presented significant challenges to timely delivery of imitating the project and timeframes for delivery of the project milestones.

Milestone 2. Provide industry stakeholder consultation in assembly and refinement of AgVet priorities. Delivery by 30 April 2016.

Milestone 2 delivered 26 May 2016. Industry stakeholder consultation in assembly and refinement of AgVet priorities has been provided in consultation with RDCs. Formal face to face meetings have taken place with RDCs to the 30 April 2016; GRDC, HIA, CRDC, FWPA, SRA, RIRDC and AWI. Further meetings have taken place with Dairy Australia and Wine Australia by the 13 May 2016. All plant industries stakeholders have been provided details on the planned Forum prioritisation workshops in June 2016. Industry peak body briefing meetings have been held with Ausveg and Grain Producers Australia. Additional meetings were held with the red-meat council members, NFF Chemicals Task Force members and Australian Dairy Farmers to discuss options for future active participation in the AgVet Collaborative Forum. A summary of the 2016 AgVet grants projects supported by the Federal Government AgVet grants program was distributed to stakeholders. Outcomes of 2015 grants projects has not yet been distributed to Forum stakeholders as this is yet to be made public by the Department of Agriculture and Water Resources. Plant and animal industry priorities for gaps lists were finalised and distributed to registrant stakeholders and planning for a prioritisation workshops was managed through separate plant and animal industries Forum steering committees.

Milestone 3. Assemble industry priorities for a prioritisation database. Delivery by 30 April 2016.

Milestone 3 delivered Plants 16 May 2016 & Animal 27 May 2016. An Excel pivot table spreadsheet detailing all ranked industry top 5 priorities and technical solution options was distributed to all Plant and Animal Forum participants.

Milestone 4. Consultation of draft industry priorities with CropLife and AMA members. Delivery by 30 April 2016.

Milestone 4 delivered 13 May 2016. Two formal meetings have been held with both CropLife Australia and Animal Medicines Australia. Formal face-to-face meetings have been held with 15 AgVet companies to the 30 April 2016 to highlight investment opportunities, proposed approach and review of priorities.

Milestone 5. Workshops delivered to prioritise and achieve consensus on co-investment options. Delivery by 30 June 2016.

Milestone 5 plant industries delivered 8 June 2016. A plant industries AgVet Collaborative Forum prioritisation for gaps workshop was held on the 8 June 2016 in Canberra involving representation from all Australian Plant industries with 60 participants including 15 registrant companies being represented.

Animal industries workshop cancelled in with agreement of RIRDC and the steering committee and delivered by 12 August 2016 - The 2016 animal industry priorities for the participating RDCs were aggregated and mapped against the 2015 response by registrants. As previously discussed with RIRDC, following significant consultation with all the veterinary medicine registrants, AMA, RIRDC and AWI, a decision was made to cancel the prioritisation for gaps workshop process for the animal industries priorities. This was due to the very low number of registrants registering for the workshop, not enabling the process to proceed as planned. A key significantly influence was the lack of red meat industry engagement in the 2016 Forum. In discussions with RIRDC, AWI and AMA, it was agreed that registrant feedback for the industry pest priorities would be facilitated through one-on-one meetings with individual companies. This task was completed by mid July 2016 enabling this updated list to be also populated onto the RIRDC website as a revised file in late August 2016. the project should be able to deliver this within the current contracted budget as long as no more than one trip to Sydney is required. While this change in plan is unfortunate, the re-worked process enabled a revised animal industries priorities list to be finalised to support RDC eligibility for the AgVet grant process.

Milestone 6. Evaluate workshop outcomes and report submitted to RDCs and registrants. Delivery by 30 June 2016.

Milestone 6 delivered to plant industries 30 June 2016, delivered to animal industries 25 August 2016, Forum outcomes were distributed to plant industries RDCs and registrants for initial comment on 17 June 2016 and finalised on the RIRDC website on the 30 June 2016. Animal industry outcomes were distributed to RDCs and registrant stakeholders on 12 August 2016 and finalised on RIRDC website on the 25 August 2016.

There was significant increased interest from CropLife Australia registrants in participating in the 2016 Forum with increased resources being provided. While the animal program was protracted due to delays from trying to bring other industries on board, the program delivered on planned milestones and outcomes around six weeks later than anticipated.

Milestone 7. Deliver a 1-day animal and 1-day plant industry strategic discussion workshop. Delivery by 30 September 2016 – Variation approved for delivery 31 October 2016.

Milestone 7 delivered to plant industries 20 October 2016, delivered to animal industries 25 October 2016. A one-day strategic workshop was delivered to plant industries on the 20 October 2016 with 30 attendees and to animal industries on the 25 October 2016 with 18 attendees. (See agenda appendix 11.1). Key issues discussed at the plant industry workshop included cross industry insecticide and fungicide resistance surveillance and management. Key concerns discussion occurred around Lepidoptera and aphids, plus Botrytis cinerea, Aspergillus sp. and other fungal pathogens. At the animal industries strategic workshop, anthelmintic resistance and metabolism of local anaesthetics for animal welfare was discussed.

Milestone 8. Support RIRDC in Delivering an annual update to the RIRDC AgVet website and communications program. Delivery by 30 September 2016 – Variation approved for delivery 31 October 2016.

Milestone 8 website update delivered 30 June 2016 and 25 August 2016, articles delivered 16 September 2016, factsheet update delivered 7 November 2016. The AgVet Collaborative Forum webpage has been updated twice on the RIRDC website. Summaries of key forum outcomes and the priorities list have also been published on an updated 2016 RIRDC AgVet website. Articles on the current AgVet Collaborative Forum project have been published in the RIRDC Diversity Magazine

and the Rural R&D Corporations Innovation in Action publication. An updated factsheet on the AgVet Collaborative Forum has been prepared and forwarded to RIRDC to be included on the RIRDC AgVet website home page.

Milestone 9. Deliver a report to stakeholders to continue the operations of the AgVet Collaborative Forum. Delivery by 30 September 2016 – Variation approved for delivery 31 October 2016.

Milestone 9 delivered 12 October 2016. A revised prospectus for animal and plant industries was developed in consultation with the plant and animal industries Forum steering committee. These prospectus have been discussed and distributed to industry stakeholders, RDCs and registrants for consideration in continuing the operations of the AgVet Collaborative Forum into Phase III for a further three years until the end of 2019.

12. Implications

Through the stakeholder engagement in delivering this project, 82 grower and RDC organisations, 23 AgVet registrant companies and 5 GLP trial services providers have participated or been contacted in the delivery of the AgVet Collaborative Forum over the 14 months of delivery of PRJ-009981. There were consistently over 40 industry stakeholders involved in each meeting of the Forum.

The AgVet Collaborative Forum Prioritisation Workshops held in Canberra during June 2015 involved over 100 participants including industry representatives, RDCs, state and federal government, APVMA and 20 registrant companies. The workshops delivered a completed priorities list for plant and animal industries, identifying where there is technical support of the registrants.

The outcome for the plant industries from the 2015 prioritisation for gaps workshops are particularly significant with the industry discussion of issues with registrants identifying solutions to 58%, or a third of the top five industry issues, which previously had no identified solution. This highlights the strategic value of this discussion and the AgVet Collaborative Forum. The outcomes of this process will have significant potential productivity benefits for these industries in the future. This discussion may not have occurred, or it may have taken much longer to identify solutions for these gaps.

The prioritisation needs of animal industries highlighted the high priority for almost all animal industries for access to local anesthetic technology for improving animal welfare. The workshop highlighted the opportunity for industries to work together on needs to address common issues.

Plant industries priorities for gaps outcomes in 2015 - 319 A's (Solutions with technical support of registrants) and 94 P's (Solutions sought by industry permit):

- 326 unique top five crop/pest priorities submitted (total of 384 priorities submitted including lower ranking priorities)
- 135 top five crop/pest priorities had no identified solution (41% of top five submissions)
- 78 new potential solutions were identified by registrants (addressing 58% of priorities with no solution)
- At least one additional new solution was identified by registrants for 90 of the 191 priorities already with a solution identified by industry (47% of all top five identified solution priorities) potentially improving resistance stewardship

Animal industries priorities for gaps outcomes in 2015 - 68 A's (Solutions with technical support of registrants) and 8 P's (Solutions sought by industry permit):

- 98 unique top five animal/pest priorities submitted (total of 183 priorities submitted including lower ranking priorities)
- At least one additional new solution was identified by registrants for four of the 98 priorities already with a solution identified by industry (4% of all top five identified solution priorities)

Plant industries priorities for gaps outcomes in 2016 - 500 unique crop/pest issues were identified for all Australian plant industries seeking solutions to registration gaps. Of these industry issues:

- A total of 315 'A-L (Label) projects and 143 'A-P' (Permit) projects were identified
- 173 had no identified solution for which 90 new potential solutions have been identified by registrants

- An additional 96 new solutions were identified by registrants adding to existing options proposed by industry
- Additionally 24 solutions already on registration track that industry was not previously aware of were identified through discussions.
- Consideration of chemical modes of action and stewardship for resistance management were discussed during the Forum. These outcomes will improve pesticide resistance management by industry through access to a wider range of modes of actions.

Animal industries priorities for gaps outcomes in 2016 - 69 unique animal pest issues, resulting in 36 solutions technically supported by registrants.

There was considerable success in maintaining a cross industry culture of collaboration in the plant industries in 2015 and 2016. The exit survey from the Plant Industries prioritisation for gaps workshop in 2016 has indicated that a high level of motivation (Mean Av score 81%) has been maintained and there is every confidence (Mean Av score 78%) that the project will deliver its planned outcomes. The recent survey has also indicated the recognised significant value of assembling a priorities list (Mean Av score 80%) The plant industries highlighted the continued significant value in discussing these priorities with registrants (mean Av score 79%). There continues to be significant alignment of motivation and confidence scores, even with a significant number of new participants to the Forum (STDDEV 16-19%).

There were a number challenges that impacted on the delivery of this project in delivery of the 2016 AgVet Collaborative Forum including:

- Delay in finalisation of financial commitment of some Plant Industry RDCs to the AgVet Collaborative Forum and delays in review of AgVet priorities by the RDC with their relevant peak industry body
- Delay of a public release of summary of projects supported by the Federal Government AgVet grants program
- Delay of finalisation of Animal Industry prioritisation due to limited Animal Industry RDC participation impacting on original plans.

The lack of registrations for the Animal Industry prioritisation for gaps workshop was a significant issue for the project. While the project worked around this to deliver options for grant outcomes for the participating industries, several key issues were identified by registrants as a major contributing factor to a lack of a business case for participation:

- The absence of the red-meat industries lowering the commercial value of participation in the Forum
- The issues of existing off label use and resistance evolution to anthelmintics is a significant concern and it was suggested that RIRDC should develop a resistance management strategy and stewardship plan for the goat and Alpaca industries before commitment to investment and technical access to drench products would be considered.

A number of broader strategic cross industry AgVet issues would benefit from further workshops providing opportunity for further feedback to industry on leading into a potential annual review of priorities beyond 2016. Plant industry workshops should potentially include further discussion on cross industry risks of fungicide resistance including *Botrytis cinerea* and insecticide resistance in Lepidoptera and aphids. Animal industry workshops should continue to focus on cross industry risks of anthelmintic resistance.

The exit surveys from the 2016 strategic meetings indicated that the facilitation ranking of the Forum had increased to a very high score of 88%. The combined plant and animal strategic meeting exits surveys also indicated reasonably high strategic value of these workshops of 77% and highlighted the continued significant value in discussing these priorities with registrants (mean Av score 87%). The exit survey indicated that there should be continue involvement of industries in both the plant and animal Forums with all but one animal industry suggesting the Forum should continue.

12.1 Delivery of project objectives and planned outcomes

The PRJ-009981 project has delivered on the planned objectives and outcomes resulting in:

Options for a new framework and functional collaborative AgVet investment program - to increase current industry and commercial registrant participation and investment being presented and achieving stakeholder consensus on models to deliver the outcome of delivering increased AgVet tools to Australian agriculture.

Delivery of a new framework and functional collaborative AgVet investment program – Delivered through consideration of the options presented to stakeholders through the project. While there was consensus support from industry and RDCs for the proposed AgVet Collaborative Forum governance and delivery model as detailed in chapter 3, to achieve agreement for financial support from RDCs and registrant peak bodies, a more cost effective approach as detailed in Appendix 7 was proposed. This has resulted in financial support for the ongoing delivery of the AgVet Collaborative Forum to industry in a model governed and managed by RIRDC with seven participating plant industry RDCs which represent all plant industry RDCs in Australia, one animal industry RDC, three peak meat council organisations plus the peak registrant organisations CropLife Australia and Animal Medicines Australia, these include:

- Horticulture Innovation Australia (HIA)
- Grains Research and Development Corporation (GRDC)
- Rural Industries Research and Development Corporation (RIRDC)
- Australian Grape and Wine Authority (AGWA)
- Cotton Research and Development Corporation (CRDC)
- Sugar Research Australia (SRA)
- Forestry & Wood Products Australia (FWPA)
- Red-Meat Council Members (Note - Non-RDC Aligned)
- Australian Wool Innovation (AWI)
- CropLife Australia (on behalf of its member companies)
- Animal Medicines Australia (on behalf of its member companies).

This achievement of stakeholder support for the Forum has far exceeded the project target that was agreed with RIRDC and the Department of Agriculture and Water to achieving the ongoing financial support of at least four plant and animal industry RDCs. This achievement should enable sufficient industry engagement through future Forums to fully subscribe the funding available through the Departments AgVet grants program.

The AgVet Collaborative Forum framework detailed in the agreed prospectus to be managed with oversight by RIRDC will result in:

- **Improved priority setting and cross industry collaboration**, particularly with all plant industry RDCs being involved
- **Agricultural industry and commercial co-investment in data generation** supported through initial government grant incentive program with HIA and GRDC submitting applications for co-investment support.
- **Potential cost savings achieved through cross industry efficiencies and national and international collaboration** and co-investment as detailed in chapter 10 for plant industries of up to \$567 million has been identified, noting potential benefits of Australian aquaculture industries of up to \$496 million if this industry chose to take up the option of participation in the future. Success in capturing benefit from this opportunity is however subject to the Australian Government signing of an MOU agreement with IR-4/CAN PMC to allow formal establishment of international collaboration including priority sharing and data sharing. Consensus through the Forum also concluded that ranking economic impact to industry from projects is important, but it must be transparent and simple to understand.
- **A cost effective and sustainable program that is supported by all stakeholders**, with participating industries and their RDCs in the future Forum accounting for over 95% of all AgVet use in Australia.

Informing chemical companies of potential market demand to assist in their decisions to register Australian uses has been a significant outcome for the project will should lead to greater commercial investment in AgVet and improve technology access for producers.

The development of the agricultural priorities list is one of the most significant outcomes for this project. There has been considerable feedback from registrant companies noting the value of this tool to improve understanding of industries needs and the business case for investment. Examples being;

“I would like to thank you for your efforts as regards minor crop usage of new chemistry, the list of crops along with pests and priority grading has been very helpful. Thanks and regards.”
Gerry Shepherd ISK

The Forum has provided significant opportunity for producers and the chemical industry to interact with the department and the APVMA to discuss the most effective and efficient methods of improving access to chemicals. This has been particularly important for the consideration of industries working together on crop grouping solutions for projects.

The population of the plant industry priorities list into the global minor use priorities list delivered through this project, is a very significant step for Australia’s crop protection needs being more widely recognised at an international level. This will significantly contribute to facilitating opportunity for greater international collaboration, particularly with IR-4 and CANMUP through global joint review programs through this awareness of common needs. Australia’s active participation in the global minor use collaboration program both through this project and through HIA agreement to lead the pilot global temperate minor use project, will lead to further collaboration opportunity through the relationships now established.

