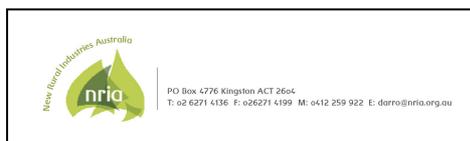


Submission On Reforms to Deliver Sustainable Minor Use Crop Protection Solutions for Australia's Agricultural Industries

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On behalf of: Australian Minor Use Industries, March 2011



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Disclaimer

The information contained in this document is based on knowledge and understanding at the time of writing (February 2011). Recognising that some of the information in this document was provided by third parties, the author and supporting horticultural and other minor use industries take no responsibility for the accuracy, currency, reliability and correctness for any information provided by them.

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Glossary of Acronyms

AAFC	Agriculture & Agri-Food Canada
ABARE	Australian Bureau of Agricultural and Resource Economics (Australia)
ABS	Australian Bureau of Statistics
AgVet	Agricultural and Veterinary
AMGA	Australian Mushroom Growers Association Limited
APAL	Apple & Pear Australia Limited
APVMA	Australian Pesticides & Veterinary Medicines Authority
COAG	Council of Australian Governments
DAFF	Department of Agriculture, Fisheries & Forestry (Australia)
EPA	Environmental Protection Agency (US)
EPPO	European & Mediterranean Plant Protection Organization
EU	European Union
FSANZ	Food Standards Australia New Zealand
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
GRDC	Grains Research & Development Corporation (Australia)
GST	Goods & Services Tax
HAL	Horticulture Australia Limited (Australia)
HC	Health Canada
IPHRG	Interstate Plant Health Regulation Working Group (Australia)
IPM	Integrated Pest Management
IR-4	Interregional Research Project No. 4 (US)
MRL	Maximum Residue Limit
MULO	Minor Use Liaison Office (Australia)
NFF	National Farmers Federation (Australia)

NRA	National Registration Authority (Australia)
NRS	National Registration Scheme
OCPPO	Office of the Chief Plant Protection Officer (Australia)
OECD	Organization for Economic Co-operation and Development
PHA	Plant Health Australia
PMC	Pest Management Center (Canada)
PMRA	Pest Management Regulatory Agency (Canada)
PSIC	Product Safety & Integrity Committee (Australia)
QA	Quality Assurance
R&D	Research and Development
SA	South Australia
SCDU	Specialty Crops Development Unit (Australia)
SOLA	Specific Off-Label Approval (UK)
UK	United Kingdom
URMULE	User Requested Minor Use Label Extension (Canada)
URMUR	User Requested Minor Use Registration (Canada)
US	United States (of America)
VFF	Victorian Farmers Federation

Executive Summary

The Submission

This submission has been prepared to detail the issues pertaining to minor use of pesticides and pesticide risk reduction in Australian agriculture.

Significantly, it also recommends a new platform for the delivery of a sustainable and effective approach through a single, national regulatory framework.

The proposed approach allows Australian agricultural industries to work with other stakeholders on a commodity and national scale, to identify and develop meaningful pest, disease and weed minor use priorities, reduced risk products, risk reduction strategies and ultimately effective, targeted crop-specific IPM programs. These will, in turn, provide cost effective and meaningful guidance to minor use agricultural sector organisations and to HAL, GRDC and RIRDC on funding priorities for IPM, biosecurity and other areas of sustainable crop protection policy. Significantly, it combines minor use with a new initiative on risk reduction, which is a first for Australia. In so doing, the proposal as outlined in the recommendations below, addresses the key objectives contained in the preamble to the Agricultural & Veterinary Chemicals Act 1994. These recognise the importance of protecting the health and safety of human beings, animals and the environment as essential to the well-being of society and of the demands of ecologically sustainable development in a regulatory system. In addition, we firmly believe that the proposal meets the required policy outcomes for three key elements of the proposed national policy framework for assessment, registration and control of use of Agvet chemicals approved on 10 August 2010 (Anon. 2010a).

Firstly, that the *'Access to Chemicals - Operating Environment* (shall ensure that)

1. Effective regulation manages the risks while minimising costs for businesses
2. Users in all jurisdictions have the same right of access to Agvet chemicals unless regional risk management measures require otherwise
3. An internationally competitive scheme that does not unduly constrain access to new and existing Agvet chemicals
4. Regulation of Agvet chemicals that does not unduly constrain industry development particularly for
 - industries with minor use demands for Agvet chemicals
 - developing chemical industries.

Secondly, under *Access to Chemicals - Assessment and Registration*, in accordance with Policy Principle Number 4, it meets the outcome of (Registration of) Agvet chemicals available for use on as wide a range of host/pest combinations as possible.

Thirdly, under *Access to Chemicals – Permits and Permissible Uses*, that access to chemicals (is available) for minor industries and minor uses in larger industries.

Aside from the submission delivering meaningful outcomes to minor use producers, it also fulfils legislative goals, plus policy outcomes in the current COAG review.

The Industry

Australian agriculture is the key supplier of safe, fresh food of the highest quality to the Australian market, with an enviable reputation as a reliable exporter. Horticulture is the third largest Australian agricultural producer, with an annual farm gate value currently at \$8 billion, behind only meat and grains. Despite this enviable contribution to the national economy, horticulture is not an industry *per*

se, but is an amalgamation of a large number of different crops that are non-broad acre in cultivation. In Australia, horticulture contains crops such as apples, beans and caper berries representing large, medium and smaller sized commodities. Surprisingly, it contains in excess of 50 individual industries, some of which, such as vegetables, embrace almost as many crops again. This profusion of disparate industries has made it difficult to organise in a coherent way and it is only through an effort such as this that horticultural industries' views and aspirations on an issue of the magnitude of Minor Use can be presented in a unified manner.

The Issue

Under the present legislation (AgVet Code) most horticultural crops fall into the '*Minor Use*' classification, where the amount of pesticide use does not satisfy the economic business case of agricultural chemical manufacturers, resulting in commercial decisions against registration.

To access the necessary range of agricultural chemicals, horticulture has to rely on the off-label permit scheme and other State control-of-use off-label provisions. This is an entirely unsatisfactory situation. Statistics clearly demonstrate that the permit scheme is used for far too many '*new use*' approvals and that horticulture has the majority of these. For example, in 2010, there were 61 registrations, compared with 96 permit approvals for new uses in agricultural crops granted by the APVMA, of which 51% and 57% respectively, were for horticulture. In 2010 64% of all applications finalised involving new uses in horticulture were as a result of a permit application.

Permits are a temporary measure that must be renewed periodically, yet they are subject to the same 'core legislative requirements' as apply to registrations. The costs fall on the applicant, which for minor uses is the end user, the producer, rather than the chemical manufacturer. This situation places a significant cost burden on horticultural producers and smaller livestock industries. This disadvantaged position is unacceptable and is a manifestation of the present outdated agricultural chemical regulation system that has been allowed to continue without reform for too long. Additionally, it is hard to reconcile the large number of permits with the significantly fewer human and funding resources available to them from all sources for R&D to generate efficacy and safety data and for the regulatory process, compared with those available for registrations.

Chemical reviews are also a contributing factor to the minor use issue that cannot be ignored. Such reviews place increased pressure on existing registered uses in minor crops where registrants, when requested for further data, choose not to protect those uses for economic reasons. De-registration of such uses has significant and often immediate consequences for producers. Recent examples include reviews into chemicals such as procymidone, carbendazim, quintozone and endosulfan, all of which have had implications for agricultural producers. On the radar are the possible and imminent implications of reviews into dimethoate and fenthion. These reviews could have significant ramifications for a large number of horticultural crops. For example, it may leave them without fruit fly treatments required to gain access to both intra and interstate markets.

A New Approach

Internationally, many governments are adopting new approaches that are focusing on delivering multi-faceted outcomes for all stakeholders. The present regulatory reviews by COAG and in the *Better Regulation of Agricultural and Veterinary Chemicals Policy Discussion Paper* afford an opportunity to implement a new approach to the minor use issue, based on the successful pioneering model of the US IR-4 program, and more recently, the Canadian Minor Use Pesticides and Pesticide Risk Reduction Programs. Furthermore the European Parliament has requested the European Commission provide it with a report on the establishment of a European fund for minor uses accompanied, if appropriate, by a legislative proposal. The report is scheduled for submission to

the European Parliament later this year. Benefits of international collaboration are indisputable and await Australia's participation to reap the rewards in cost and resource savings as well as sharing regulatory risk assessments. Australia cannot afford to be left behind as the invitations to join these international programs are there. The financial return on public investment in minor use schemes is indisputable following the economic analysis of the IR-4 scheme reported in 2007, which demonstrated a 780 fold return on investment.

The proposed new approach to addressing minor use-risk reduction issues will require a budgetary allocation by the federal government. There is no avoiding this conclusion. The myriad of horticultural industries, despite their combined value, are in no position to individually meet the financial demands of pesticide registration to enable industry to meet its obligations and to remain competitive. The fundamental aim of this legislative reform process, aside from developing a single, national regulatory framework for the assessment, registration and control of use of Agvet chemicals, is to reduce the cost burden on industry and this should apply equally to the end user as well as to chemical manufacturers.

It is important to recognise that government has a key role to play in ensuring the necessary delivery of appropriate crop protection solutions and influencing that delivery through policy development as to the type of crop protection mechanisms Australia's agricultural industries adopt.

RECOMMENDATIONS

It is recommended that the Australian government develops a reform agenda that brings together a 'whole-of-systems' approach, which recognises the needs of consumers and agricultural producers, facilitates the private sector's engagement in that process, and has desired outcomes underpinned by policies and legislation in the regulatory approval process. In so doing, it is recommended that two fundamental and interrelated approaches should be adopted.

- the establishment of a *National Sustainable Minor Use Crop Protection Program*, and
- for that program to be complemented with appropriately tailored *Regulatory Processes and Incentives*.

The elements of these are summarised below, while details are *fully described on pages 31 - 42*.

- *A National Sustainable Minor Use Crop Protection Program* should include:
 - a) A Minor Use Crop Protection Program
 - b) A Pesticide Risk Reduction Initiative
 - c) The following working groups comprising industry stakeholders:
 - National Crop Protection Technical Working Group
 - Pesticide Risk Reduction Technical Working Group
 - Commodity Stakeholder Working Groups
 - Biosecurity & Market Access Technical Working Group
 - d) A budgetary allocation from the Australian Government on a 5-year cycle to support all of the above activities; the APVMA, to increase its capacity to review submissions and to provide shorter timelines for registration of new minor use and reduced risk products and uses; and the activities of the working groups.
- *Regulatory Processes and Incentives* should offer regulatory reforms in:
 - a) Data Protection
 - b) Expedited Reviews
 - c) Fee waivers

- d) Conditional registration
- e) Data waivers
- f) International collaboration
- g) User Requested/Supported Registrations.

Introduction

This submission sets out to raise awareness of the minor use issue with the PSIC and the Federal Agriculture Minister, and to stress the seriousness with which these issues affect Australian horticultural industries. It points out the successful common approaches taken in the US, Canada and presently by the EU, to address the same issues and industry concerns, and recommends components of regulatory reform, with the complementary establishment of a *National Sustainable Minor Use Crop Protection Program* in Australia. It is important that the Federal government understands the extent of this problem and the level of industry support for real change to restore its competitiveness.

In the submission, the pesticide-related issues of registration (national), control-of-use (State), minor use (a crop classification impacting on registration and control-of-use), risk reduction and industry participation in decision-making processes, will be discussed and recommendations made. This is not a literature review on what is a complex topic, but out of necessity, information has been sought and obtained from a number of sources both locally and internationally, to develop this submission into a credible document.

Internationally, there is increasing acknowledgment of the significance of speciality crops and minor uses, the need to ensure the availability of crop protection solutions for them and recognition that government has a role to play in meeting the cost of these actions. For example, with the implementation of new European Union Regulations concerning the placing of plant protection products on the market (Anon. 2009a), Article 51 of the Regulation states that *“By two years after the entry into force of this Regulation, the (European) Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal”* (due date is 14 Dec 2011). To consider options in addressing this, an EU conference on specialty crops and minor uses was held on the 4 November 2009, involving representatives of the European Commission, member states and a number of food chain organisations. A key finding of this conference was that the government funded IR-4 program in the US was an excellent model that provided solutions and had *shown a high return on investment* (Anon. 2009b). Economic analysis had shown that an investment of \$US10 million in minor use initiatives provided nearly \$US7.8 billion to the US gross domestic product (Miller 2007). It was concluded that a similar approach could be beneficial in Europe and it is believed that this would be true for Australia also. The following quotation and key conclusions from the Specialty Crops and ‘Minor Use’ Conference could well have been written about Australia.

‘A large number of crops that are of major importance for the food industry and consumers are relatively minor, both in scale of production and also in their use of plant protection products, when compared to the total agricultural production. While the magnitude of pest problems faced in these crops is similar to major crops, many newer and more efficient plant protection solutions are often unavailable to farmers and the food chain operators, mostly for economic reasons. The availability of an adequate crop protection toolbox for the future is a key element to support farmers to continue producing minor crops as well as ensuring a safe and efficient completion of the food supply chain.’

Presently in Australia, the chief beneficiaries of the NRS are producers of major-use crops, where manufacturers/registrants in the majority of instances undertake the necessary R&D and make regulatory submissions and defend those major uses when subject to chemical reviews. The same is not true for producers of minor use crops where their uses do not satisfy the economic business case decisions of manufacturers/registrants. These producers or industry associations (on behalf of producers) must themselves fund and conduct the necessary R&D as a precursor to making regulatory submissions via the off-label permit scheme to seek legal access to pesticides, and in

responding to chemical reviews, by either defending essential uses or seeking new use approvals. This has led to a number of problems. The effect of this disparity has meant that many of the minor use industries, most of which are horticultural, have to all intents and purposes been disenfranchised. Additionally, State control-of-use legislation has resulted in varying requirements from State to State for legal access to pesticides. This non-uniform approach is unsatisfactory, particularly for producers who have operations in different States of Australia.