Success in promoting information sharing and co-investment opportunities and technical solutions has been a major outcome for the project. The consensus of the early Forum discussion suggested that the AgVet Collaborative Forum would need to explore suitable options for priority sharing both by industries and registrants, recognising that Australia may have some unique drivers due to its small market size. While it was recognised that there are some significant commercial and

risk concerns for both industry and registrants, the success of the AgVet Collaborative Forum is dependant on finding workable solutions to deliver this outcome. Delivering a workable model for information sharing between industries and registrants is a major factor in the success of the project. Especially enabling a detailed and structured discussion, matching industry needs for pest management to a significant number new solutions identified by registrants.

Considerable progress made on developing a new cross industry culture of collaboration and survey has indicated that a high level of motivation has been achieved and there is every confidence from stakeholders that the project will deliver its planned outcomes. The most recent of 3 stakeholder surveys, has also indicated the recognised significant value of assembling a priorities list. The value of the plant industries noted greater value of the process and there was significant value in discussing these priorities with registrants. There continues to be significant alignment of motivation and confidence scores, even with a significant number of new participants to the Forum.

The PRJ-010406 project has delivered on the following planned project outcomes:

Delivery of a functional and sustainable system for growers to effectively share their priorities for chemical access needs with other growers, RDCs and chemical companies. The project has continued to deliver a functional and sustainable system with increased support from all stakeholders in 2016 compared with the 2015 Forums.

Deliver cost savings from investment and reduce current impacts of AgVet chemical market failure. The project has continued to deliver additional cost savings to industry through identification of new solutions to emerging pest issues through an efficient and transparent process, enabling discussions with international programs on future collaborations to take place potentially delivering future cost savings and increased market access for produce.

Facilitate cross industry prioritisation and investment for improved access to uses of AgVet chemicals. The project has delivered an improved priority setting and cross industry collaboration process in 2016, building on those established in 2015. The project has achieved significant increased interest and activity in agricultural industry and commercial co-investment in data generation supported through initial government incentive, with grant applications increasing from less than 50 in 2015 to just under 90 in 2016. The PRJ-010406 project has continued to deliver cost savings to industry, RDCs, registrants and government through cross industry efficiencies by bringing all stakeholders together in an efficient and structured program of discussion.

12.2 International collaboration

Australian plant industry AgVet minor use priority list for global joint review

Building on the original 35 priorities submitted in February 2015, a revised list of 566 Australian plant industry AgChem priorities was submitted to the OECD Global Joint Review Program. This list was submitted as agreed as an outcome of the AgVet Collaborative Forum prioritisation meeting including all crop/pest priorities plus a nominated potential chemical solution if classified as an A priority.

While there may be future requests for changes to this priorities list, this submission marks a major milestone for Australia in bringing together for the first time a combined cross plant industry AgChem priority list for which Australian priorities and potential solutions can be directly compared to other OECD nations. This list to be released in final form in August 2015 clearly identifies potential opportunity for collaboration with other OECD nations and potential cost savings in delivery of trial data. The list of 566 Australian priorities have now been mapped against current and previous IR-4, NRSP-7 and Canadian PMC Minor Use Program projects to identify data sharing and collaboration opportunity. This list has been distributed to the relevant RDCs.

Through the project, Australia participated in the 2014 and 2015 IR-4 and CANMUP prioritisation workshops. The project also supported Australian participation in the Global Minor Use Workshop delivering 3 potential and 6 reserve projects relevant to Australia. This workshop had participation of over 35 countries. Following discussions with HIA, it was agreed that Australia would lead the temperate program for the global minor use collaboration project. This was confirmed to the Global minor use coordinating committee at a meeting on the 13 November 2015.

Formal meetings have taken place face to face with the executive of the North American IR-4 program and the Canadian minor use program (CANMUP) to gain insight into the key steps and recommendations for the establishment of an effective and functional collaborative Australian minor use program. IR-4 and CANMUP have expressed significant support and goodwill towards the establishment of an Australian minor use program with offers of potential collaboration. This would potentially include participation in joint prioritisation and data sharing. Both the IR-4 program and Canadian Minor Use Program executive have recommended the following key considerations, which are essential for the establishment and success of an Australian AgVet collaborative minor use program;

1. Open discussion between industries and their priorities with companies on potential solutions
2. Adopting a consensus approach to reaching agreement with stakeholders
3. Effective financial and non-financial incentives program to maximise commercial investment support for the program
4. Mechanism for effective engagement with the regulator to receive advice at key decision points in the prioritisation process
5. Agreement by all stakeholders on the agreed program outcomes and success measures

Items 1,2 and 5 have been agreed to and recommended for implementation within the AgVet Collaborative Forum. There is clearly a need for Government proposals for incentives to be tabled to the AgVet Collaborative Forum as detailed in item 3 above. In discussions with CANMUP and IR-4 it has been indicated that the Australian AgVet Collaborative program would potentially fail without effective incentives.

There is currently no legislative or regulatory framework for engagement of the regulator APVMA with the AgVet Collaborative Forum to receive advice at key decision points in the prioritisation process as adopted by IR-4 and CAN MUP as detailed in item 4 above. This includes early vetting of proposed priorities for amber and red flags in regard to environment, human health and trade. This will require urgent discussion within Government to enable a mechanism for this to occur. Without this mechanism both IR-4 and CAN MUP have indicated that there will be significant wastage of prioritisation time and costs in trying to reach agreement on final recommended priorities.

The PRJ-010406 project has continued to provide representation and support on behalf of the Australian agricultural industries in follow-up teleconferences to the Global Minor Use Workshop held in September 2015. This included support to the Australian and EU led - Temperate Project being supported by Horticulture Innovation Australia. There was feedback from the USA IR-4 Program was that they were disappointed that Australia was unable to participate in the annual meeting in 2016 and would welcome continued engagement and participation going forward. The AgVet Collaborative Forum priority list outcomes were shared with IR-4, Canadian Pest management Centre Minor Use Program and the EU minor use Coordinator. These programs have continued to reciprocate in providing access to outcomes of their priority discussions and investment programs.

12.3 Promotion of the Agvet Collaborative Forum to Stakeholders

There have been 75 plant and animal industries invited to the Forum, plus national peak agricultural stakeholder bodies, registrant members of CropLife Australia and Animal Medicines Australia and representatives of the Department of Agriculture and Water and APVMA (See Appendix 1). During PRJ-009981, three AgVet Collaborative Forum agendas (See 2015 agendas in appendices 2-6), eight discussion papers, two prioritisation workshop agendas and four outcomes documents including the finalised prioritisation list have been circulated to all stakeholders by direct email.

The AgVet Collaborative Forum webpage has been updated for PRJ-009981 on the RIRDC website. Summaries of key Forum outcomes and the priorities list have also been published on the RIRDC Website and communicated to Forum stakeholders by email. The Department of Agriculture and Water has also linked to these pages on the AgVet program website (Appendix 13).

A press release distributed on the 17 July 2015 has been widely picked up in the national rural press and radio. With information provided by the project communications consultant to RIRDC - Sauce Communications, of the 35 media stories, 15 were online news, 11 were radio and 9 were print. The stories and interviews that have been published were positive, conveyed the key messages in the media release and all mentioned RIRDC and the AgVet priority list. Of the articles that were provided via RIRDC's media monitoring service, indicate a combined audience reach of almost 120,000 people.

ABC Rural radio showed the strongest support, broadcasting 10 of the 11 radio interviews. They broadcast a pre-recorded package comprising interviews with Simon Winter and Reg Kidd that ran for about five minutes on ABC Country Hour in Queensland, South Australia and the Northern Territory, as well as on Breakfast Rural Reports across a number of regional stations across NSW, Victoria and SA. The fact ABC Rural broadcast this story as a five-minute interview, indicates the value, timeliness and interest of the story to the agricultural community.

Fairfax Agricultural Media's mastheads of The Land (NSW), Queensland Country Life (Qld), Stock Journal (SA) and Farm Weekly (WA) ran stories on their websites drawing content almost directly from the media release, with The North Qld Register published this story in print. The QCL print edition also published an opinion piece by fruit and vegetable body GrowCom about the priority list and their involvement in the process. The online agricultural news site Beefcentral.com published the media release verbatim, while a number of regional papers published excerpts from the release.

The updated RIRDC website project also holds the official link to AgVet Collaborative Forum priorities list which has been used as a criteria by the Department of Agriculture and Water Assistance Grants – Access to Industry Priority Uses of AgVet Chemicals Grants Program. An AgVet Collaborative Forum fact sheet developed with the support of this project has been completed and circulated to all stakeholders.

The PRJ-010406 project in 2016 has delivered three AgVet Collaborative Forum meetings including a plant industry prioritisation for gaps workshop plus separate plant and animal industry strategic discussion workshops (See 2016 agendas in appendices 7-9). In the AgVet Collaborative Forum meetings in 2017, there have been 9 RDCs, 14 plant and animal industry producer organisations plus national peak agricultural stakeholder bodies, and 17 plant industry registrants including members of CropLife Australia and 7 animal industry registrants including members of Animal Medicines Australia, plus representatives of the Department of Agriculture and APVMA (See appendix 10).

All project communications in PRJ-010406 have continued to be by direct email as per the agreed methodology of the AgVet Collaborative Forum prospectus. All stakeholders were provided background information and links on the 2016 AgVet grants program, an agenda and registration for

the Agvet Collaborative Forum Plant industry prioritisation for gaps workshops in June 2016 and outcomes of the prioritisation for gaps process for both plant and animal industries.

Forum outcomes in 2016 have been direct emailed to all participating investing RDC industry stakeholders and updated on the RIRDC website (Appendix 13). A summary of 2016 Forum outcomes has been made public on the RIRDC website and detailed forum discussions and outcomes have been forwarded to all participation industry and RDC stakeholders by direct email.

The AgVet Collaborative Forum webpage has been updated for PRJ-010406 on the RIRDC website. Summaries of key forum outcomes and the priorities list have also been published on an updated 2016 RIRDC AgVet website and communicated to Forum stakeholders by direct email. The Department of Agriculture has indicated that they would also continue to provide links to these pages on the AgVet program website.

Articles on the current AgVet Collaborative Forum project have been published during 2016 in the RIRDC Diversity Magazine and the Rural R&D Corporations Innovation in Action publication. An updated factsheet on the AgVet Collaborative Forum has been prepared for RIRDC to be included on the RIRDC AgVet website home page.

13. Recommendations

The following key considerations are considered essential for the establishment and continued success of an Australian AgVet collaborative minor use program:

- Open discussion between industries and their priorities with companies on potential solutions
- Adopting a consensus approach to reaching agreement with stakeholders
- Effective financial and non-financial incentives program to maximise commercial investment support for the program
- Mechanism for effective engagement with the regulator to receive advice at key decision points in the prioritisation process
- Agreement by all stakeholders on the agreed program outcomes and success measures.

The AgVet Collaborative Forum should continue to address the key principals in addressing stewardship and priorities including:

1. An industry issue selected should have no ‘viable’ registered solution. Establish and implement an effective prioritisation process through identification with producers where there are no, or limited products registered for effective control of pests including where current pesticides are:
 - Ineffective due to resistance
 - Incompatible with IPM systems, or
 - Unsuitable for trade / market access
2. Establish data generation projects to support registration and permit approvals demonstrating that new uses sought would;
 - Not pose unacceptable risks to the environment, users or the crop.
 - Not result in unacceptable residues
 - Be effective, and
 - Not adversely affect Australia’s trade
3. AgVet products selected should take into consideration of chemical actives currently under Australian APVMA Priority 1-4 review.

With survey feedback on the AgVet Collaborative Forum on motivation for involvement at the last Forum in the 89% range and confidence of success of the Forum currently in the 75% range, there is clearly opportunity to further boost industry confidence in the delivery of outcomes. Significant progress and industry consensus from a diverse group of stakeholders has been achieved in a relatively short time. While the Agvet Collaborative Forum is only the first step, there is every confidence based on survey results and feedback from registrants that the project will successfully deliver on providing improved AgVet technologies for producers.

While the lower number of supporting animal industries is a disappointing outcome, it was clear from discussion at the Forums, the strategic thinking and approach to addressing market failure of AgVet needs by the plant industries was much more mature in development due to the significant engagement on the issue over the last 7 years. There clearly needs to be continued ongoing dialogue with these now non-participating animal industries if there is a change in strategic need for these organisations. The most appropriate mechanism for this dialogue to take place is through Animal Health Australia.

There has however been considerable progress made on developing a new cross industry culture of collaboration and there is every confidence that this will continue. To facilitate the continued culture of collaboration of the AgVet Collaborative Forum, it will be important that the Australian Government through the Department of Agriculture and Water carefully manage their potential financial investment in this program through strategic allocation of funds into suggested groups of 'like industries'. This will avoid issues with squeaky wheels and compartmentalise investment priority discussions around more common elements of need.

It is recommended that future investment consider measurement of impacts from the AgVet Collaborative Forum. Due to the long timeframes for resulting delivery of permit or label outcomes from the initial Forum program, estimated benefits will need to be modelled forward based on the delivery of actual outputs. A commissioned impact assessment should report on the following;

- Profitability and productivity benefit
- Market access benefit
- Resulting industry growth potential
- Resistance and sustainability benefit
- OH&S and environment benefit
- Estimated cost savings and efficiency in delivery of projects

While the commissioned impact assessment approach is highly dependent on agreed assumptions, these can be well managed with industry and registrant stakeholder input. There should also be consideration of the economic measures and indicators used in the North American IR-4 impact studies. The costs of undertaking the review and reporting will need to be factored into program budgets.

It is recommended that further consideration be given by the Department of Agriculture and Water Resources for future discussion within the AgVet Collaborative Forum on the following;

- Utilising the plant and animal industry priorities identified including the list of plant industry priorities resulting from the workshop, give consideration to continued co-investment with industry and registrants in these priorities to incentivise continued engagement in the Agvet Collaborative Forum
- Engage in discussion with agricultural industry investors, particularly the RDCs and registrants on the effective financial and non-financial incentives program to maximise commercial investment support for the program, including funding for regulatory support of the priorities identified in the Forum
- Explore regulatory options to improve mechanisms for effective engagement with the regulator to receive advice at key decision points in the prioritisation process

- Establishment of an MOU agreement with IR-4/CANMUP to allow formal establishment of international collaboration including priority sharing and potential data sharing
- Discuss non-participation of key animal industries and options to increase the value of this program to these industries, including red-meat and aquaculture.

GLP residue laboratory capacity could be a potential trial bottleneck as a consequence of an increase in AgVet investment through the Department of Agriculture and Water Resources AgVet trial grants program. With a potential time lag of at least 6 months to order, commission equipment and train staff to increase GLP residue analysis, combined with a maximum storage period of 6 months for GLP residue materials before processing, it will be critical for study directors to ensure GLP laboratories have adequate capacity on stream and commissioned to process a potential initial potential backlog of GLP field trial materials.

To reduce the impact of these issues to the delivery of the outcomes from increased Federal Government grant and RDC investment, it is recommended that:

- Consideration and encouragement be given to increased international collaboration of RDC funded programs, based on principles of agro-ecological co-equivalence, especially for animal studies, to reduce unnecessary duplication of trials and increase the use of international field and laboratory GLP capacity
- Regulatory options or temporary exemptions to allow for the lack of aquaculture specific GLP expertise in Australia should be considered
- Utilisation by RDCs of the commercial company GLP capacity for animal studies with companies such as Bayer and Elanco should be considered
- Encourage utilisation of GLP field service providers, especially in the first 12 months with access to international GLP laboratory analytics to reduce any initial backlog of field trial samples
- A survey of RDCs within the first 12 months of the Federal Government grant program is implemented to determine timeliness of delivery of both field and laboratory GLP services to determine if adjustment to investment timeframes is warranted.

It is recommended that industries continue to co-invest and collaborate in the Agvet collaborative Forum. It is also recommended that RIRDC continues to take cross industry leadership in facilitating the management and delivery of the Forum. While the current model of delivery through consultants is a low cost and effective model for access to the necessary expertise during its establishment, the Forum should explore longer-term models where the Forum is delivered through larger multi-industry organisations facilitating currently facilitating stakeholder engagement on similar issues. Organisations such as Plant Health Australia and Animal Health Australia should be considered as options.

The outcome of PRJ-009981 was that all plant industry RDCs and three animal industry RDCs entered into a funding agreements with RIRDC, under the recommended governance model as identified in the investment prospectus in late 2015. A second round of AgVet prioritisation workshops were delivered in June 2016.

In review of survey feedback on the 2016 AgVet Collaborative Forum, motivation for involvement has increased to 88% and confidence of success of the Forum has been maintained. It is recommended that RDCs continue to invest in the AgVet Collaborative Forum to deliver continued benefits to their industry producers as identified in the investment prospectus. The Forum process and operations should continue to be reviewed and modified to ensure that the opportunity for addressing

market failure needs is optimised. This includes a need for greater dialogue between industry and registrants on pest issues where there are no identified solutions.

It is important that the AgVet Collaborative Forum continues to engage in international collaboration programs to enhance investment in minor and emerging industries. It will be important that Australia is well represented at the next Global Minor Use Summit to be held in Canada in October 2017.

Following delivery of PRJ-010406, it is anticipated that the Plant industries will transition to the recommended investment, governance and delivery model identified in the investment prospectus September 2016. Based on written response to RIRDC from RDCs to the 31 November 2016, it looks likely that all industries that participated in the 2016 Agvet Plants Forum will participate in the 2017-2019 program. There is however significant concern that there appears to be inadequate interest from a broad range of animal industries in 2016 for transition to future investment in the Animal Industries AgVet Collaborative Forum.

Appendices

Appendix 1. RIRDC Access to AgVet Chemicals Collaborative Forum Invited Organisations List

Department of Agriculture and Water

Australian Pesticides and Veterinary Medicines Authority (APVMA)

Victorian State Government COAG representative - Agricultural and Veterinary Chemicals

Plant Health Australia (PHA)

Animal Health Australia (AHA)

Australian Pork

Dairy Australia

Fisheries Research and Development Corporation (FRDC)

National Aquaculture Council

Meat and Livestock Corporation (MLA)

Australian Meat Processor Corporation (AMPC)

Australian Wool Innovation Limited (AWI)

Red Meat Council of Australia

Sheep Meat Council of Australia

Cattle Council of Australia

Australian Lot Feeders' Association (ALFA)

Goat Industry Council of Australia (GICA)

Australian Chicken Meat Federation

Australian Egg Corporation Limited (AEC)

Forrest and Wood Products Australia (FWPA)

Rural Industries Research & Development Corporation (RIRDC)

Australian Honey Bee Industry Council

Ricegrowers Association of Australia (RGA)

Australian Fodder Industry Association (AFIA)

Horticulture Australia Limited (HAL) and their member organisations

Almond Board of Australia,

Apple and Pear Australia Limited (APAL)
Australian Asparagus Council
Avocados Australia Limited
Australian Banana Growers' Council (ABGC)
Australian Blueberry Growers Association (ABGA)
Canning Fruit Industry Council of Australia Ltd
Cherry Growers of Australia Inc (CGA)
Chestnuts Australia Inc.
Custard Apples Australia Inc
Dried Fruits Australia Inc.
Australian Dried Tree Fruits Inc.
Australian Garlic Industry Association
Hazelnut Growers of Australia Inc.
Australian Lychee Growers' Association (ALGA)
Australian Macadamia Society Limited (AMS)
Australian Mango Industry Association (AMIA)
Australian Melon Association Inc.
Australian Mushroom Growers' Association (AMGA)
Australian Nashi Growers' Association Ltd (ANGA)
Nursery & Garden Industry Australia (NGIA)
Australian Nut Industry Council Ltd (ANIC)
Australian Olive Association Ltd.
Australian Onion Industry Association (AOIA)
Papaya Australia Ltd
Passionfruit Australia Inc.
Australian Pecan Growers Association Inc.
Persimmon Australia Inc.
Pistachio Growers Association Inc.
Processing Tomato Research Council Inc.

AusPrune
Pyrethrum Industry/Botanical Resources Australia
Raspberries and Blackberries Australia Inc
Strawberries Australia Inc.
Australian Table Grape Association Inc.
Turf Australia
Australian Walnut Industry Association
Horticulture Coalition of SA
Protected Cropping Australia
Growcom
Ausveg
Citrus Australia
Summerfruit Australia
Australian Herb & Spice Industry Association
Sugar Research Australia (SRA)
Canegrowers
Cotton Research and Development Corporation (CRDC)
Cotton Australia
Australian Grape and Wine Authority (AGWA)
Wine Grape Growers Australia (WGGA)
Grains Research and Development Corporation (GRDC)
Grain Producers Australia (GPA)
National Farmers Federation (NFF) - AgVet Chemicals Taskforce
Plastics and Chemicals industries Association
CropLife Australia and member companies
Animal Medicines Australia and member companies
National Working Party on Pesticide Applications (NWPPA)

Appendix 2. First RIRDC Access to AgVet Chemicals Collaborative Forum Agenda

Federal Golf Club Federal Golf Club, Gowrie Drive Red Hill Canberra ACT

Friday 7 November 2014 - 9.30 am to 3 pm

9.30 am 1. Introductions and background to Access to AgVet Chemicals Collaborative Forum

- Introduction of presenters/facilitators and participants
- Background to RIRDC project PRJ-009981 - Delivery of Access to AgVet Chemicals Collaborative System.
- Department of Agriculture – Government Election Commitment for AgVet
- Overview of the day and expected outcomes

10.10 am 2. Update on cross industry AgVet access discussions and activities to date

- Presentation of issues presented in the tabled discussion document
- Outcomes of RIRDC PRJ-009454 - AgVet investment prioritisation options - Workshop outcomes report
- General discussion

11.00 am 3. Purpose and outcomes for the AgVet forum

(Discussion paper to be circulated prior to the forum)

- Identify what success looks like for the AgVet forum and how it will benefit industries
- Industry indicators and measures of the success in increasing access to minor use, including the collaborative system
- Establishment of baseline indicator measures
- General discussion

1.00 pm 4. Access to AgVet Chemicals Collaborative Forum governance

- Development and implementation of a sustainable governance structure for the forum
- Focus of management and oversight by cross-industry RDCs and other stakeholders
- General discussion

1.30 pm 5. Forum operation and communication

- Discussion on options for agreed processes for operation of the forum
- Role of stakeholders and options for advisory sub-committees
- Forum communications
- General discussion

1.45 pm 6. Identifying and sharing industry priorities at the forums

- Issues and options for a recommended approach
- General discussion

2.15 pm 7. Department of Agriculture - AgVet chemical regulation reform agenda

- Role of the collaborative forum in the regulation reform agenda
- Questions and discussion

2.40 pm 8. Next steps on agenda planning for next forum 5 December 2014

- Discussion on key forum agenda issues for 5 December 2014 and forums 2015

3.00 pm Forum close

Appendix 3. Second RIRDC Access to AgVet Chemicals Collaborative Forum Agenda

Canberra Business Event Centre - Regatta Point, Commonwealth Park, Acton, Canberra ACT

Friday 5 December 2014 - 9.30 am to 4 pm

9.30 am **1. Introductions and background to Access to AgVet Chemicals Collaborative Forum**

- Introduction of presenters/facilitators and new Forum participants
- Overview of the day and expected outcomes

9.45 am **2. Update on cross industry AgVet access discussions and activities to date**

- Outcomes of 1st AgVet Collaborative Forum 7 November 2014
- Survey respondent feedback from 1st AgVet Collaborative Forum
- Global plant minor use priority list development update
- General discussion

10.00 am **3. Maintenance of the minor use system for industry**

- Ensuring that industries current needs and gaps are met
- Strategies to avoid transitional program market failure
- General discussion

11.00 am **4. Mechanisms for industry and registrant priority sharing**

- Discussion on draft discussion paper on the establishment of a cross industry priorities register
- AgVet Collaborative forum discussion and consensus on recommended mechanisms for priority sharing

11.45 am **5. Industry common issues and AgVet needs**

- Round table discussions with similar related industries in relation to AgVet technology access needs and gaps
- Reporting back to Forum

1.15 pm **6. Measurement of success**

- Draft discussion paper on recommended success measures for the AgVet Collaborative Forum
- AgVet Collaborative forum discussion and consensus on recommended measures

1.45 pm **7. AgVet forum terms of reference (TOR) and operation**

- Discussion paper on the key roles and operational activities and responsibilities of the AgVet Collaborative Forum
- Process to transition from the AgVet Collaborative Forum Interim Steering Committee to an AgVet Forum executive committee by May 2015
- AgVet Collaborative forum discussion and consensus on recommended options for TOR and operation

2.45 pm **7. AgVet forum terms of reference (TOR) and operation (continued)**

- AgVet Collaborative forum discussion and consensus on recommended options for TOR and operation

3.15 pm **8. Next steps on agenda planning for next forum 5 December 2014**

- Discussion on key forum agenda issues for Forums 2015
- Agenda items flagged and still outstanding from the 7th November 2014 Forum include:
 - Permit to label regulation and registrant discussion
 - A mechanism for access to international data for cross industry use
 - Department of Agriculture reform option discussions
 - Discussion paper of a new system
 - Mechanism to address stewardship issues and priorities
 - Maintenance of the minor use permit system for key gaps
- Other business matters
 - Industry priority list submission

4.00 pm *Forum close*

Appendix 4. Third RIRDC Access to AgVet Chemicals Collaborative Forum Agenda

Canberra Business Event Centre - Regatta Point, Commonwealth Park, Acton, Canberra ACT

Thursday 26 February 2015 - 9.30 am to 4 pm

9.00 am *Arrival and coffee*

9.30 am **1. Introductions and background to Access to AgVet Chemicals Collaborative Forum**

- Introduction of presenters/facilitators and new Forum participants
- Overview of the day and expected outcomes

9.45 am **2. Update on cross industry AgVet access discussions and activities to date**

- Outcomes of 2nd AgVet Collaborative Forum 5 December 2014
- Survey respondent feedback from 2nd AgVet Collaborative Forum
- Global plant minor use priority list development update
- Australian industry priority list submission

10.00 am **3. Forum steps to support permit to label process**

- Presentation and discussion of permit to label process and options
- Presentation of discussion paper on mechanisms to address stewardship issues, priorities, processes and principles
- General discussion

10.45 am *Coffee break*

11.00 am **4. Implementation of the following where consensus agreement has been reached**

- Measurement of success
- Mechanism for industry and registrant priority sharing
- AgVet forum terms of reference (TOR) and operation
 - Section 6 board structure discussion

11.45 pm **5. RIRDC project PRJ-009454 tool for use in AgVet prioritisation**

- Presentation of AgVet investment benefit/cost and economic analysis approach
- Options for implementation into the AgVet Collaborative Forum prioritisation process
- General discussion

12.15 pm **6. Roundtable on industry common issues and AgVet needs to deliver on Forum outcomes**

- Round table discussions with similar related industries in relation to AgVet technology access needs and gaps and – Specific discussion on next steps for delivery of industry prioritisation.

1.00 pm *Lunch (available from 1pm and available to groups that wish to eat and continue round tables)*

1.40 pm **6. Industry common issues and AgVet needs continued**

- Reporting back to Forum

2.00 pm **7. AgVet Collaborative Forum transition to recommended TOR and operations**

- Discussion paper on mechanisms for access to international data for cross industry use
- Discussion paper on a AgVet minor use operational system
- Transition to the AgVet Collaborative Forum Advisory Board – Options for appointment process
- General discussion

2.45 pm *Afternoon tea*

3.00 pm **8. Planning for AgVet Collaborative Forum Pilot Prioritisation Meetings May/June 2015**

- Interim Steering Committee implementation of consensus recommendations in agenda item 4.
- Industry priorities for permit to label process
- Industry prioritisation of new plant/animal AgVet technologies

3.30 pm **9. Next steps on agenda planning for next Forum late May/early June 2015?**

- Discussion on key forum agenda issues for Forums 2015
- Agenda items flagged and still outstanding from the 5th December 2014 Forum include:
 - Department of Agriculture reform option discussions

- Maintenance of the minor use permit system for key gaps

4.00 pm *Forum close*

Appendix 5. RIRDC Access to AgVet Collaborative Forum prioritisation workshop Agenda – Plant Industries

Federal Golf Club Federal Golf Club, Gowrie Drive Red Hill Canberra ACT

Tuesday 9 June 2015 Starting 11.00 am to Wed 10 June 2015 Finishing 4.30 pm

Day 1 Tuesday 9 June 2015

10.30 am *Registration - Arrival and coffee*

11.00 am **1. Welcome and Introductions**

- RIRDC welcome – Update on AgVet Collaborative Forum governance
- Introduction of all prioritisation workshop participants - Facilitator
- Status of the government's improved access to AgVet chemicals initiative – Department of Agriculture

11.25 am **2. Overview of the day and expected outcomes**

- Priority setting process outline – R. Rainbow
- Case study presentation – R. Rainbow
- Post workshop database use by industry, RDCs and registrants
- Post workshop submission into Global Minor Use database – Department Agriculture/APVMA/R. Rainbow

11.45 am **3. Prioritisation process - 'C' priorities** (crop x pest priorities voted by industry)

1.00 pm *Lunch (industry/registrant discussion on potential solutions should be discussed)*

1.40 pm **3. Prioritisation process – 'C' Priorities continues**

2.45 pm *Afternoon tea*

3.15 pm **4. Prioritisation process – 'B' Priorities** (crop/pest viable solution identified)

- Registrants can identify if better or alternate solution available

5.30 pm *Workshop close Day 1*

Day 2 Wednesday 10 June 2015

8.30 am **4. Prioritisation process – 'B' Priorities continues**

- Registrants can identify if better or alternate solution available

10.00 am *Morning tea (Extended break for industry/registrant solution discussions)*

10.45 am **5. Prioritisation process – 'A/P' Priorities** (crop/pest solution supported by registrants)

- Registrants detail support for potential solutions

12.30 pm *Lunch (industry/registrant discussion on support for potential solutions should be discussed)*

1.30 pm **5. Prioritisation process – 'A/P' Priorities continues**

- Registrants detail support for potential solutions

2.45 pm *Afternoon tea*

3.15 pm **5. Prioritisation process – 'A/P' Priorities continues**

- Registrants detail support for potential solutions

4.15 pm **6. Next steps for prioritisation workshop outcomes and the AgVet Collaborative Forum**

4.30 pm *Workshop close Day 2*

Appendix 6. RIRDC Access to AgVet Collaborative Forum prioritisation workshop Agenda – Animal Industries

Federal Golf Club Federal Golf Club, Gowrie Drive Red Hill Canberra ACT

Animal Industries - Friday 12 June 2015 starting at 8.30 am finishing at 4.30 pm

8.00 am *Registration - Arrival and coffee*

8.30 am **1. Welcome and Introductions**

- RIRDC welcome – Update on AgVet Collaborative Forum governance
- Introduction of all prioritisation workshop participants - Facilitator
- Status of the government's improved access to AgVet chemicals initiative – Department of Agriculture

8.55 am **2. Overview of the day and expected outcomes**

- Priority setting process outline – R. Rainbow
- Case study presentation – R. Rainbow
- Post workshop database use by industry, RDCs and registrants
- Post workshop collaboration with global veterinary medicine priorities programs – Department of Agriculture/APVMA/R. Rainbow