Minor use has a lengthy history of discussion and inaction in this country (Appendix 1), despite considerable interaction between the APVMA and their overseas counterparts, where minor use registration is available, and with the OECD Expert Group on Minor Uses, of which Australia provides the chair.

Issues that Concern Australian Minor Use Producers

Minor use

Defining minor uses

Minor uses as outlined in the Consultant's Discussion Paper (Rose and Sheppard 2009), are principally associated with uses that do not attract commercial interest by product registrants, where the potential economic return from those uses is insufficient to justify the costs of registration.

This is not simply about the fee charged by the regulator, but rather the cost of the research that needs to be conducted to generate data on efficacy, crop safety, residues, occupational exposure and environmental impacts. Minor uses are not an issue faced solely by Australian producers and regulators, but exist in all countries internationally for similar reasons.

A recent OECD document (Anon. 2009c) stated:

'Minor use is the use of chemical pesticides or non-chemical means of crop protection where the potential use is on a scale not sufficiently large to justify registration of that use from an applicant's perspective alone. The key driver for minor uses is a lack of economic return to an applicant from registration of those uses, in particular the associated costs of generating the data required for obtaining and maintaining regulatory approval and potential liability from those uses once approved.'

Typically minor uses involve crops grown on a small scale (minor crops) and often are high value specialty crops. Additionally minor uses can involve uses within major crops in terms of controlling minor pests and diseases. This results in a situation where specialty crop industries are either without, or are lacking, sufficient access to pesticides to adequately protect those crops.

The major factor hindering the regulatory approval of minor uses is a lack of data that is largely attributable to a lack of funding required to generate data.'

The document outlines approaches used by regulators internationally in defining minor uses and where those are either based on *risk assessment* or *economic return* principles or a combination of both. The document discusses how different approaches, when utilised, can result in different conclusions, highlighting the difficulties faced in clearly defining minor uses. The guidance concludes with four key elements that should be considered in developing and maintaining a definition.

- Development and implementation of minor use definitions should be conscious of and reflect the different factors that result in minor uses. In particular the mechanism(s) should be specifically designed to enable considerations to be made for those uses that do not provide sufficient economic return for an applicant to justify registration of the use.
- Determinations of what are minor uses derived via an economic return approach should remain independent from determinations of regulatory risk assessment and establishing data requirements of major and minor crops derived via the risk assessment approach.
- Definitions of and mechanism(s) for determining minor uses should be regularly reviewed to ensure that they are current and up to date with the crop protection trends and needs of agricultural producers.

- Minor use definitions should be complemented by regulatory incentives that are developed to encourage the registration of more minor uses

The first two points are self explanatory and require no further comment. The final two points are extremely important to the Australian debate.

USA

In the United States the EPA has defined a minor (use) crop in one of two ways:

- It is produced on fewer than 300,000 acres or
- It is a major crop (a crop grown on more than 300,000 acres) for which the pesticide use pattern is so limited that revenues from the expected sales will be less than the cost of registering the pesticide, and
 - there are insufficient efficacious alternatives for the use
 - alternatives pose greater risks to the environment or human health
 - the minor use is significant in managing pest resistance or
 - the minor use plays a significant part in integrated pest management.

The following crops do not meet the acreage definition for a minor crop and are therefore, by default, major crops: Almonds, apples, barley, beans (snap and dry), canola, corn (field, sweet and pop), cotton, grapes, hay (alfalfa and other), oats, oranges, peanuts, pecans, potatoes, rice, rye, sorghum, soybeans, sugar beets, sugarcane, sunflower, tobacco, tomatoes, turf and wheat. However, these major crops can have minor protection needs for certain pests and in certain regions. This routinely applies to regional/pest specific requests for apples, grapes, snap and dry beans, pecans, potatoes, sugar beets and tomatoes, which meet the economic definition of a minor use.

CANADA

In Canada, the PMC uses the US definition for minor use. It is however, interpreted as the pesticide use in high-value, low-acreage crops. This includes all horticultural, ornamental, fruit (including berries), greenhouse and forage crops. It excludes grains, canola, field corn and soybeans.

AUSTRALIA

In Australia, the AgVet Code currently defines a minor use as:

'A use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose.'

To assist in the interpretation of this legislative definition, in 2000 the APVMA released its *Guidelines for Determining Minor Uses* listing major food crops and non-food situations, with implications that the remaining crops were minor crops.

Major food crops: almonds, apples, apricots, asparagus, avocados, bananas, barley, beans (french and runner), broccoli, cabbages, canola, carrots, cauliflowers, cherries, chick-peas, cotton, field peas, grapes (wine and table), green peas, nectarines, oats, onions, oranges, lettuce, lupins, macadamias, maize, mandarins, mangoes, melons (except watermelons), potatoes, peaches, pears, sweet peppers (capsicums), pineapples, plums, pumpkins, rice, sorghum, strawberries, sugarcane, sunflowers, tomatoes, triticale and wheat.

Major non-food situations: non-crop areas, commercial forests, fallow land, commercial and industrial areas, domestic and public service areas, ornamentals (when used as a group), bushland / native forests, turf areas, pastures and aquatic areas.

There is a significant difference between the number of crop categories classified as major in the US (25) compared with in Australia (45). By way of explanation, it should be noted that Australia represents only approximately 2% of the global crop protection market, which further contributes to the number of minor uses likely in this country compared to other larger markets such as the US. At the end of the day though, in Australia the practicalities rest with the chemical manufacturers who determine which pesticide uses are worth their while to register (major) and those that are not, which by default then become minor uses.

It is recommended that a review and amendment to the Australian listing of major crops is long overdue. These considerations should include movement of several currently listed major commodities to a status of minor and in accordance with the OECD guideline (Anon. 2009c) that those classifications be complemented by regulatory incentives that are developed to encourage the registration of more minor uses.

Minor use needs and activities in Australia

An examination of minor use permit applications submitted to the APVMA is the most obvious focal point when seeking an understanding of their impact on agricultural industries subject to minor use needs.

In 2005 a PSIC report (Anon. 2005) noted several major trends for agricultural chemicals including;

- a large number of fragmented stakeholders exists, despite some good representation from peak industry bodies and government agencies
- a significant proportion of applications seek older chemistry, including those subject to current chemical review
- horticulture is the most prominent sector (52%), followed by broad-acre crops (12%) and forestry (5%)
- applications to control environmental, noxious and/or declared weeds are common
- 87% of applications seek approval in new crops/situations (71%) or for additional pests (16%)
- 83% of applications are submitted as either no product is currently approved for that purpose (52%) or limited effective options exist (31%)
- approximately 50% of new applications require a residue assessment
- >90% of applications are similar to existing registered use regimes and do not pose an unacceptable risk to occupational health or the environment.