9.15 am **3. Prioritisation process - 'C' priorities** (animal x pest priorities identified only)

10.00 am *Morning tea (Extended break for industry/registrant solution discussions)*

10.30 am **4. Prioritisation process – 'B' Priorities** (animal/pest viable solution identified)

- Registrants can identify if better or alternate solution available

12.30 pm *Lunch (industry/registrant discussion on potential solutions should be discussed)*

1.15 pm **4. Prioritisation process – 'B' Priorities continues**

1.45 am **5. Prioritisation process – 'A/P' Priorities** (animal/pest solution supported by registrants)

- Registrants detail support for potential solutions

2.45 pm *Afternoon tea (Extended break for industry/registrant solution discussions)*

3.15 pm **5. Prioritisation process – 'A/P' Priorities continues**

- Registrants detail support for potential solutions

4.15 pm **6. Next steps for prioritisation outcomes and the AgVet Collaborative Forum**

4.30 pm *Workshop close*

Appendix 7. AgVet Collaborative Forum Agenda – 2016 Prioritisation for gaps workshop

Federal Golf Club, Gowrie Drive Red Hill Canberra ACT

Plant industries - Wednesday 8 June 2016 Starting 9.00 am to Thursday 9 June 2016 Finishing 3.30 pm

Day 1 Wednesday 8 June 2016

8.30 am *Registration - Arrival and coffee*

9.00 am **1. Welcome and Introductions**

- Introduction of all prioritisation workshop participants - Facilitator
- Improved access to AgVet chemicals initiative – Grants program outcomes/update– Department of Agriculture and Water Resources

9.30 am **2. Overview of the day and expected outcomes**

- Prioritisation for gaps process outline – R. Rainbow
- Post workshop database use by RDCs, industry and registrants

9.40 am **3. Registrant presentations on new solution opportunities**

- Registrants have opportunity to present for up to 8 minutes on *potential of 'new mode of action'* actives for consideration by the Forum – focussed new solutions for pest groupings relevant industry priorities

11.00 am Morning tea (RDC, industry/registrant discussion on potential solutions should be discussed)

11.20 am **4. Prioritisation discussions - Weeds**

- *Weeds - other, major weed groups*

12.30 pm Lunch (RDC, industry/registrant discussion on potential solutions should be discussed)

1.30 pm **5. Prioritisation discussions - Diseases**

- *Diseases - other, major disease groups*

2.45 pm Afternoon tea (Extended break for RDC, industry/registrant solution discussions)

3.15 pm **5. Prioritisation discussions continued - Diseases**

- *Diseases - other, major disease groups*

5.30 pm Workshop close Day 1

Day 2 Thursday 9 June 2016

8.30 am **6. Prioritisation discussions - Invertebrate pests**

- *Invertebrate pests - other, major pest groups*

10.00 am Morning tea (Extended break for RDC, industry/registrant solution discussions)

10.45 am **6. Prioritisation discussions continued - Invertebrate/vertebrate pests**

- *Invertebrate/vertebrate pests - other, major pest groups*

12.30 pm Lunch (*industry/registrant discussion on support for potential solutions should be discussed*)

1.30 pm **7. APVMA presentation and discussion** - Including updates update on:

- Permit to label program plus timelines
- Crop grouping project plus timelines
- Minor use program application and assessment
- International data and assessments, and applicability of international (data) guidelines

2.30 pm **8. Open Forum Discussion**

- AgVet Collaborative Forum reflections on the revised process/surveys

3.30 pm *Forum Close*

Pest grouping discussion order

1. Prioritisation discussions – Weeds & misc

- Broadleaf weeds
- Grass weeds
- Grass and broadleaf weeds
- Woody weeds

2. Miscellaneous

- PGRs, desiccants & fumigants

3. Prioritisation discussions – Diseases

- Alternaria
- Anthracnose
- Bacterial diseases
- Botrytis
- Cercospora
- Downy mildew
- Fusarium, Pythium, Rhizoctonia
- Leaf blights and spots
- Moulds and rots
- Nematodes
- Other Fungus
- Powdery mildew
- Rusts
- Sclerotinia
- Viruses

4. Prioritisation discussions - Invertebrate pests

- Aphids
- Bugs and leafhoppers
- Fruit Fly
- Lepidoptera
- Mealybugs
- Mites
- Other insect pest
- Other sucking pests
- Scales
- Slugs and snails
- Soil insects
- Thrips
- Weevils, borers & beetles
- Whitefly

Appendix 8. AgVet Collaborative Forum Agenda – 2016 plant industries strategic spring workshops

Federal Golf Club, Gowrie Drive Red Hill Canberra ACT

Plant industries - Thursday 20 October 2016 Starting 10.30 am - finishing 3.30 pm

10.00 am Registration - Arrival and coffee

10.30 am **1. Welcome and Introductions, overview of the day and expected outcomes**

- Introduction of all workshop participants – Facilitator

10.45 am **2. AgVet Collaborative Forum activities for plant industries 2016**

- Outcomes of the prioritisation for gaps process and database use by RDCs, industry and registrants
 - Improved access to AgVet chemicals initiative – Grants program outcomes/update– Department of Agriculture and Water Resources

11.00 am **3. Research update on AgVet options for managing resistance in minor plant Industries**

- Dr Fran Lopez-Ruiz – Managing Fungicide Resistance - Centre for Crop and Disease Management Curtin University <http://ccdm.com.au/>
- Dr Paul Umina – Managing cross industry insecticide resistance - cesar and The University of Melbourne <http://www.cesaraustralia.com/>
- General discussion on implications for strategic industry approached and R&D

12.30 pm Lunch

1.15 pm **6. Strategic discussion on potential next steps for cross industry collaboration:**

- Fungicide resistance management – Future cross industry discussion needs and strategic options
- Insecticide resistance management and stewardship – Future cross industry discussion needs and strategic options

1.45 pm **7. APVMA presentation and discussion - Including updates update on:**

- Permit to label program plus timelines
- Minor use program application and assessment
- International data and assessments, and applicability of international (data) guidelines

2.30 pm **8. Open Forum Discussion**

- AgVet Collaborative Forum reflections on the future of the AgVet Collaborative Forum for Plant Industries
- 2017 and beyond investment options – Consideration of revised prospectus
- Potential facilitation role of Plant Health Australia or other organisation?

3.30 pm Forum Close

Appendix 9. AgVet Collaborative Forum Agenda – 2016 animal industries strategic spring workshops

Federal Golf Club, Gowrie Drive Red Hill Canberra ACT

Animal industries - Tuesday 25 October 2016 Starting 10.30 am - finishing 3.30 pm

10.00 am Registration - Arrival and coffee

10.30 am 1. Welcome and Introductions, overview of the day and expected outcomes

- Introduction of all workshop participants – Facilitator

10.45 am 2. AgVet Collaborative Forum activities for animal industries 2016

- Outcomes of the prioritisation for gaps process and database use by RDCs, industry and registrants
 - Improved access to AgVet chemicals initiative – Grants program outcomes/update– Department of Agriculture and Water Resources

11.00 am 3. Research update on AgVet options for minor animal Industries

- Dr Abdul Jabbar - Melbourne University, Anthelmintic resistance management in alpaca
- Dr Robert Woodgate – Charles Sturt University, Anthelmintic resistance management in goats
- Dr Dominique Blache at UWA, Animal welfare products for castration in alpaca
- General discussion on implications for strategic industry approached and R&D

12.30 pm Lunch

1.15 pm 6. Strategic discussion on potential next steps for cross industry collaboration:

- Animal welfare – local anaesthetic products – Future cross industry discussion needs and strategic options
- Anthelmintic resistance management and stewardship – Future cross industry discussion needs and strategic options

1.45 pm 7. APVMA presentation and discussion - Including updates update on:

- Permit to label program plus timelines
- Minor use program application and assessment
- International data and assessments, and applicability of international (data) guidelines

2.30 pm 8. Open Forum Discussion

- AgVet Collaborative Forum reflections on the future of the AgVet Collaborative Forum for Animal Industries
- 2017 and beyond investment options – Consideration of revised prospectus
- Potential facilitation role of Animal Health Australia or other organisation?

3.30 pm Forum Close

Appendix 10. 2016 AgVet Collaborative Forum participating organisations list

Investing and participating RDCs

- Rural Industries Research & Development Corporation (RIRDC)
- Horticulture Innovation Australia Limited (HIAL)
- Sugar Research Australia (SRA)
- Cotton Research and Development Corporation (CRDC)
- Wine Australia
- Grains Research and Development Corporation (GRDC)
- Dairy Australia
- Australian Wool Innovation Limited (AWI)
- Forrest and Wood Products Australia (FWPA)

Non-investing RDCs involved in strategic spring workshops

- Australian Egg Corporation Limited (AEC)
- Australian Pork

Producer industry organisations

- Horticulture New Zealand
- Australian Alpaca Association
- Australian Mango Industry Association (AMIA)
- Australian Banana Growers Council
- Ausveg
- Citrus Australia
- Costa Exchange
- Turf Australia
- Ricegrowers Association of Australia (RGA)
- National Farmers Federation (NFF) - AgVet Chemicals Taskforce
- NSW Farmers
- AgForce Queensland
- Grain Producers Australia
- Wool Producers Australia

CropLife Australia and member companies

- AgNova
- Accensi
- Agronico
- Adama
- Arysta Lifesciences Australia
- BASF
- Bayer Cropscience
- Dow Agrosiences

- Du Pont Crop Protection
- FMC
- ISK
- Landmark
- Nufarm
- Sipcam
- Sumitomo Chemical Australia Pty Ltd
- Syngenta Australia

Animal Medicines Australia and member companies

- Bayer Animal Health
- Elanco
- MSD
- Merial
- Virbac
- Zoetis

Other registrant companies

- Animal Ethics
- 4 Farmers Australia
- Intrade
- UPL Australia

Other organisations

- AKC Consulting
- Alpha Group Consulting
- Australian Pesticides and Veterinary Medicines Authority (APVMA)
- cesar & University of Melbourne
- Charles Sturt University
- Curtin University Centre for Disease Management
- Department of Agriculture and Water Resources
- Horticulture New Zealand
- HVP Plantations Research
- Market Access Solutionz NZ
- Plant Health Australia (PHA)
- University of Melbourne
- University of Western Australia

Appendix 11. AgVet Collaborative Forum Industry Investment Prospectus 2015 – As submitted by RIRDC to industry, RDCs and stakeholders

Introduction

Australian farmers currently have less access to agricultural and veterinary (AgVet) chemicals than many of their competitors. From this perspective, there is a need to increase investment in AgVet chemicals in Australia, particularly compared with competing investment opportunity in Asia and South America. One way of addressing this ‘investment market failure’ in the longer term (as demonstrated in some competitor countries) is to facilitate cross-sector discussion with government and commercial chemical companies on options to increase AgVet chemical access.

In support of this approach, RIRDC has established the **AgVet Collaborative Forum** (‘Forum’) to provide a platform for the agricultural industries, AgVet chemical registrants and governments to consider options for more efficient and effective AgVet investment. The aim is to increase participation and investment in addressing Australian AgVet chemical needs. It is anticipated that this will reduce the current impacts of market failure through a more coordinated and structured approach.

The outcomes from continued investment and delivery of the Forum include;

- Delivery of a functional and sustainable system for producers to effectively share their priorities for chemical access needs with other producers, RDCs and chemical companies
- Deliver cost savings from investment and reduce current impacts of AgVet chemical market failure.
- Facilitate cross industry prioritisation and investment for improved access to uses of AgVet chemicals resulting in:
 - Improved priority setting and cross industry collaboration
 - Achieving agricultural industry and commercial co-investment in data generation supported through initial government incentive.
 - Achieving cost savings through cross industry efficiencies and national and international collaboration and co-investment

In delivery of these outputs, the scope of the Forum in addressing AgVet investment market failure as described in the RIRDC PRJ-009454 final report²⁸ includes;

- Market failure in major crop and animal industries in addition to existing minor industries will be within scope of the Forum
- that ‘market failure’ is considered real if an industry case can be given to identify that market failure has occurred, rather than continuing to accept the current regulation term of crop or animal ‘minor use’ as being likely market failure.

²⁸ Rainbow, R. and Krause M. (2015) Improved access to AgVet chemicals for agricultural industries. *RIRDC Final Report Project No PRJ-009454*

- Ie, where pesticide use for which the anticipated volume of sales is not high enough for a manufacturer to justify the costs to register and sell the product.

Considerable progress has already been made in developing a new cross-industry culture of collaboration within the Forum. The most recent participant survey has indicated that there is a high level of motivation to engage in the AgVet Collaborative Forum and significant value from identifying industry priorities and discussion with registrants to identify new solutions.

The first Forum prioritisation workshops were held in Canberra in June 2015. The workshops were well attended on the 3 days with over 100 participants including industry representatives, RDCs, state and federal government, APVMA and 20 registrant companies. Industry discussion of issues with registrants identified solutions to a large number of industry priorities, which previously had no identified solution. This highlights the strategic value of the discussion generated by the Forum. The outcomes of this process will have significant potential productivity benefits for the participating industries in the future.

The establishment phase of the Forum was funded by the Department of Agriculture. This prospectus details the governance arrangements, operations and investment options for a second, operational phase of the Forum. To enable the Forum to successfully continue beyond the 31 October 2015, stakeholders must agree on an approach to collectively support the on-going operations of the Forum for the next three years, which coincides with the proposed Department of Agriculture AgVet grants program.

Background - Key issues impacting on agricultural productivity

Plant and animal industries are facing increasing emergence of biosecurity threats and impact from pesticide and veterinary medicines resistance. Australia is no longer recognised as a global priority for pesticide and veterinary medicine commercialisation, as it was 20 years ago. Many Australian agricultural industries are currently missing out on up to 50% of the potential new technologies to which key competitors in Europe and the USA have access. Strategically, Australia requires access to new AgVet chemicals to address new threats and growing resistance, while experiencing increasing market failure due to declining investment. Australia is also missing out from productivity improvement through commercial investment in a large number of potential emerging biological, biochemical and biotechnology based AgVet technologies.

Through facilitated discussions with the agricultural industry Research and Development Corporations (RDCs), peak industry bodies, both Plant and Animal Health Australia, Department of Agriculture, APVMA and key registrant groups CropLife Australia and the Animal Medicines Australia, the major factors resulting in declining investment in Australia were identified. These factors include:

- Australia is a small AgVet market in a global context < 1.5%
- Australia is experiencing difficulties with complex AgVet regulations, timeliness and costs relative to commercial return on investment
- Global multinational companies face a poor rate of return on commercialisation investment compared with major developing markets including Brazil and China.

There is clearly increasing market failure for investment in AgVet technologies in Australia. While traditionally market failure has been recognised in minor or establishing industries, in recent years market failure has been increasing impacting on traditional major plant and animal industries creating a larger grey area of market failure. The increasing number and variety of RDC, government and

commercial priorities are increasing this market failure well beyond the previously well-defined market failure areas of minor use and specialty crops programs, as illustrated below (Figure 11).

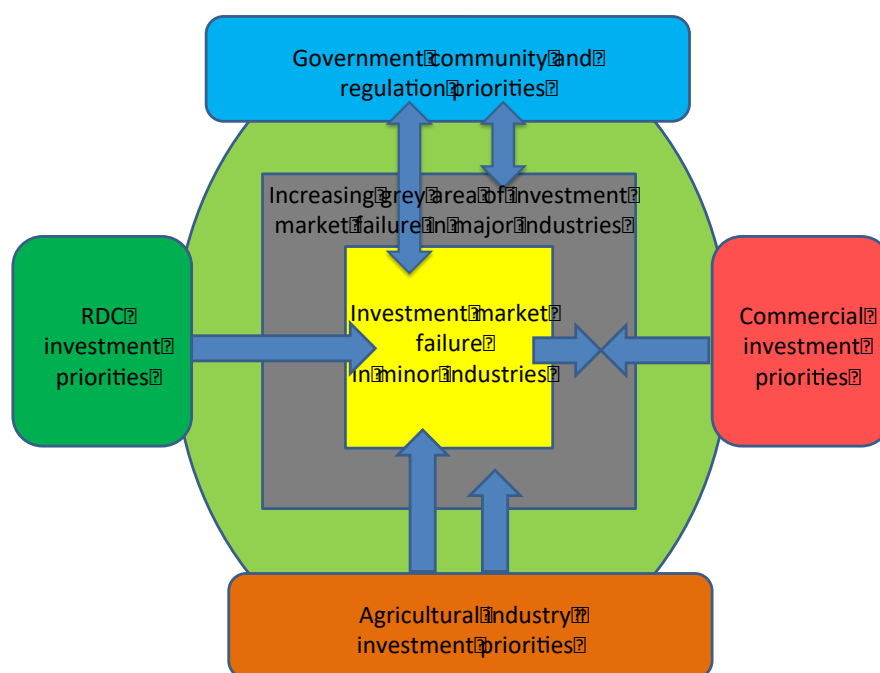


Figure 11. Investment priorities and commercial AgVet investment market failure

Benefits of a collaborative approach

Minor use permits have historically been developed in response to urgent industry demand and usually result in a rapid adoption. This has been clearly demonstrated in the Australian grains and horticulture industries. There has also been permits issued for minor use (or limited regional use) in major industries, usually in response to immediate new pest threats or resistance issues. Due to increasing investment market failure, there are increasing AgVet technology needs for major crop and animal industries.

A study funded by the GRDC and HAL by Woods 2014²⁹, identified cost - benefit ratios of minor use permits from 13:1 to 95:1. In the United States under a total economic impacts model, benefits from minor use permits has been shown to be as high as 462:1. The benefits applied to the 8.1 million expenditure by GRDC and HAL for the 3 years 2010-13 had a total economic impact of, at least \$113.5 million and potentially as high as \$3.565 billion. The combined benefit of a broader minor use program when applied to other industries would be significantly higher.

Public Benefits from an effective AgVet program addressing market failure include:

²⁹ Woods, P. (2014) Analysis of the impact of proposed APVMA cost recovery changes to GRDC and HAL minor use programs – AvantAgri report to HAL/GRDC http://www.daff.gov.au/__data/assets/pdf_file/0012/2376768/grdcattachment

- Improving storage or shelf life for food products
- Meeting consumer expectations for safe residue free food, noting in 2008/09 the majority of MRLs established in Australia arose from minor use permits, highlighting the demand for minor uses.
- Maintaining a diversity of food types for an increasingly multi-cultural society
- Contributing to protection of the environment
- Managing Australia's international reputation for food production
- Reducing impediments to free trade
- Flow on effects to other industries such as the use in fodder and grain products for livestock and dairy product industries.

Market-opportunity benefits from an effective AgVet program addressing market failure with appropriate prioritisation include:

- Managing Australia's international reputation for food production
- Reducing impediments to free trade
- Flow on effects to other downstream animal industries such as for use in fodder and grain products for livestock and dairy product industries.

Building on the experiences of overseas programs and their success, the key question for Australian industry is whether we can we afford not to deliver a new sustainable collaborative AgVet program to remain internationally competitive?

There is a need to increase investment in AgVet chemicals in Australia, particularly when compared to competing investment opportunity in Asia and South America. One way of addressing this investment market failure in the longer term (as demonstrated in some competitor countries) is to facilitate cross-sector discussion with government and commercial chemical companies on options to increase AgVet chemical access. Industry has identified outcomes that need to be achieved in relation to AgVet chemicals include:

- Increased domestic and foreign investment in AgVet chemical development and registration
- Increased agricultural profitability and sustainability through the adoption of new AgVet technologies
- Increased delivery of a diverse range of foods to an increasingly multicultural community
- Increased productivity and scale of industries that contribute to GDP and balance of trade
- Improved safety to community, environment and trade.

Experience from other countries that are facing similar issues is that there is opportunity to deliver these outcomes through a collaborative approach. Improved prioritisation of needs; identification of benefits of co-investment by industry, government and commercial registrants; and establishment of investment incentive frameworks to support these programs has had a significant impact in delivering benefits to industry and the community.

Outputs and Success to Date

As part of a program of work to improve producers' access to AgVet chemicals, the Australian Government Department of Agriculture contracted the Rural Industries Research and Development Corporation (RIRDC) to establish a sustainable system for producers to effectively share their priorities for AgVet chemical access needs with other producers, research and development corporations (RDCs) and chemical companies; to deliver cost savings from investment and reduce current impacts of AgVet chemical market failure.

To facilitate this, RIRDC has established the **AgVet Collaborative Forum** ('Forum') to provide a platform for consideration of options for collaborative cross-industry AgVet investment. This aims to increase current industry and commercial registrant participation and investment in addressing Australian AgVet chemical needs. It is anticipated that this will reduce the current impacts of market failure through a more coordinated and structured approach.

In delivering the Forum outcomes detailed in the introduction, the AgVet Collaborative Forum will deliver the following outputs and milestones:

1. Maintain a list of cross-industry AgVet chemical priorities to:
 - a) Provide a basis for information sharing and consideration of co-investment opportunities to better use national and international resources for supporting applications to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for AgVet chemical uses including;
 - i) Provide industry stakeholder consultation support in assembly and refinement of priorities
 - ii) Assemble industry priorities for prioritisation database
 - b) Provide a mechanism for producers to have informed discussions with chemical companies of potential market demand to assist in their decisions to register Australian uses including;
 - i) Consultation of draft industry priorities with CropLife and AMA members
 - ii) Workshops delivered to prioritise and achieve consensus on technical registrant support
 - iii) Evaluate workshop outcomes and report submitted to RDCs and registrants
2. Provide a forum for producers and the chemical industry to interact with the Department of Agriculture, APVMA to:
 - a) Identify current AgVet priorities for each participating industry sector
 - b) Deliver a report to stakeholders to continue the operations of the AgVet Collaborative Forum
3. Support a framework for government conditional co-investment with industry and registrants including;
 - a) Deliver an annual update to the RIRDC AgVet website and communications program
 - b) Deliver a report to stakeholders to continue the operations of the AgVet Collaborative Forum

Current deliverables from the RIRDC project PRJ-009981 for the AgVet Collaborative Forum program which have not been budgeted in this proposal include;

- Identification of alignment of national and international IR-4 priorities and potential cost savings

- Maintain engagement with Canadian minor use program (CANMUP) /USA IR-4 programs and identify collaboration and data sharing opportunities
- Assemble performance indicators (not including survey costs) for the success of the Forum and benefits of investment outcomes

While measurement of Forum performance, identification of potential international collaboration for data sharing and generation of cost savings are seen as important, their importance is secondary to the delivery of Forum discussion and prioritisation. Specific discussion with forum stakeholders on these deliverables and potential funding will be discussed in the agenda of the next meeting of the Forum.

The first Forum prioritisation workshops were held in Canberra in June 2015. The workshops were well attended on the 3 days with over 100 participants including industry representatives, RDCs, state and federal government, APVMA and 20 registrant companies.

The outcome for the plant industries from this workshop is particularly significant with the industry discussion of issues with registrants identifying solutions for over half of the top third of industry priorities, which previously had no identified solution. This highlights the strategic value of this discussion generated by the AgVet Collaborative Forum. The outcomes of this process will have significant potential productivity benefits for these industries in the future. Without the Forum, these discussion may not have occurred, or it may have taken much longer to identify solutions..

The workshops highlighted the opportunity for industries to work together on needs to address common AgVet issues. For example, the prioritisation needs of animal industries highlighted the high priority for almost all animal industries for access to local anesthetic technology for improving animal welfare.

From these initial forum workshops, the following outcomes were achieved:

Plant industries priorities:

- 319 A's (Solutions with technical support of registrants)
- 94 P's (Solutions sought by industry permit);
- 326 unique 'top 5' crop/pest priorities submitted (total of 384 priorities submitted including lower ranking priorities)
- 135 'top 5' crop/pest priorities had no identified solution (41% of top 5 submissions)
- 78 new potential solutions were identified by registrants (addressing 58% of priorities with no solution)
- At least 1 additional new solution was identified by registrants for 90 of the 191 priorities already with a solution identified by industry (47% of all top 5 identified solution priorities) potentially improving the ability to address resistance issues

Animal industries priorities outcomes:

- 68 A's (Solutions with technical support of registrants)
- P's (Solutions sought by industry permit);
- 98 unique 'top 5' animal/pest priorities submitted (total of 183 priorities submitted including lower ranking priorities)

- At least 1 additional new solution was identified by registrants for 4 of the 98 priorities already with a solution identified by industry (4% of all top 5 identified solution priorities) potentially improving the ability to address resistance issues

Future AgVet Collaborative Forum operations

a) Participation

It is intended that the Forum is open to all representatives of producers that have a need to use agricultural chemicals and veterinary medicines or contribute towards the regulation, investment or commercialisation of these products in the delivery of agricultural production. While it is recognised that this could result in a large number of stakeholders, it is essential that the program deliver the long term strategic needs of all industries.

The Forum is also open to:

- Representatives from all AgVet chemical companies with a presence in Australia, together with their representative organisations
- Representatives from all rural RDCs
- Representatives from the Australian Government Department of Agriculture and Water
- Representatives from the APVMA
- AgVet chemical technical resources
- Representatives from state and territory governments chemical regulation and compliance bodies
- Other parties as agreed by the Forum.

b) Management

Corporate governance oversight of the Forum resides with RIRDC, which will include consideration of advice from the Forum. RIRDC has well-defined and tested policies and procedures in place to support this approach.

RIRDC will appoint a part time Forum Manager, who will have responsibility for the day-to-day management of the Forum, to:

- manage the business of the Forum, including oversight of Forum operations and out of session processes.
- implement decisions of the Forum.
- establish and maintain appropriate administrative arrangements for the Forum, including:
- preparation, monitoring and reconciliation of a budget;
- the provision of a secretariat service to the Forum;
- ensuring that all documentation is prepared, maintained and accessible to Forum participants

- manage any financial affairs of the Program, as required
- arrange for the provision of effective corporate governance and accountability services for the Forum, including legal and audit services if required
- establish and maintain contract management services, as required
- provide general business support, including management of intellectual property
- oversee maintenance of the Forum's communications requirements, including the relevant web pages.

c) General Forum Meetings

The Forum will meet annually (or as otherwise agreed by the Forum) face-to-face to:

- Review the cross-industry list of AgVet chemical priorities
- Consider alterations / improvements to the operations of the Forum
- Any other business raised by Forum participants or unresolved out of session issues.

RIRDC will appoint a facilitator that will, in consultation with RIRDC:

1) Chair the face-to-face meetings

2) Develop meeting agendas, ensuring the industry members of Plant Health Australia and Animal Health Australia, the National Farmers Federation, the company members of CropLife Australia and Animal Medicines Australia, the Department of Agriculture and Water and the APVMA are engaged in the process.

3) Maintain a record of all meetings.

4) Maintain an accurate, up to date record of the AgVet Forum database and Priority List.

5) Support RIRDC's management of OOS issues, as required.

The forum will operate by consensus. It will be the responsibility of the facilitator to ensure this occurs.

d) Prioritisation workshop process

The AgVet Collaborative Forum workshop prioritisation process will be delivered in 2 phases:

- Phase 1 – Industry facilitation and identification of needs - based on crop/animal/pest. Each industry sector will be invited to submit its priorities prior to the workshop
- Phase 2 - AgVet Collaborative Forum prioritisation workshop – an annual workshop, run separately for plants and animals

The inputs for the process include:

- A target number of 'A' projects nominated by the Department of Agriculture and Water
- Industry priorities with at least the 'top 5' being identified

The Forum prioritisation workshop incorporates six key steps. Voting of ‘C’, ‘B’, then ‘A’ or ‘P’ priorities by industries is a key step to identify the high priority needs. Interaction of industries with registrants during the workshop is an important component, which aims to result in registrants providing ‘in principle’ support for potential solutions for ‘A’ priorities, which can be developed into projects for investment. Alternatively industries can nominate for ‘P’ or permit projects, but this will likely result in industries bearing most of the project cost (see figure 12).