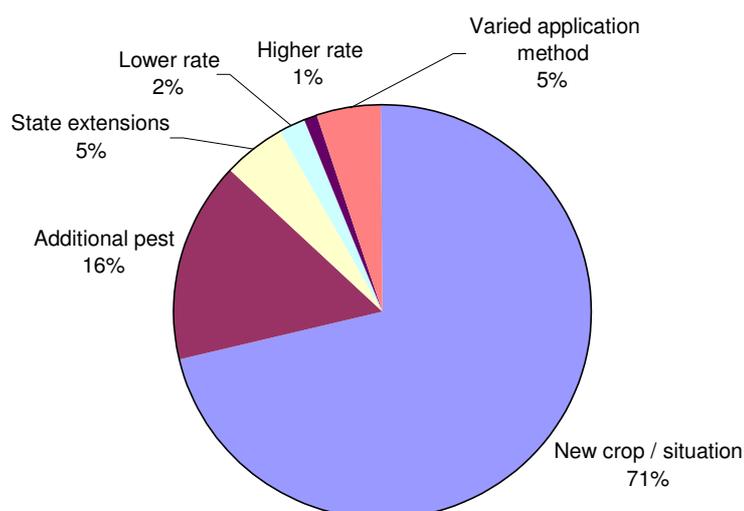
For agricultural chemicals (pesticides) the report also noted trends by sector and purpose including;

Five major sectors make up the minor use pesticide permit applications. Over the previous three years (2002-04), minor use applications for vegetables accounted for 27%, fruit and tree nuts 25%, non-crop situations 16%, broad-acre 12%, and forestry 6%. Application situations are shown in Fig. 1 with the majority of applications (87%) involving minor uses in new crops/situations or against new target species.

Four major reasons are provided in support of minor use permit applications for pesticides:

- either no registered product is available for that purpose (52%)
- existing registered products are unsuitable, ineffective or limited including the ability to implement IPM or resistant management strategies (31%)
- changes from the registered use pattern such as rate or method of application are required (12%) or
- the use is required for quarantine purposes (5%).

Figure 1: Purposes of minor use permit applications for pesticides



Whilst detailed analysis similar to that performed and reported by PSIC (Anon. 2005), has not been undertaken recently, the APVMA considers that the trends and major sectors noted in Fig. 1 remain indicative of current applications and minor use needs within Australia (A. Norden pers. comm., 2011).

An account of national and international activities in minor use, which Australia initiated or participated in, is given in Appendix 1. It is impressive considering the paucity of funding for minor use, but talk is no substitute for action. Australia has been long on the former, but short on the latter.

Permit scheme

In 1995, the NRA established the national minor use permit scheme. Currently, applicants are charged \$350 for each application and approvals have a relatively short lifespan of around 2-5 years. However permit applications, like registration applications, must be supported by data. In some cases this can be obtained from overseas, but where new data must be generated, this cost has to be borne by industry and there is no data protection provision. Further background to the assessment of minor uses is contained in the following section on *Risk assessment of minor uses*.

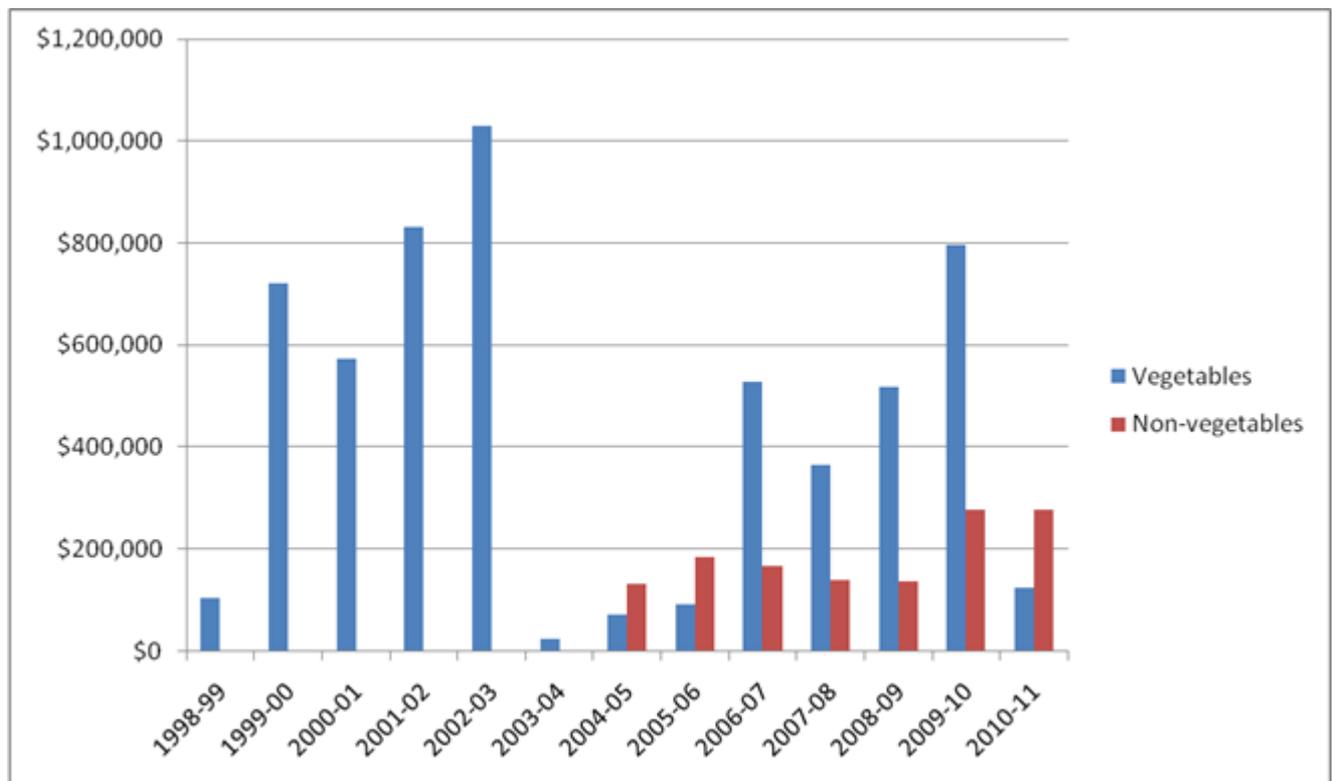
Persons who apply to the APVMA for minor use permits vary in both their frequency as applicants and regulatory knowledge. Some persons/organisations are infrequent users and may only have 1-2 needs that require consideration, whilst others may have a significant number of

needs and may be regular applicants on an ongoing basis. Applicants include individual growers, peak industry bodies, state and federal departments (i.e. primary industries, natural resources, conservation and land management, health departments etc.), local councils, water corporations, forestry enterprises and Landcare/bushcare regeneration groups.

Minor use funding

The only publicly identifiable funding for minor use requests comes from horticultural industries through the HAL Minor Use Project. Minor use investment by HAL is shown in Figure 2 (Brad Wells, HAL R&D Strategy Implementation Manager, pers. comm. 2010).

Figure 2. Funding provided for minor use permit requests by Horticulture Australia Ltd Minor Use Project 1998-2011.



This funding includes the overall management of the minor use project as well as efficacy and residue generation and the submission of minor use permit applications. In the 13 years since its inception in 1998, approximately \$7.2 million has been invested by HAL through the minor use project, with approximately \$5.8 million of this by the vegetable industry. These funds are derived from producer compulsory levies and matched Government R&D funds and managed by HAL. Despite the significant engagement and investment by industry and government via HAL, it must be noted that HAL is only administering approximately 50% of minor use applications originating from the horticultural sector. The remainder of horticultural submissions are lodged independently by individual growers or industry peak bodies at their own cost. Taking into account that horticultural crops represent approximately half of all minor use permit applications, the HAL project is administering only one quarter of all minor use permits lodged with the APVMA. The HAL investment equates to an average of almost \$554,000 per annum and a full cost would therefore be \$2.216 million for a population of about 22 million. Compare this with \$10.9 million per annum invested by the Canadian government for a population of 32 million in Canada (see Table 1, p30). On

a per capita basis, Canada invests almost five times more than Australia on minor use and in developing reduced-risk pesticides and strategies per annum, but this is from Government appropriation compared with mainly out-of-growers' pockets in Australia.

Non-horticulture minor use

In addition to activities in the horticulture sector administered by HAL, the GRDC has also, for a number of years, run a program that seeks to address minor use issues facing Australia's grain, oilseed and pulse industries. The program engages with industry bodies such as Pulse Australia and the Australian Oilseeds Federation and provides regulatory assistance to those organisations in the development and submission of minor use permits. As noted previously, minor grains, oilseeds and pulses comprise approximately 12% of all minor use submissions, although as with HAL, the program does not administer all permits applied for by this sector.

A high level of fragmentation still exists, particularly for industries that do not have a compulsory levy to fund this activity. It would be reasonable to estimate that a high proportion of minor use permit applications lodged with the APVMA (outside of those provided by HAL and GRDC programs) come from non coordinated sources involving persons who are infrequent users of the system and unfamiliar with regulatory requirements, representing a significant cost burden to those industries. This can result in many permit applications being lodged that do not contain the necessary supporting information resulting in unnecessary delays in assessment. These deficient applications also place an increasing burden on the overall regulatory system affecting the timely assessment of all applications where the regulator must expend time providing guidance to applicants unfamiliar with the requirements for making applications and in rectifying deficiencies.

Resource allocation

Consideration must also be given to the current human resource allocations provided for both the approval of registrations and permits in Australia. Despite the greater number of permits approved for new uses for Australian agriculture in 2010, compared with registrations (see page 21), there are far fewer resources specifically dedicated to permits compared with that provided for registration. This applies to those who prepare and submit applications and the regulatory resources provided by the APVMA to assess those applications. For example, chemical registrants have dedicated and experienced regulatory affairs teams who make submissions. These comprise anywhere from one up to as many as five full time person units, and in a number of cases, further support is available from global regulatory affairs teams. Taking just the top five or six companies there could be as many as 15-20 full time person units dedicated to making registration submissions locally. Whereas amongst the dedicated activities of HAL and GRDC there are only approximately three full time person units working on submitting permit applications. Within the APVMA there are about eight full time person units working on the assessment of permit applications, which represents only 5% of the organisation's staffing complement of 150 (Anon. 2010b).

Previous minor use strategies

During 2005, a Minor Use Task Force was established to address a range of key strategies presented to PSIC, in order to progress initiatives and reforms for minor use. One key strategy was 'enhancing the availability of new reduced-risk chemistry'. The APVMA's Community Consultative Committee also identified the progression of reduced-risk chemistry as a high priority. The first action, however, was the creation in 2006 of the MULO, a joint initiative of the APVMA and DAFF. The MULO hosted an international minor use forum in Canberra in 2007, involving representation from the United States IR-4 Project and the Canadian PMRA. A comprehensive discussion paper containing the key strategies in the Strategic Framework set out a proposed future for minor use in Australia (Anon. 2007). The discussion paper noted that many of the required regulatory initiatives to help address minor use needs could be introduced with little fuss, would come at little or no cost and offer better

regulatory outcomes for all stakeholders. Additionally, it also recommended the establishment of a broad-based industry forum similar to the IR-4 Food Use Workshops and the Canadian regional and national stakeholders groups, to make recommendations and set priorities, and to stimulate research to develop new biopesticides. It noted, however, that one of the key factors present in the US and Canada, and absent in Australia, was adequate funding. Clearly this highlighted the need for action although it is unclear why a joint initiative of DAFF and APVMA specifically established to provide recommendations was not followed through in any way.

Current mechanisms for addressing minor uses in Australia

Rose and Sheppard (2009) identified three avenues for addressing minor use needs. The first two of these are product registration or the issuance of a minor use permit, both administered by the APVMA. The third mechanism is via off-label provisions that are available through State's control-of-use legislation.

As to the first avenue, current arrangements for seeking the registration of new products and new use patterns are only available to product registrants and not to end users. No formal mechanisms currently exist for persons other than the product registrant to seek registration of new products or for changes to be made to product labels. It is noted, however, that the APVMA has been exploring possible mechanisms to enable user groups to seek the assessment of uses for registration (on-label). For example, a pilot submission made by Pulse Australia to the APVMA, resulted in variations being made to product labels. It is considered that such mechanisms could be further pursued and implemented to reduce the reliance on minor use permits. This would allow user groups to have their needs addressed where the private sector cannot justify the required investment, but where they would otherwise be satisfied to label those uses. However, the prohibitive costs of this approach put it outside the availability of most small crop producers.

The failure of the current registration arrangements for approving new uses and addressing minor uses is evidenced by the frequency of utilisation of the APVMA permit scheme. In examining applications for new uses in agricultural crops finalised by the APVMA in 2010, there were 61 registrations (Appendix 2), compared with 96 permit approvals (Appendix 3), of which 51% and 57% respectively, were for horticulture. In 2010 permits were responsible for 64% of all approvals (registrations and permits) involving new uses in horticulture.

However, the permit system is not in the best long term interest of end users. As noted previously, mechanisms that allow for user groups to seek registration approvals rather than minor use permits could facilitate better engagement between users and the private sector in having minor uses registered and in doing so reduce reliance on, or even negate, most of the need for a permit scheme.

Legal off-label use (*control-of-use*) & minor use

Background

Currently all States have some provisions for legal off-label use through their respective control-of-use legislation. This varies amongst States (Rose and Sheppard 2009). Control-of-use regulation applies from the point of retail sale to, and including, on-farm use. The Productivity Commission report (July 2008) stated that establishing a national control-of-use regime would likely lead to improved overall effectiveness of the national registration scheme. Greatest benefits would most likely come from having a uniform approach to off-label use of chemicals. However, there is a range of different opinions on what precise approach to legal off-label uses could be implemented with

some suggesting a need to adopt approaches available in states like Victoria and/or South Australia that have the most flexible approaches to off-label chemical use.

South Australia

In SA, producers accredited in an approved QA scheme can obtain a three year exemption from Regulation 6 of the Act. This was enacted primarily to provide local growers with off-label approval to insert into their QA systems and in return the SA government obtained new information on pesticide usage.

Regulation 6 requires that:

- Agricultural chemical products only be used on crops that are listed on the label
- The rate and frequency used must not be higher or more often than stated for that crop in SA
- If there is no instruction for SA, then the chemical can be used on a crop listed for another State, but must not be used at a higher rate or frequency than listed for that crop in another State.

The conditions do not apply if an exemption has been granted, although the highest rate or frequency listed on the product label must still not be exceeded. This exemption can apply to minor crops. It is interesting to note that SA recognises the following as major crops: citrus (oranges, lemons), grapes, onions, pome fruit (apples, pears) and potatoes, as opposed to the more detailed national list identified by the APVMA (see page 16).