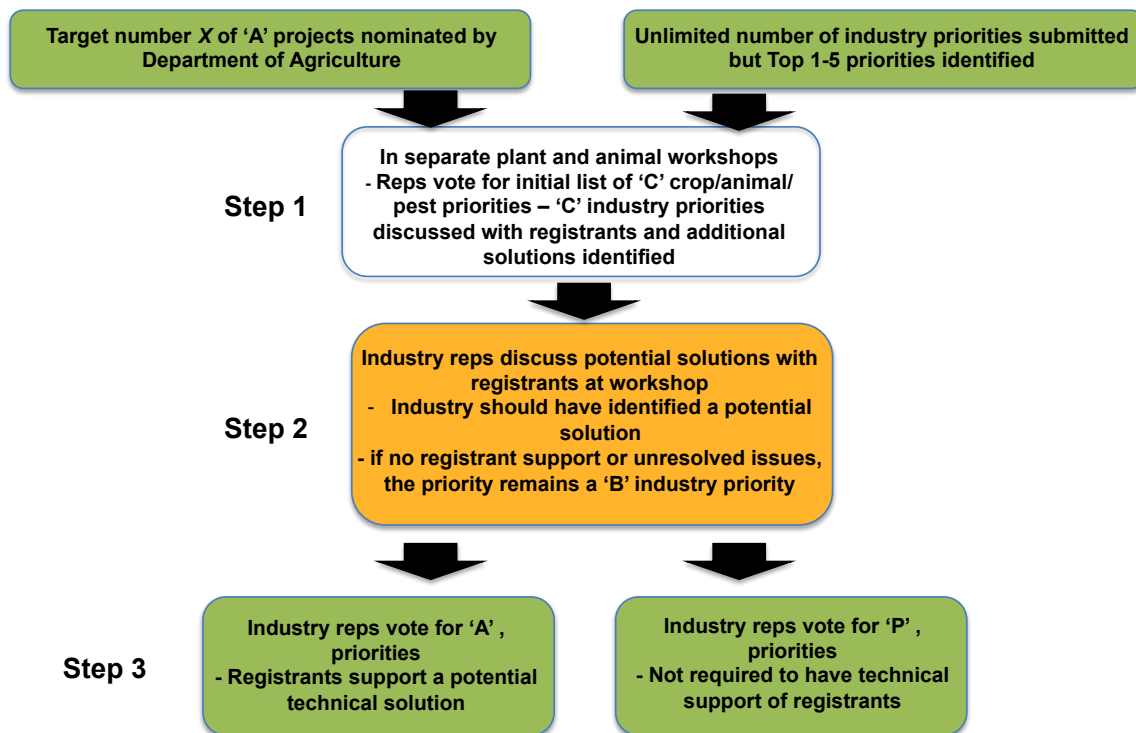


Figure 12. AgVet Collaborative Forum prioritisation workshop process

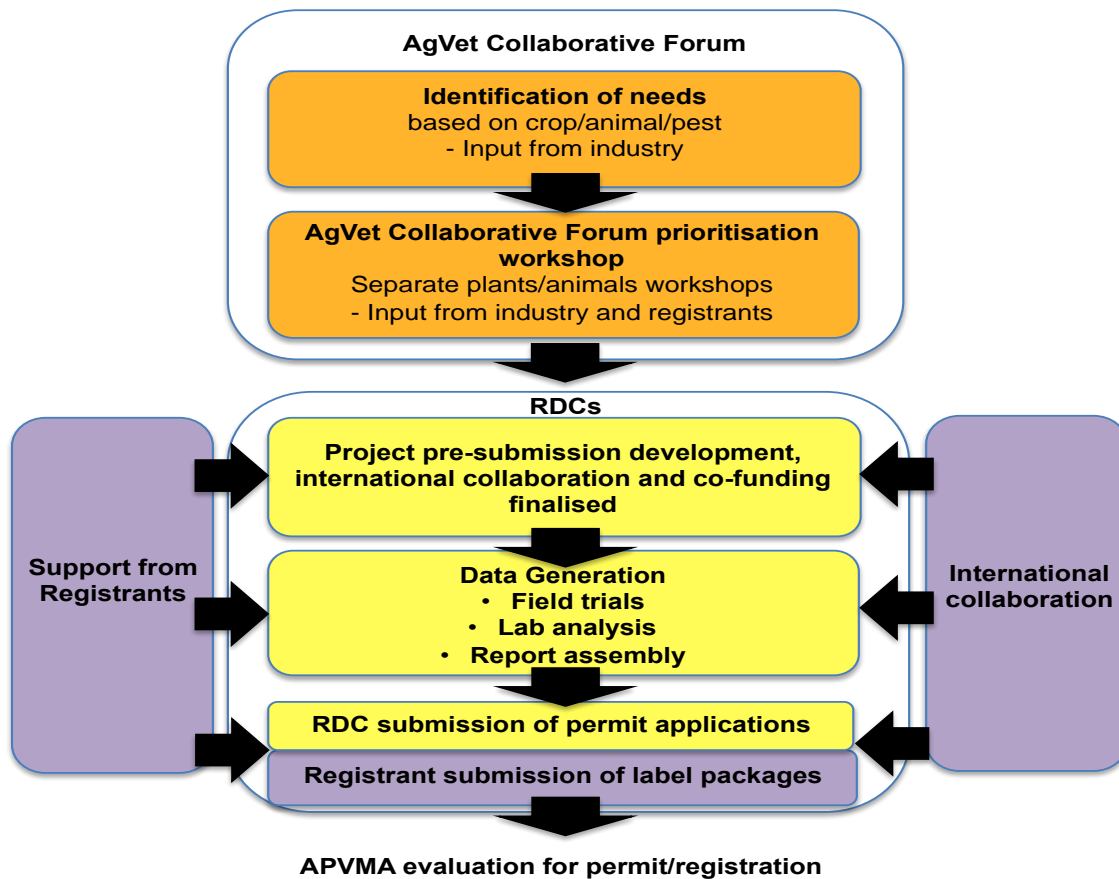


Figure 13. AgVet Collaborative Forum prioritisation process next steps for RDCs delivering industry access to AgVet technologies

Although outside the scope of this project, the next steps for delivery of project development and co-funding by industry, government and registrants will be managed by the respective industry RDC as detailed in figure 13. Where projects are supported by one or more RDC, then the industry contributing the most significant component of the funding will take overall leadership responsibility. The relevant RDC will be responsible for contracting data generation including field trials and laboratory analysis. The RDC will also be responsible for liaison with the relevant registrant for report assembly for submission of data packages to the regulator APVMA.

e) Out of Session Business

As the Forum only plans to meet once per year, there will be a requirement to consider issues out of session (OOS). The conduct of OOS business will be as follows:

- OOS business will be conducted by email and/or teleconference
- The list of Forum participants (including email addresses) will be maintained by the Forum Manager
- The Forum Manager is responsible for the preparation of papers addressing issues to be considered OOS
- Issue papers must include:

- Background to the issue
- Consideration of the issue
- Recommendation
- Forum participants will have 10 working days from the date of dispatch of the email to consider issue papers and provide one of the following responses:
 - Endorse the recommendation
 - Not endorse the recommendation
 - Request additional information / actions. This must include details of what additional information / actions are required and why they are needed.
- The Forum Manager will be responsible for engaging with Forum participants and resolving any issues
- OOS decision-making will be by consensus. Any unresolved issues will be included on the agenda for the next face-to-face Forum meeting or if resolution is time critical, addressed under Item 7. Dispute Resolution.
- Any Forum participant that does not respond within the 10 working days will not be considered in the assessment of responses.

Communications

RIRDC has established a communications program to support the program, which has the following goals:

1. To clearly articulate the purpose and objectives for the project.
2. To describe the achievements and benefits of the Forum.
3. To communicate the operations and activities of the Forum and provide linkages to related projects or activities.

This will be achieved by:

1. Maintaining a set of communications materials that will be drawn upon for all communications activities relevant to the project.
2. Targeting the materials to the relevant target audiences using the most effective communications channels available.

It will be the responsibility of the Forum Manager to maintain the communications materials.

Forum Review

Within 12 months of the establishment of the Forum (and two face-to-face meetings of the Forum have been completed) a review of the Forum will be undertaken by an independent party. The Terms of Reference for the review include:

- Engagement with all Forum participants to:

- Identify the strengths and weaknesses of the Forum, as well as the opportunities not yet realised and the threats or challenges facing the Forum
- Assess the benefits delivered by the Forum to date
- Consider opportunities for improving the operations of the Forum.

Dispute Resolution

Where Forum consensus cannot be reached, including the resolution of time critical decisions, the issue will be referred to the RIRDC Managing Director, who will establish a process, in consultation with the relevant / affected Forum participants, to resolve the dispute.

Funding

The principles of funding for the continuation of the AgVet Collaborative Forum are based on a shared benefit and equity for investment by all agricultural industries. The proposal is also based on the benefits that registrants and government will receive in reducing their consultation costs with stakeholders. Estimated costs for delivery of the following milestones in the delivery of the Forum are shown in Table 4. Budgets for all workshops are based on an industry attendance of up to 150 persons per day (100 plant and 50 animal attendees per day).

Based on the principle of shared equity, it is proposed that investment in the AgVet Collaborative Forum is based on the following equity investments, recognising that some industries are the larger beneficiaries of the program, particularly Horticulture and Grains and emerging plant and animal industries via RIRDC. There is also the option that participants contribute towards the costs of the Forum workshops and this is proposed as a second investment option. On this basis, it is proposed that the following organisations contribute to the AgVet Collaborative Forum as proposed in table 5 below.

Table 4. Estimated annual costs for continued delivery of the AgVet Collaborative Forum

Milestone	Deliverable	Budget
Milestone 1	Provide industry stakeholder consultation in assembly and refinement of priorities	\$24,000
Milestone 2	Assemble industry priorities for prioritisation database	\$20,000
Milestone 3	Consultation of draft industry priorities with CropLife and AMA members	\$23,000
Milestone 4	Workshop delivered to prioritise and achieve consensus on technical registrant support	\$38,000
Milestone 5	Evaluate workshops outcomes and report submitted to RDCs and registrants	\$6,000
Milestone 6	Deliver a 1 day animal and 1 day plant industry strategic discussion workshop	\$7,000
Milestone 7	Deliver an annual update to the RIRDC AgVet website and communications program	\$5,000
Milestone 8	Deliver a report to stakeholders to continue the operations of the AgVet Collaborative Forum	\$6,000
Milestone 9	Progress/Annual/Final reports submitted to RIRDC.	\$6,000
Total Budget		\$135,000

Table 5. Proposed annual stakeholder investment in the AgVet Collaborative Forum

Contributor	\$ Investment contribution
Horticulture Innovation Australia (HIA)	\$15,000
Grains Research and Development Corporation (GRDC)	\$15,000
Rural Industries Research and Development Corporation (RIRDC)	\$15,000
Australian Grape and Wine Authority (AGWA)	\$9,000
Cotton Research and Development Corporation (CRDC)	\$9,000
Sugar Research Australia (SRA)	\$9,000
Dairy Australia (DA)	\$9,000
Australian Pork Limited (APL)	\$9,000
Forests and Wood Products Australia	\$9,000
Meat and Livestock Australia (MLA)	\$9,000
Australian Wool Innovation (AWI)	\$9,000
Fisheries Research and Development Corporation (FRDC)	\$9,000
CropLife Australia and member companies	\$5,000
Animal Medicines Australia and member companies	\$5,000
Total proposed contributions	\$136,000

Response timeline for stakeholder decisions

To enable the AgVet Collaborative Forum to successfully continue beyond the 31 October 2015, there needs to be a consensus decision among stakeholders to continue the investment in the AgVet Collaborative Forum for at least another 24 months. For continuity of this program and meet Department of Agriculture and Water expectations for the successful continuation of the AgVet Collaborative Forum, an investment decision by stakeholders is required by the 31 August 2015.

Ideally this investment should continue annually for 3 years until the 30 June 2018 to coincide with the delivery of the Australian Government priority and \$8 million investment commitment - A Competitive Agriculture Sector - improved access to agricultural and veterinary chemicals.

Appendix 12. AgVet Collaborative Forum Phase III Industry Investment Prospectus 2016 – As submitted by RIRDC separately to plant and animal industries, RDCs and stakeholders

1. Introduction

Australian farmers currently have less access to agricultural and veterinary (AgVet) chemicals than many of their competitors. From this perspective, there is a need to increase investment in AgVet chemicals in Australia, particularly compared with competing investment opportunity in Asia and South America. One way of addressing this ‘investment market failure’ in the longer term (as demonstrated in some competitor countries) is to facilitate cross-sector discussion with government and commercial chemical companies on options to increase Agvet chemical access such as through the north American United States IR-4 and Canadian minor use programs.

In support of this approach, RIRDC established the **AgVet Collaborative Forum** (‘Forum’) in 2016 to provide a platform for the agricultural industries, AgVet chemical registrants and governments to consider options for more efficient and effective AgVet investment. The aim is to increase participation and investment in addressing Australian AgVet chemical needs. It is anticipated that this will reduce the current impacts of market failure through a more coordinated and structured approach.

The outcomes from continued investment and delivery of the Plant industry Forum include:

- Delivery of a functional and sustainable system for growers to effectively share their priorities for chemical access needs with other growers, RDCs and chemical companies
- Deliver cost savings from investment and reduce current impacts of AgVet chemical market failure.
- Facilitate cross industry prioritisation and investment for improved access to uses of AgVet chemicals resulting in:
 - Improved priority setting and cross industry collaboration
 - Achieving agricultural industry and commercial co-investment in data generation supported through initial government incentive.
 - Increasing the opportunity for international collaboration and data access
 - Achieving cost savings through cross industry efficiencies and national and international collaboration and co-investment

The scope of the Forum to address AgVet investment market failure was previously described in the RIRDC project PRJ-009454³⁰ and PRJ-009981³¹ final reports. Drawing on this, the scope of the Forum is proposed to address the following:

Market failure in major crop and animal industries in addition to existing minor industries will be within scope of the Forum.

³⁰ Rainbow, R. and Krause M. (2015) Improved access to AgVet chemicals for agricultural industries. *RIRDC Final Report Project No PRJ-009454*

³¹ Rainbow R. (2015) Delivery of Access to AgVet Chemicals Collaborative System *RIRDC Final Report Project No PRJ-009981*

Market failure is:

- Considered real if an industry case can be given to identify that market failure has occurred, rather than continuing to accept the current regulation term of crop or animal 'minor use' as being likely market failure.
- Where pesticide use for which the anticipated volume of sales is not high enough for a manufacturer to justify the costs to register and sell the product.

Considerable progress has already been made in developing a new cross-industry culture of collaboration within the Forum. The most recent participant survey has indicated that there is a high level of motivation to engage in the AgVet Collaborative Forum and significant value from identifying industry priorities and discussion with registrants to identify new solutions.

The first plant industry Forum prioritisation workshops were held in Canberra in June 2015 and the second in June 2016. The workshops were well attended at both the two day workshops with over 60 participants including industry representatives, RDCs, state and federal government, APVMA and 15 registrant companies. Industry discussion of issues with registrants identified solutions to a large number of industry priorities, which previously had no identified solution. This highlights the strategic value of the discussion generated by the Forum. The outcomes of this process will have significant potential productivity benefits for the participating industries in the future.

The initial establishment Phase of the Forum in 2015 was funded by the Department of Agriculture. The second phase of the Forum was funded by all plant industry RDCs, plus the animal industry RDCs, Australian Wool Innovation and Dairy Australia. This prospectus details the governance arrangements, operations and investment options for the third phase of the Forum. To enable the Forum to successfully continue beyond 31 October 2016, stakeholders must agree on an approach to collectively support the on-going operations of the Forum for the next three years, ensuring the on-going operations beyond the Department of Agriculture and Water Resources *Improved access to AgVet chemicals initiative* – Grants program.

2. Background - Key issues impacting on agricultural productivity

Plant and animal industries are facing increasing emergence of biosecurity threats and growing impacts from pesticide and veterinary medicines resistance. Australia is no longer recognised as a global priority for pesticide and veterinary medicine commercialisation, as it was 20 years ago. Many Australian agricultural industries are currently missing out on up to 50% of the potential new technologies to which key competitors in Europe and the USA have access. Strategically, Australia needs to access new AgVet chemicals to address these new threats and growing resistance. However, Australian agriculture is missing out on productivity improvement through commercial investment in new chemicals and a large number of potential emerging biological, biochemical and biotechnology based AgVet technologies.

Through facilitated discussions with the agricultural industry Research and Development Corporations (RDCs), peak industry bodies, both Plant and Animal Health Australia, Department of Agriculture, APVMA and key registrant groups CropLife Australia and the Animal Medicines Australia, the major factors resulting in declining investment in Australia were identified. These factors include:

- Australia is a small AgVet market in a global context, < 1.5% of total investment
- Australia is experiencing difficulties with complex AgVet regulations, timeliness and costs relative to commercial return on investment

- Global multinational companies face a poor rate of return on commercialisation investment compared with major developing markets including Brazil and China.

There is clearly increasing market failure for investment in AgVet technologies in Australia. While traditionally market failure has been recognised in minor or establishing industries, in recent years market failure has been increasingly impacting on traditional major plant and animal industries. The increasing number and variety of AgVet chemical priorities reflect a growing market failure well beyond the areas of minor use and specialty crops programs, as illustrated below (Figure 14).

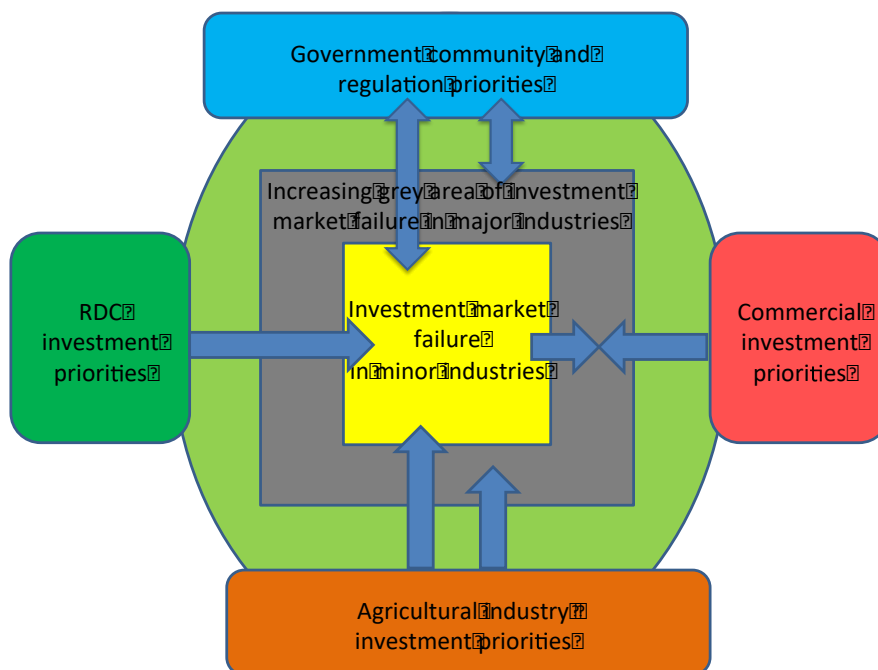


Figure 14. Investment priorities and commercial AgVet investment market failure

3. Benefits of a collaborative approach

Minor use permits have historically been developed in response to urgent industry demand and usually result in a rapid adoption. This has been clearly demonstrated in the Australian grains and horticulture industries. There has also been permits issued for minor use (or limited regional use) in major industries, usually in response to immediate new pest threats or resistance issues. Due to increasing investment market failure, there are increasing AgVet technology needs for major crop and animal industries.