Victoria

It is widely acknowledged that Victoria has the most permissive regulations concerning off-label use. In this State it is not an offence to use a pesticide off-label without recourse to a permit, unless that use is specifically prohibited by regulation. However, in developing approaches as to the types of off-label uses that could be permitted under a national control-of-use regime and whether those approaches would provide solutions for minor uses, two important considerations are required. Firstly one must understand what types of off-label uses are likely to be required and secondly whether certain approaches adopted to legalise off-label use will provide the necessary outcomes for producers of minor crops.

Minor use permit applications lodged with the APVMA provide the most reliable information on the types of off-label uses being undertaken by Australian producers. As noted earlier, off-label uses commonly seeking minor use permits include one or more of the following variations, compared to the approved product label (Fig. 1);

- new crops and situations (71%)
- new pests or diseases (16%)
- new application technology/equipment (5%)
- new states (5%)
- varied (lower or higher) rates of application (3%).

Clearly the vast majority have involved extensions into new crops and situations and, of all minor use permit applications lodged with the APVMA, 50% required a residue assessment and establishment of an appropriate MRL (Anon. 2005). Furthermore, during 2008-09 two-thirds of all MRLs established in food crops, were as a result of a permit application (A. Norden, pers. comm. 2011).

The case for seeking and/or retaining a flexible approach to legal off-label use understandably seems more associated with addressing deficiencies in the registration and permit process. In its submission to Rose and Sheppard (2009), the VFF stated '*The continuing need for off-label provisions in Victoria to ensure adequate pest control options are available for growers of minor and niche crops clearly illustrates the inadequacy of the current registration arrangements*'. Further,

the VFF made a number of other points associated with the current need to retain off-label uses, including *'the lack of incentive for companies to undertake research and development, to invest in minor use permits or add additional uses to labels,, is a long term problem for all farmers'* and *'It is a common economic understanding that Government should act in areas of market failure'* and *'The continued government support for minor use programs in the US, Canada and the UK as well as many other agricultural nations makes it obvious that minor use continues to be an important aspect of pest, disease and weed control options for farmers across the globe'* and *' Whilst VFF acknowledge the concerns raised by others regarding off-label use, the off label minor use is clearly only going to be addressed by implementation of a scheme similar to the Government funded ones in the UK, USA and Canada'*.

It appears therefore, that the right of producers to operate off-label seems to be both a reflection of a lack of confidence in the present regulatory system by those producers, particularly producers of minor crops, as well as a lack of delivery.

It has been argued that off-label uses, where available, can be appropriately managed. For example Rose and Sheppard (2009) outlined the off-label provisions available in Victoria and stated *"Despite the apparent risks of off-label use, there is no evident pattern of residue violations in Victoria, where off-label use is most extensively permitted. Of tests carried out in the Victorian Produce Monitoring Program in 2007-08, 97.0 per cent contained no measurable residue and only 0.1 per cent contained residues above FSANZ MRLs"*. This conclusion is misleading for two reasons. Firstly, in reporting its monitoring program results, Victoria has relied on the total number of tests and not the number of samples in which violations (where residues exceed MRL or where no MRL exists) were detected, as the basis for its analysis. For example, in 2007/08 there were 32, 314 chemical tests conducted in the Victorian monitoring program on 457 samples. The number of violations per sample resulted in non-compliance rates of 8.5%, 85x greater than the 0.1%, reported on the basis of the number of tests. The disparity between the two reporting methods is stark and does not present the rosy picture in support of such an approach to off-label use nationally. In any sample, the vast majority of pesticide tests would be irrelevant and thus including them in the analysis, misleading. The 'number of samples' in which violations are detected is therefore the only credible basis for reporting such data. The former method seems to be a manipulation of the facts in order to justify the retention of a more 'flexible' system over a more rigorous approach. An analysis of the residue data from the Victorian Produce Monitoring Program (<http://www.dpi.vic.gov.au/dpi/nrenfa.nsf/LinkView/DE6E151F47EBBB7ECA256C8E007C9505A99EE DDADACC70F8CA256C38001965CA#targeted>) for the period 2002-08 is presented in Appendix 4. Violations expressed as a % of number of samples for this period are; 8.5% (2007-08), 11.4% (2006), 8.7% (2005), 4.4% (2004), 5.2% (2003), and 3.6% (2002). Some commodities, regularly tested over a number of years within the program, had consistent residue violations. It is apparent that under this flexible system for off-label use, a large number of pesticides were used without an MRL for that situation. This could be due to a false sense of security created by a poor grower understanding of the system. Also there were an alarming number of excessive violations and violations where no MRL exists, identified. Of the ten commodities tested in 2007-08, only two were without violative residues. For eight individual commodities, violative non-compliance rates ranged from 2% to as high as 43%. Secondly, no information is provided as to what, if any, off-label uses had been undertaken by producers, where compliances achieved may have been as a result of existing registrations on label or, as Rose and Sheppard (2009) note *"many of the uses may be covered by APVMA permits valid in other states"*. Therefore, whilst off-label uses may be permissible in Victoria and legally a permit may not be required from the APVMA, the off-label provisions are beneficiaries of approvals granted in the first instance by the APVMA as required in other States.

Residue violations are not entirely a Victorian issue. For example results of pesticide monitoring in NSW for the period 1995-2005 were 4% (2004-05), 1.8% (2003-04), 1.4% (2002-03), 2.4% (2000-01), 4.9% (1997-2000) and 10.5% (1995-96)

<http://www.dpi.nsw.gov.au/agriculture/horticulture/vegetables/soil/monitoring>). It could also be concluded that similar violations to those of Victoria and NSW are occurring nationally. These violations are perhaps more a reflection of the minor use problem nationally and issues that can arise and proliferate if mechanisms are not available to provide producers with adequate access to approved crop protection products. However, it is not arguing that off-label uses should not be permitted at all, as there is clearly a place for legal off-label use provisions to alleviate some minor use needs, although there needs to be careful consideration of the implications particular approaches may have on agricultural producers. The solutions must seek to address and prevent unnecessary residue violations occurring in produce that may arise simply because producers did not have adequate access to approved products in protecting their crops.

On the basis of the above matters discussed, it is questionable whether a national approach to legal off-label use as provided in some States, would provide producers with the required solution. Particularly where those approaches are principally underpinned by a requirement that produce resulting from an off-label use must comply with an MRL. Rather, leaving producers solely with legal off-label use as the suggested solution to the minor use problem, could see producers of minor crops in an even more precarious situation than they already are in. It is clear that approaches need to provide mechanisms for the establishment of MRLs in minor crops and where users have available clear guidance in the form of use instructions (rates, WHP's etc.) to ensure compliance as currently afforded by product labels and permits.

Case for national control

It is widely acknowledged, and the statistics reported in this paper support, that the most prominent sector facing minor use issues is horticulture, often requiring the use of products regularly and close to and following harvest. These commodities include fresh fruit and vegetables that are often regularly harvested at short intervals following application. Under existing arrangements, MRLs are established as a result of registration or permit applications with the provision of supporting data, in accordance with GAP. Off-label uses without a defined and agreed GAP would present problems in enabling determination of an appropriate MRL and provision of data in establishing that MRL. Additionally, under the legal off-label use arrangement provided in SA and Victoria, the grower is required to assume responsibility for ensuring any produce treated off-label complies with an MRL. In doing so, it is then recommended that the grower undertakes analysis of produce following application and then only supplies produce once it meets or falls below the MRL. This places the onus on each grower to undertake testing and analysis of their produce, at some cost, to determine how they may use a product in compliance with an MRL. Such testing is typically not performed to agreed or consistent standards nor is it sufficiently robust, which could bring into question the validity of results. If errors in either occur there could be possible implications for human health and trade. It is suggested that a centralised process of testing and analysis conducted to international standards, such as the OECD GLP guidelines, which already apply to many regulatory approvals in registering products and issuing permits, might be a more effective way of managing the costs. A centralised approach would also result in the provision of instructions for use in the form of a label or permit, which the user could follow to ensure compliance. Additionally those studies may also enhance and be used for the purposes of seeking Codex and/or other import tolerances in export markets in facilitating trade.

As previously noted, a high proportion of off-label uses seeking minor use permits involve uses in new crops and situations, and 50% of all minor use permit applications require a residue assessment and establishment of an appropriate MRL (Anon. 2005). Furthermore, during 2008-09 two-thirds of all MRLs established in food crops, were as a result of a permit application (A. Norden, pers. comm. 2011). Therefore, on the basis of these figures, it is doubtful whether off-label uses such as those applied in SA and Victoria would provide the required national solution for producers of food crops. Rather such an approach could see minor uses in an even more precarious situation than

they already are, resulting in a significant decrease in the establishment of MRLs in minor crops (that both SA and Victorian schemes rely upon) and the provision of guidance in the form of permits and labels.

It is therefore suggested that careful consideration needs to be given to ensure that what may seem to some to be a possible easy fix for minor uses in enabling legal off-label uses does not actually have the reverse effect, leaving growers of minor crops without required MRLs and use instructions for them.

Risk assessment of minor uses

Under the existing legislation, minor uses either in the form of an application for registration or permit, are subject to the same legislative requirements as apply to major uses with respect to safety and efficacy as contained within Sections 14 and 112 of the AgVet Code.

In some responses to Rose and Sheppard (2009), it was suggested that the legislative requirements for minor uses should be reduced and/or removed in some areas to enhance their registration. It is noted that the OECD has outlined in its publication [OECD Guidance on Defining Minor Uses of Pesticides](#) that *'Determinations of what are minor uses derived via an economic return approach should remain independent from determinations of regulatory risk assessment and establishing data requirements of major and minor crops derived via the risk assessment approach'* (Anon. 2009c). The OECD guidance document discusses that whilst different crops may have similar volumes of production and dietary consumption they may be considered by registrants as minor uses or major uses depending upon several factors and, concludes that from a registrant's economic perspective *'there is a 'see-sawing' affect to determining what may be a minor use'*. In other words factors leading to registrant's decisions can be different to those factors used in determining the required level of risk assessment. For these reasons, a lack of potential economic return to a registrant for registration of a use should not be used solely as justification for reducing the rigour of the regulatory risk assessment required for a use. Therefore the key principle of risk assessments for minor uses is that they should remain independent of likely economic return to a registrant.

The APVMA in considering and assessing applications for minor uses undertakes a risk assessment comparative to the level of risk posed by the proposed new use. As Rose and Sheppard (2009) noted, *'the APVMA may draw on data from one or more of several sources data'* and *'Around 85% of minor use permit applications are assessed without a requirement for applicants to provide new test data'*. In doing so the APVMA frequently extrapolates from existing registered uses or from relevant data available both locally and internationally and for related crops and uses.

Risk assessments required for minor uses can vary considerably and are determined by the current regulatory status of the product or active within Australia, including existing registered use patterns, available data and established regulatory standards (i.e. MRLs). The scope of minor uses can include those involving existing registered products for very similar or quite different purposes to those registered, to those seeking the approval of unregistered products not previously considered for use in Australia. The vast majority of minor use permit requests (estimated at >90%) however, involve extensions to products currently registered in Australia, probably explained in part by the claim that impediments can exist in bringing some new products to the Australian market due to market size. Explanation of the major types of minor uses being sought under permit was given on page 18 and in Fig. 1. Lesser types of minor uses sought under permit include higher application rates, new application methods or equipment and uses in non-food producing situations that deviate from how the product is currently registered, can present risks to workers, bystanders or the environment. Furthermore many non-food situations can often include uses of herbicides for weed control in aquatic environments, novel poisons or techniques for controlling vertebrate and

invertebrate pests or uses in new environments such as enclosed spaces (greenhouses) that may similarly present risks to workers, bystanders or the environment.

For food producing situations, however, the obvious risk assessment is that pertaining to dietary risk, whether or not an appropriate MRL can be established and that those uses would not pose unacceptable risks to trade.

Risk Reduction

In addition to minor use, another issue presents itself. Risk reduction or reduced risk is not defined within the Australian pesticide registration process or in any other legislation within this country, but it is nonetheless an important part of this discussion. In both the US and Canada, risk reduction programs have been introduced by regulators, while the OECD Pesticide Risk Reduction Steering Group has published a paper on a strategic approach to pesticide risk reduction (Anon. 2009d). In it, four core elements are identified which contribute to the reduction of risks arising from the use of pesticides. So how do we interpret 'reduced risk'? Pesticide risk to humans is a key consideration in the registration process for every pesticide. While environmental safety to wildlife (birds, bees, fish etc) is also a consideration, this does not necessarily result in the development and registration of pesticides that are selective to invertebrate natural enemies ('beneficials'), a critical component in IPM programs. Risk reduction can simply mean safer than existing products, but this is not quite the same as saying a pesticide has negligible risk to natural enemies and biocontrol agents. Canada has introduced a *Pesticide Risk Reduction Program* that addresses the issue of pesticide safety with biocontrol agents and is a worthy model for Australia.

While Australia does not have a specific Risk Reduction Program as occurs in Canada, in 2005 the APVMA did introduce *Guidelines for the Registration of Biological Agricultural Products*. Such a product has an active constituent comprising or derived from a living organism with or without modification. This includes many products that are commonly referred to as 'botanicals', 'organics' or 'herbals'.

The APVMA has identified four groups in this classification:

Group 1 – biological chemicals e.g. pheromones, hormones, growth regulators, enzymes and vitamins

Group 2 – extracts e.g. plant extracts, oils

Group 3 – microbial agents e.g. bacteria, fungi, viruses, protozoa

Group 4 – other living organisms e.g. microscopic insects, plants and animals plus some organisms that have been genetically modified.

This product classification has its own biological data requirements. There is presently a strong push to improve the availability of biopesticides produced from bacteria, fungi, viruses and protozoa, in the UK and the EU. In 2008, Warwick University compiled a list of papers (<http://www2.warwick.ac.uk/fac/soc/pais/biopesticides/publications/>) typified by one entitled 'Do we need regulatory changes to make biopesticides a mainstream solution?' (Greaves, 2007). The development and adoption of safer pesticides for IPM programs should be seen as an important component of a safe and effective crop protection toolbox and a significant goal for the current regulatory reform process in Australia.