A study funded by the GRDC and HAL by Woods 2014³², identified cost - benefit ratios of minor use permits from 13:1 to 95:1. In the United States under a total economic impacts model, benefits from minor use permits has been shown to be as high as 462:1. The benefits applied to the \$8.1 million expenditure by GRDC and HAL for the 3 years 2010-13 had a total economic impact of at least \$113.5 million and potentially as high as \$3.565 billion. The combined benefit of a broader minor use program when applied to other industries would be significantly higher.

Public benefits from an effective AgVet program addressing market failure include:

- Improving storage or shelf life for food products

³² Woods, P. (2014) Analysis of the impact of proposed APVMA cost recovery changes to GRDC and HAL minor use programs – AvantAgri report to HAL/GRDC http://www.daff.gov.au/__data/assets/pdf_file/0012/2376768/grdcattachment

- Meeting consumer expectations for safe residue free food, noting in 2008/09 the majority of MRLs established in Australia arose from minor use permits, highlighting the demand for minor uses.
- Maintaining a diversity of food types for an increasingly multi-cultural society
- Contributing to protection of the environment
- Managing Australia's international reputation for food production
- Reducing impediments to free trade
- Flow on effects to other industries such as the use in fodder and grain products for livestock and dairy product industries.

Market-opportunity benefits from an effective AgVet program addressing market failure with appropriate prioritisation include:

- Managing Australia's international reputation for food production
- Reducing impediments to free trade
- Flow on effects to other downstream animal industries such as for use in fodder and grain products for livestock and dairy product industries.

Building on the experiences of overseas programs and their success, the key question for Australian industry is whether we can we afford not to deliver a new sustainable collaborative AgVet program to remain internationally competitive?

There is a need to increase investment in AgVet chemicals in Australia, particularly when compared to competing investment opportunity in Asia and South America. One way of addressing this investment market failure in the longer term (as demonstrated in some competitor countries) is to facilitate cross-sector discussion with government and commercial chemical companies on options to increase Agvet chemical access. Industry identified outcomes that need to be achieved in relation to AgVet chemicals include:

- Increased domestic and foreign investment in AgVet chemical development and registration
- Increased agricultural profitability and sustainability through the adoption of new AgVet technologies
- Increased delivery of a diverse range of foods to an increasingly multicultural community
- Increased productivity and scale of industries that contribute to GDP and balance of trade
- Improved safety to community, environment and trade

Experience from other countries that are facing similar issues is that there is opportunity to deliver these outcomes through a collaborative approach. Improved prioritisation of needs; identification of benefits of co-investment by industry, government and commercial registrants; and establishment of investment incentive frameworks to support these programs has had a significant impact in delivering benefits to industry and the community.

4. Outputs and Success to Date

As part of a program of work to improve producers' access to AgVet chemicals, the Australian Government Department of Agriculture contracted the Rural Industries Research and Development Corporation (RIRDC) in 2014 to establish a sustainable system for producers to effectively share their priorities for AgVet chemical access needs with other producers, research and development corporations (RDCs) and chemical companies; to deliver cost savings from investment and reduce current impacts of AgVet chemical market failure.

To facilitate this, RIRDC established the **AgVet Collaborative Forum** ('Forum') in 2015 to provide a platform for consideration of options for collaborative cross-industry AgVet investment. This aims to increase current industry and commercial registrant participation and investment in addressing Australian AgVet chemical needs. It is anticipated that this will reduce the current impacts of market failure through a more coordinated and structured approach.

In delivering the Forum outcomes detailed previously, the AgVet Collaborative Forum from 2017 will deliver the following outputs and milestones:

1. Maintain a list of cross-industry AgVet chemical priorities to:
 - a) Provide a basis for information sharing and consideration of co-investment opportunities to better use national and international resources for supporting applications to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for AgVet chemical uses including:
 - i) Provide industry stakeholder consultation support in assembly and refinement of priorities
 - ii) Assemble industry priorities for prioritisation database
 - b) Provide a mechanism for producers to have informed discussions with chemical companies of potential market demand to assist in their decisions to register Australian uses including:
 - i) Consultation of draft industry priorities with CropLife and AMA members
 - ii) Workshops delivered to prioritise and achieve consensus on technical registrant support
 - iii) Evaluate workshop outcomes and report submitted to RDCs and registrants
2. Provide a forum for producers and the chemical industry to interact with the Department of Agriculture and APVMA to:
 - a) Identify current AgVet priorities for each participating industry sector
 - b) Consider opportunities to improve access to chemicals
3. Provide a mechanism to efficiently coordinate and increase access to international data generation programs,
 - a) Formalise collaboration with the north American United States IR-4 and Canadian minor use programs.
 - b) Identification of alignment of national and international IR-4/CANMUP priorities delivering potential cost savings in data generation
4. Support a framework for government conditional co-investment with industry and registrants including:
 - a) Deliver an annual update to the AgVet website and communications program

- b) Deliver a report to stakeholders to continue the operations of the AgVet Collaborative Forum

Current deliverables from the RIRDC project PRJ-009981 for the AgVet Collaborative Forum program which have not been budgeted in this 2016 proposal include:

- Assemble performance indicators (not including survey costs) for the success of the Forum and benefits of investment outcomes

While measurement of Forum performance, identification of potential international collaboration for data sharing and generation of cost savings are seen as important, their importance is secondary to the delivery of Forum discussion and prioritisation. Specific discussion with forum stakeholders on these deliverables and potential funding will be discussed in the agenda of the next meeting of the Forum.

Considerable progress has been made since the first stakeholder meeting in November 2014, in developing a new cross-industry culture of collaboration. The most recent participant survey in June 2016 identifies that there is a high level of motivation to engage in the AgVet Collaborative Forum and significant value in identifying industry priorities and discussion with registrants to identify new solutions.

Forum prioritisation workshops were held in Canberra in June 2015 and 2016. The plant industry workshops were well attended on the 2 days with over 60 participants including industry representatives, RDCs from all Australian plant industries, state and federal government, APVMA and 15 registrant companies.

The outcome for the plant industries from this workshop is particularly significant with the industry discussion of issues with registrants identifying solutions for over half of the top third of industry priorities, which previously had no identified solution. This highlights the strategic value of this discussion generated by the Agvet Collaborative Forum. The outcomes of this process will have significant potential productivity benefits for these industries in the future. Without the Forum, these discussions may not have occurred, or it may have taken much longer to identify solutions.

The workshops highlighted the opportunity for industries to work together on needs to address common AgVet issues. For example, the prioritisation needs of animal industries highlighted the high priority for almost all animal industries for access to local anesthetic technology for improving animal welfare.

From these plant industry Forum workshops, the following outcomes were achieved:

- In 2016, 500 unique crop/pest issues were identified for all Australian plant industries seeking solutions to registration gaps. Of these industry issues, 173 had no identified solution for which 90 new potential solutions have been identified by registrants. An additional 96 new solutions were identified by registrants adding to existing options proposed by industry. A total of 315 'A-L (Label) projects and 143 'A-P' (Permit) projects were identified. Additionally 24 solutions already on registration track that industry was not previously aware of were identified through discussions. Consideration of chemical modes of action and stewardship for resistance management were discussed during the Forum. These outcomes will improve pesticide resistance management by industry through access to a wider range of modes of actions.
- In 2015, 326 unique crop/pest issues, of which 319 solutions are technically supported by registrants. Of these industry issues, 135 had no identified solution for which 78 new potential solutions have been identified by registrants. An additional 90 new groups of solutions were identified by registrants adding to existing options proposed by industry.

From the 2015 Forum workshop and 2016 animal industries prioritisation process, the following outcomes were achieved:

- In 2016, 69 unique animal pest issues, resulting in 36 solutions technically supported by registrants.

- In 2015, 98 unique animal pest issues, resulting in 68 solutions technically supported by registrants. Four additional groups of solutions to industry issues were identified by registrants.

5. Future AgVet Collaborative Forum operations

a) Participation

It is intended that the separate Forums are open to all representatives of plant and animal industry primary producers that have a need to use agricultural chemicals and veterinary medicines or contribute towards the regulation, investment or commercialisation of these products in the delivery of agricultural production. It has been proposed that a separately operated and funded plant and animal industry Forum is funded for continuation beyond 2016. While it is recognised that this could result in a large number of stakeholders, it is essential that the program deliver the long term strategic needs of all industries.

The Forum is also open to:

- Representatives from all AgVet chemical companies with a presence in Australia, together with their representative organisations
- Representatives from all rural RDCs
- Representatives from the Australian Government Department of Agriculture
- Representatives from the APVMA
- AgVet chemical technical resources
- Representatives from state and territory governments chemical regulation and compliance bodies
- Other parties as agreed by the Forum.

b) Management

Corporate governance oversight of the Forum would reside with RIRDC or an alternate nominated RDC supported by a separate plant and animal industry steering committee made up of investing RDCs, CropLife Australia and Animal Medicines Australia, which would seek consideration of advice from the wider Forum. RIRDC and the RDCs have well-defined and tested policies and procedures in place to support this approach. Transition to Phase 3 of the Forum will be overseen by the current Phase 2 AgVet Collaborative Forum Plant Industries steering committee.

RIRDC or an alternate RDC will appoint an organisation through an open multi-stage tender process providing a potentially separate part-time Forum Manager for the animal and plant industry Forums, who will have responsibility for the day-to-day management of the Forum, to:

- manage the business of the Forum, including oversight of Forum operations and out of session processes.
- implement decisions of the Forum.
- establish and maintain appropriate administrative arrangements for the Forum, including:
 - preparation, monitoring and reconciliation of a budget;
 - the provision of a secretariat service to the Forum; and
 - ensuring that all documentation is prepared, maintained and accessible to Forum participants.
- manage any financial affairs of the Program, as required.
- arrange for the provision of effective corporate governance and accountability services for the Forum, including legal and audit services if required.
- establish and maintain contract management services, as required.
- provide general business support, including management of intellectual property.
- oversee maintenance of the Forum's communications requirements, including the relevant web pages.

c) General Forum Meetings

The separate plant and animal industry Forums will meet annually (or as otherwise agreed by the Forum) face-to-face to:

- Review the cross-industry list of AgVet chemical priorities
- Consider alterations / improvements to the operations of the Forum
- Any other business raised by Forum participants or unresolved out of session issues.

RIRDC or an alternate RDC will appoint a potentially separate facilitator for each of the plant and animal industry Forums that will, in consultation with RIRDC or an alternate RDC:

- 1) Chair the face-to-face meetings
- 2) Develop meeting agendas, ensuring the industry members or investors of RDCs, members of Plant Health Australia, the National Farmers Federation, the company members of CropLife Australia, the Department of Agriculture and the APVMA are engaged in the process.
- 3) Maintain a record of all meetings.
- 4) Maintain an accurate, up to date record of the AgVet Forum database and Priority List.
- 5) Support RDC's management of OOS issues, as required.

The Forums will operate by consensus. It will be the responsibility of the facilitator to ensure this occurs.

d) Prioritisation workshop process

The separate plant and animal industry AgVet Collaborative Forum workshop prioritisation process will be delivered in 2 phases:

- Phase 1 – Industry facilitation and identification of needs - based on crop/pest. Each industry sector will be invited to submit its priorities through its RDC prior to the workshop
- Phase 2 - AgVet Collaborative Forum prioritisation workshop – an annual workshop, run separately for plants and animals

The inputs for the process include:

- A target number of 'A' projects nominated by the Department of Agriculture and Water Resources
- Industry priorities with at least the 'top 5' being identified

Preparation:

- All industries submit draft priority lists – Identify top 1-5 priorities based on crop/pest – potential solutions identified. Any registrant support is noted
- Plant and animal prioritisation will be run as a separate funded Forum.
- Industry/registrant discussions on identified issues prior to the workshop will be an advantage to those industries (Figure 15).

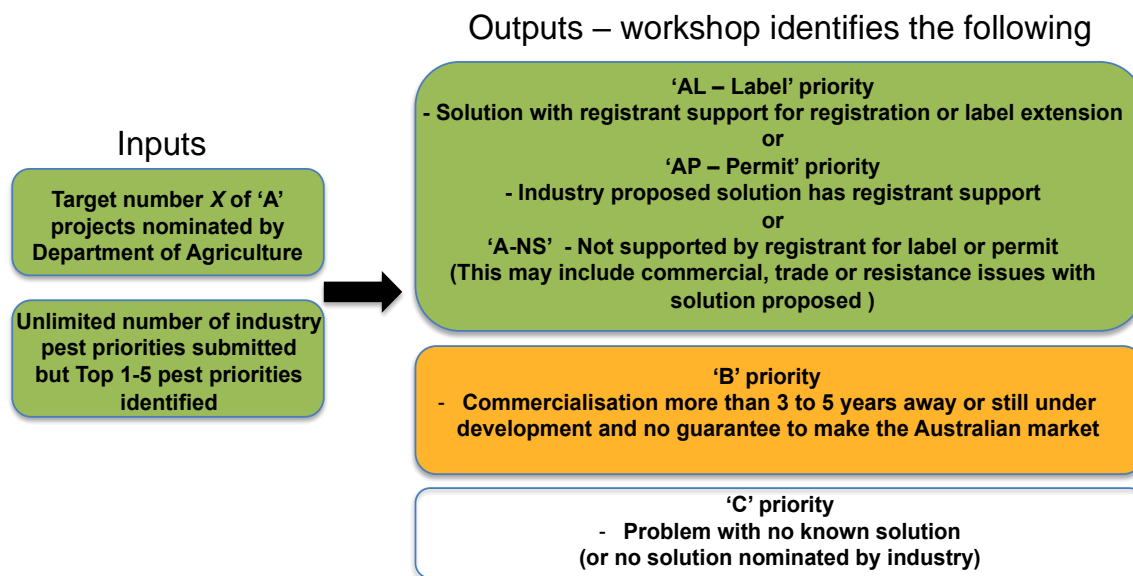


Figure 15. AgVet Collaborative Forum inputs and outputs for prioritisation

The Forum prioritisation workshop incorporates three key steps. Voting of 'A-P' or 'A-L' priorities by industries is a key step to identify the high priority needs. Interaction of industries with registrants during the workshop is an important component, which aims to result in registrants providing 'in principle' support for potential solutions for 'A-P and A-L' priorities, which can be developed into projects for investment. It is however recognised that industries which nominate for 'A-P' or permit projects, will likely result in industries bearing most of the project cost (see figure 16).

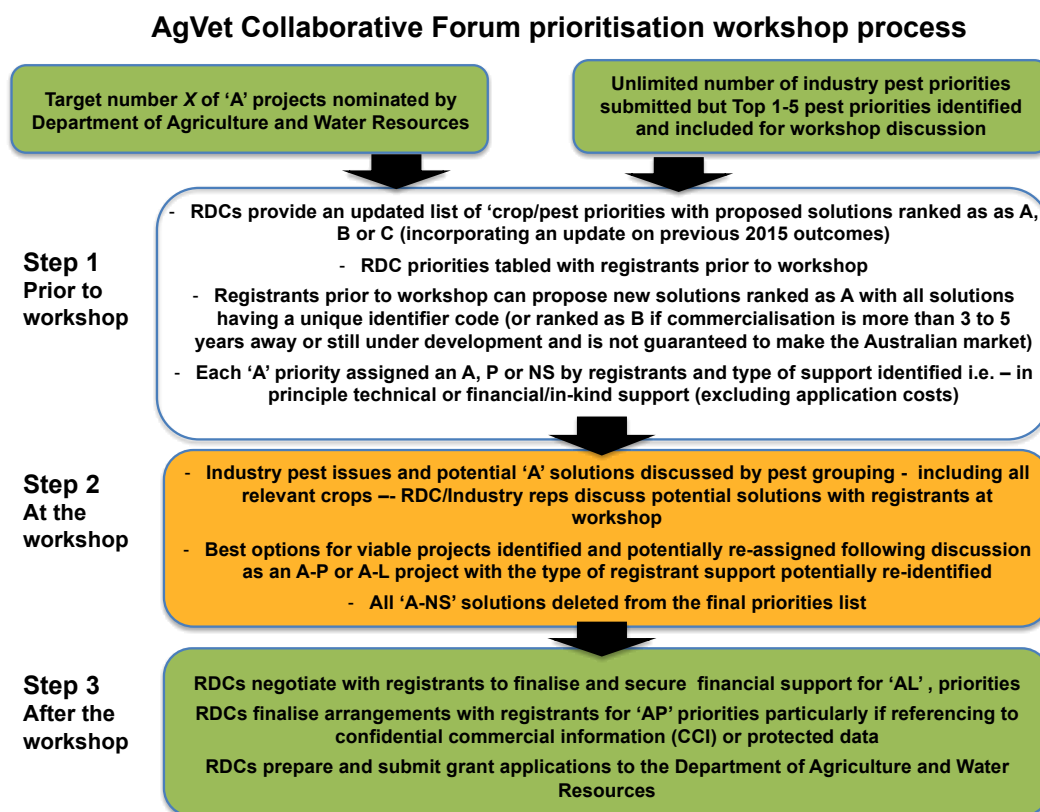


Figure 16. AgVet Collaborative Forum prioritisation workshop process

Although outside the scope of this Forum coordination project, the next steps for delivery of project development and co-funding by industry, government and registrants will be managed by the respective industry RDC as detailed in figure 17. Where projects are supported by one or more RDC, then the industry contributing the most significant component of the funding will take overall leadership responsibility. The relevant RDC will be responsible for contracting data generation including field trials and laboratory analysis. The RDC will also be responsible for liaison with the relevant registrant for report assembly for submission of data packages to the regulator APVMA.

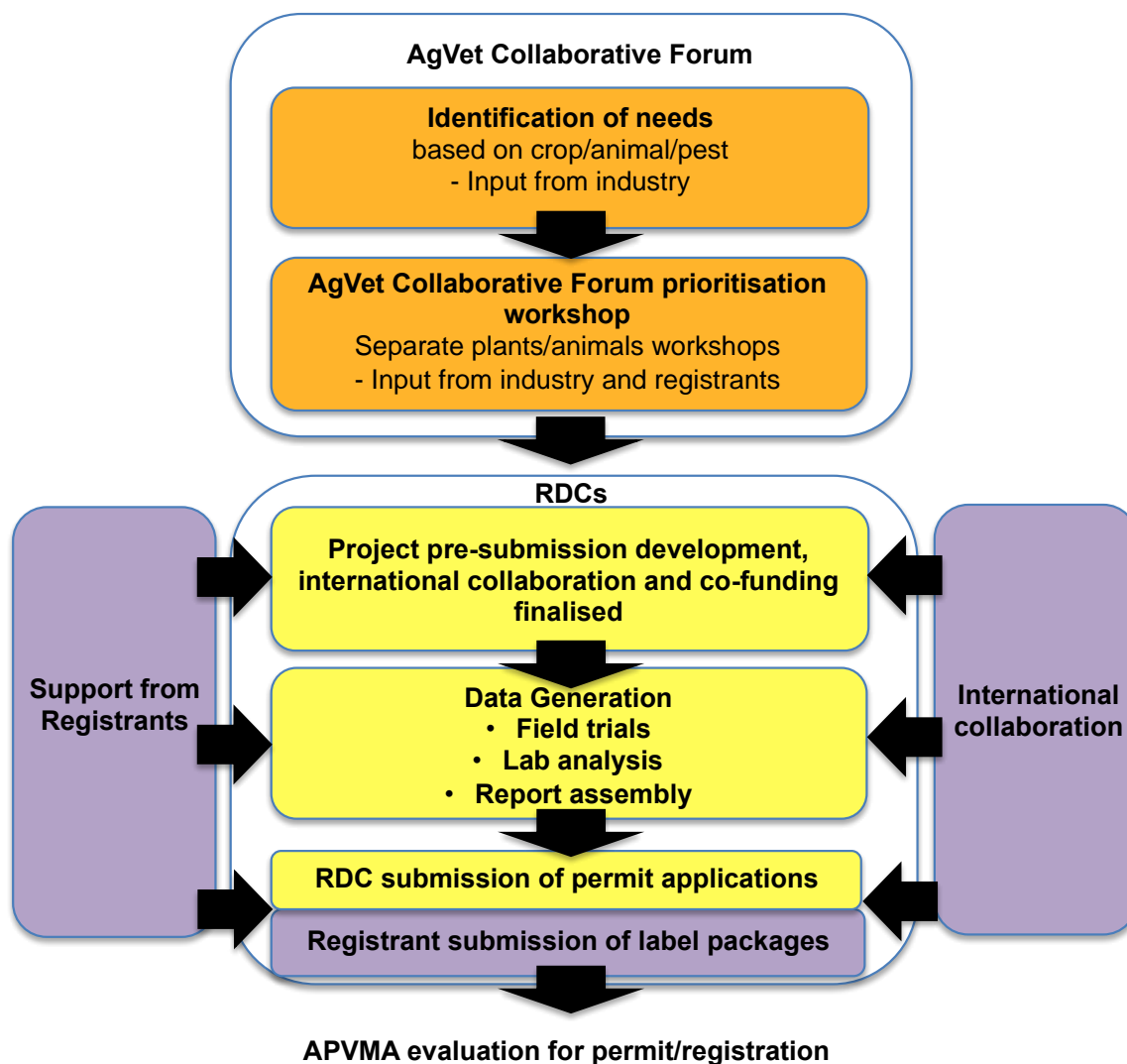


Figure 17. AgVet Collaborative Forum prioritisation process next steps for RDCs delivering industry access to AgVet technologies

e) Out of Session Business

As the Forum only plans to meet once per year, there will be a requirement to consider issues out of session (OOS). The conduct of OOS business will be as follows:

- OOS business will be conducted by email and/or teleconference.

- The list of Forum participants (including email addresses) will be maintained by the Forum Manager.
- The Forum Manager is responsible for the preparation of papers addressing issues to be considered OOS.
- Issue papers must include:
 - Background to the issue
 - Consideration of the issue
 - Recommendation
- Forum participants will have 10 working days from the date of dispatch of the email to consider issue papers and provide one of the following responses:
 - Endorse the recommendation
 - Not endorse the recommendation
 - Request additional information / actions. This must include details of what additional information / actions are required and why they are needed.
- The Forum Manager will be responsible for engaging with Forum participants and resolving any issues.
- OOS decision-making will be by consensus. Any unresolved issues will be included on the agenda for the next face-to-face Forum meeting or if resolution is time critical, addressed under Item 7. Dispute Resolution.
- Any Forum participant that does not respond within the 10 working days will not be considered in the assessment of responses.

6. Communications

RIRDC has established a communications program to support the program. It is proposed that this program would continue to be managed by RIRDC or an alternate RDC which has the following goals:

1. To clearly articulate the purpose and objectives for the project.
2. To describe the achievements and benefits of the Forum.
3. To communicate the operations and activities of the Forum and provide linkages to related projects or activities.

This will be achieved by:

1. Maintaining a set of communications materials that will be drawn upon for all communications activities relevant to the project.
2. Targeting the materials to the relevant target audiences using the most effective communications channels available.

It will be the responsibility of the Forum Manager (s) to maintain the communications materials.

7. Forum activity timeframes

Plant and animal industries Forum Phase 3 start date – 25 January 2017

Proposed 3 year Forum completion date – 1 December 2019

The key activities for the Forum would be delivered around the following timeframe:

1. Finalisation of industry priorities – March each year
2. Consultation with industry and registrants – March each year
3. Distribution of a final list of industry gaps for AgVet priorities to registrants – Mid April each year
4. Agvet Collaborative Forum prioritisation workshop – early May each year
5. Finalisation of prioritisation workshop outcomes – by late May each year

6. AgVet Collaborative Forum strategic discussion workshop – September each year
7. Annual report to Forum investors – November each year

8. Forum Review

Within 2 years of the establishment of Phase 3 of the Forum (and two face-to-face meetings of Third Phase Forum have been completed), consideration will be given to a review of the Forum undertaken by an independent party. The Terms of Reference for the review could include:

Engagement with all Forum participants to:

- Identify the strengths and weaknesses of the Forum, as well as the opportunities not yet realised and the threats or challenges facing the Forum.
- Assess the benefits delivered by the Forum to date.
- Consider opportunities for improving the operations of the Forum.

Funding of an independent review has not been incorporated in the budget underpinning this prospectus.

9. Dispute Resolution

Where Forum consensus cannot be reached, including the resolution of time critical decisions, the issue will be referred to the RDC program manager, who will establish a process, in consultation with the relevant / affected Forum participants, to resolve the dispute.

10. Funding

The principles of funding for the continuation of the AgVet Collaborative Forum are based on a shared benefit and equity for investment by all agricultural industries. The proposal is also based on the benefits that registrants and government will receive in reducing their consultation costs with stakeholders. Estimated costs for delivery of the following milestones in the delivery of the Forum are shown separately for plant and animal industries in tables 6 and 7. Separate plant and animal industry budgets are based on an industry attendance of up to 80 persons per day for the plant industries Forum and 40 persons per day animal industries Forum. Any unspent funds from one year will be rolled over to the next and an annual account of expenditure will be reported to investors in the Forum.

For involvement in the Forum of non-investing industries/chemical companies that do not contribute to the funding of the forum through a peak Crop Protection organisation or RDC, there will be additional charges set by the steering committee.

Table 6. Estimated plant industry annual costs for continued delivery of the Agvet Collaborative Forum

Milestone	Deliverable	Budget \$ excluding GST
Nominated RDC	RDC Coordination costs	\$6,500
Milestone 1	Provide industry stakeholder consultation in assembly and refinement of priorities	\$13,000
Milestone 2	Assemble industry priorities for prioritisation database	\$7,000
Milestone 3	Consultation of draft industry priorities with CropLife members	\$11,000
Milestone 4	Workshop delivered to prioritise and achieve consensus on technical registrant support	\$21,500
Milestone 5	Evaluate workshop outcomes and report submitted to RDCs and registrants	\$5,000
Milestone 6	Deliver a plant industry strategic discussion workshop	\$6,000
Milestone 7	Deliver an annual update to the AgVet website and communications program	\$5,000
Milestone 8	Coordinate communication and increase access to international data generation programs including IR-4 and CAN MUP,	\$10,000
Milestone 9	Deliver a report to stakeholders	\$5,000
Milestone 10	Progress/Annual/Final reports submitted to RIRDC or nominated RDC.	\$5,000
Total Budget		\$95,000

Table 7. Estimated animal industry annual costs for continued delivery of the Agvet Collaborative Forum

Milestone	Deliverable	Budget \$ excluding GST
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Nominated RDC	RDC Coordination costs	\$6,500
Milestone 1	Provide industry stakeholder consultation in assembly and refinement of priorities	\$5,000
Milestone 2	Assemble industry priorities for prioritisation database	\$1,500
Milestone 3	Consultation of draft industry priorities with Animal Medicines Australia members	\$8,000
Milestone 4	Workshop delivered to prioritise and achieve consensus on co-investment options	\$13,750
Milestone 5	Evaluate workshop outcomes and report submitted to RDCs and registrants	\$5,000
Milestone 6	Deliver a 1 day animal industry strategic discussion workshop	\$4,250
Milestone 7	Deliver an annual update to the AgVet website and communications program	\$2,000
Milestone 8	Deliver a report to stakeholders	\$5,000
Milestone 9	Annual report/Final report submitted within 1 month to RIRDC or the nominated RDC.	\$4,000
Total Budget		\$55,000

Based on the principle of shared equity, it is proposed that investment in the AgVet Collaborative Forum is based on the following equity investments, recognising that some industries are larger beneficiaries of the program, particularly horticulture and grains and emerging industries via RIRDC. Based on this principle, the following separate funding arrangements for plant and animal industries are proposed in tables 8 and 9.

Based on the principle of shared equity, it is proposed that investment in the AgVet Collaborative Forum is based on the following equity investments, recognising that some industries are larger beneficiaries of the program, particularly horticulture and grains and emerging industries via RIRDC. Based on this principle, the following funding arrangements are proposed

For involvement in the Forum of non-investing industries/veterinary medicine companies that do not contribute to the funding of the forum through a peak AgVet organisation or RDC, there will be additional charges set by the steering committee.

11. Response timeline for stakeholder decisions

To enable the AgVet Collaborative Forum to successfully continue beyond 31 October 2016, there needs to be consensus by stakeholders to continue the investment in the AgVet Collaborative Forum for at least another 36 months. For continuity of this program and meet Department of Agriculture expectations for the successful continuation of the AgVet Collaborative Forum, an investment decision by stakeholders is required by 30 November 2016, formalised through signing of the MOU provided to investors by RIRDC.

Ideally this investment should continue annually for 3 years until 1 December 2019 to ensure delivery beyond the Australian Government priority and \$8 million investment commitment – A Competitive Agriculture Sector - improved access to agricultural and veterinary chemicals.

Table 8. Proposed plant industry annual stakeholder investment per annum over 3 years in the AgVet Collaborative Forum

Contributor	\$ Investment contribution excluding GST
Horticulture Innovation Australia (HIA)	\$15,000
Grains Research and Development Corporation (GRDC)	\$15,000
Rural Industries Research and Development Corporation (RIRDC)	\$10,000
Wine Australia	\$10,000
Cotton Research and Development Corporation (CRDC)	\$10,000
Sugar Research Australia (SRA)	\$10,000
Forestry and Wood Products Australia (FWPA)	\$10,000
Dairy Australia (Pastures only) [#]	\$5,000
CropLife Australia and member companies	\$10,000
Total proposed contributions	\$95,000
Total proposed contributions over 3 years	\$285,000

[#]Amount would be revised to \$10,000 if participation in animal industries Forum does not occur.

Table 9. Proposed animal industry annual stakeholder investment per annum over 3 years in the AgVet Collaborative Forum

Contributor	\$ Investment contribution excluding GST
Rural Industries Research and Development Corporation (RIRDC)	\$10,000
Australian Wool Innovation (AWI)	\$10,000
Meat and Livestock Australia (MLA)	\$10,000
Dairy Australia	\$10,000
Plus an additional RDC	\$10,000
Animal Medicines Australia and member companies	\$5,000
Total proposed contributions	\$55,000
Total proposed contributions over 3 years	\$165,000

Appendix 13. Excel data files

- AgVet Collaborative Forum priorities list outcomes (Excel file) – Finalised 14 July 2015.
- Revised Australian plant industry priority list for OECD Global joint review (Excel file) – Finalised 15 July 2015.
- Global data options 2015 plant and animal AgVet priorities (Excel file) – Completed 30 September 2015.
- AgVet Collaborative Forum priorities list outcomes (Excel file) – Plant industries list finalised 30 June 2017 – Animal Industries list finalised 12 August 2016.



NATIONAL RURAL ISSUES

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by Rohan Rainbow

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