Overseas Experience with Minor Use and Risk Reduction Crop Protection Programs

In the US and Canada, minor uses are subject to registration approval and labelling, while in the UK a process similar to the Australian permit scheme applies. As previously stated, in Australia, minor uses are subject to temporary off-label permits in most States. For the purposes of this document discussion is limited to the US, where government funding for minor use originated, and to Canada, because this is the model recommended for consideration in the regulatory review and development of a new *National Sustainable Minor Use Crop Protection Program* for Australia.

USA

Established in 1963, the US IR-4 minor use program has delivered over 10, 000 food crop approvals to low acreage, high value 'speciality crop producers'. IR-4 has been the major resource for supplying pest management tools to these crops by developing research data to support registration applications to the EPA. The success of the IR-4 program is not solely the result of enlightened EPA activity, but because it receives annually generous government funding targeted at the program. Recently published registration activities from the US show the benefits of the IR-4 program to end users (Anon. 2010c). Of applications submitted in the report period, 28% were from IR-4. Five reduced risk chemicals were amongst the total group of registrations and in one case, EU data based on IR-4 argument was included, demonstrating the value of international collaboration and data sharing.

Under the IR-4 project, there are no 'off-label' permits issued. In 2007, funding amounted to \$32 million. The successes of the IR-4 Program are based around adequate funding, effective partnerships with all stakeholders in delivering common goals and a demonstrated high rate of return on investment. Results of an economic analysis of this program were reported on p11.

In 1994 the EPA established a reduced-risk initiative for conventional pesticides. Biopesticides were excluded. It is worth noting that 80% of IR-4 approvals were for reduced-risk chemistry. However, this program, referred to as *Reduced Risk Organophosphate Alternative Registration Decisions*, is more about risk reduction than low risk. Some of the EPA approvals include chemistry such as fipronil, a number of synthetic pyrethroids, thiomethoxam and chlorfenapyr that, while providing lower toxicities than organophosphates, would be unacceptable to IPM practitioners in Australia. In Australia, we would seek a definition of 'low' risk that emphasises environmental safety such as selectivity to natural enemies and biocontrol agents essential to successful IPM programs.

CANADA

In Canada, prior to 2002, growers were seeing a growing gap developing between Canada and the U.S. in the number of new minor uses of pesticides that were becoming available. A lack of a national program with appropriate funding resulted in an inconsistent approach to the minor use issue, creating a lack of capacity to deliver new pesticide products to industry. As occurs in Australia, manufacturers claimed that the cost of registration for a minor use exceeded the potential returns, hence their lack of interest. The problem was compounded with Canadian growers, who despite sharing an agricultural market with the US, were unable to access the same pesticides to control the same pests in the same crops as their American counterparts (most times MRLs were established in Canada). This caused a pesticide 'technology gap'. The need to close this technology gap and thus provide competitive parity was the grower argument and impetus for the government to fund the program. Growers approached the federal government and used the example of the U.S. IR-4 Project as a potential model which could be developed in Canada.

In response to these calls from the horticultural sector, in 2002 the Canadian Government announced the *Minor Use Pesticides Program* and the *Pesticide Risk Reduction Program* and committed \$CA54 million over five years from 2003, to develop a joint initiative between its research arm, AAFC's PMC, and its regulatory arm, Health Canada's PMRA. This funding was renewed in 2008. The PMC was allocated \$CA33.7 million to improve access to minor use pesticides and to conduct field trials to generate data essential for minor use registration, including \$CA16.8 million for a *Pesticide Risk Reduction Program* to develop and implement new, reduced-risk approaches to managing crop pests, including biological controls, natural products and low-risk minor use pesticides, something we can identify with in Australia. The PMRA was allocated \$CA20.8 million to increase its capacity to review submissions and to provide shorter timelines for registration of new reduced-risk products. In Australia, funding for minor use data generation and permit submissions provided through HAL (page 19) was only \$AUD 554,000 per annum (\$7.2 million over 13 years) compared with approximately \$CA6.74 million per annum in Canada. Additionally as noted on page 20, only 5% of the APVMA staffing resource is directed to minor use permit assessments. Also, with a total APVMA budget of approximately \$26.3 million in 2009-10, of which 96% comes from registrant's fees, the current allocation for the assessment of such purposes in Australia was therefore only approximately \$1.3 million per annum, whereas the PMRA has been provided with in excess of \$CA4 million per annum.

As noted by the IR-4 Project in its submission to the review (Rose & Sheppard 2009) (http://www.daff.gov.au/data/assets/pdf_file/0010/1536274/sub-ir-4-project.pdf) the US IR-4 Project and Canada's PMC identify mutual needs and work collaboratively to conduct the necessary trials. This has led to joint submissions to both US EPA and PMRA who undertake a joint review and sharing of the regulatory risk assessment. There are obvious cost and resource savings for all concerned, both for each program, regulators and growers. There is obvious scope for this collaboration to be extended to other countries and regions where similar programs to that of IR-4 and PMC exist. This would include the conduct of joint research by national programs followed by joint/shared risk assessments by regulators, where the outcomes of that work ensure producers of the same crops internationally have the same access and where that does not impact on trade/market access issues. A European fund for minor uses if established, will seek to engage and benefit from this process, and hopefully Australia will have seen the advantages of this approach and acted also.

Third party authorisations

The current legislative process within Australia for enabling third party authorisations via permits is relatively unique internationally. A similar scheme operates in the UK via the ability for growers to seek SOLAs that are equivalent to a permit. The current fee for a SOLA is £1085 and is scheduled to increase by £205 on 1st April each year until a maximum fee of £2000 is reached. Assessment timeframes for SOLA applications for emergencies or with no data is nine weeks and for applications with data it is 18 weeks. In the UK approximately 100-150 SOLA applications are lodged each year.

Whilst within Canada and the US, regulators may accept submissions and data from third parties; the use must be supported and labelled by the registrant. The US, Canada and some European countries provide fee waivers or reduced fees for minor use applications. For example submissions lodged by the US IR-4 Program receive a fee exemption from the US EPA. In Canada two schemes operate for minor uses. Firstly, a URMULE allows for a new use of an existing registered product and attracts a fee of \$CAN154 with an assessment timeframe of approximately eight months. Secondly a URMUR process exists where growers can seek regulatory consideration of a new product not currently registered in Canada, where the registrant via that process can seek a fee reduction for low volume, niche products. The fee reduction is set at a maximum of 10% of the revenue from sales of the product registered during the sales verification period of three years. However, the fee reduction cannot reduce the fee payable to below 10% of the total fee, otherwise

payable and sales records must be submitted at the end of the 3-year verification period. In Canada over the last five years, approximately 90 applications for URMULE and less than three URMUR have been received per annum.

Data protection

Both the US and Canada have data protection provisions for the registration of uses and additional years of protection are provided as an incentive for the registration of minor uses. For example in Canada 10 years of exclusive protection from the date of first registration is provided for a new active. This period can be extended by from one up to a maximum of five additional years (15 years total) for every three minor uses registered. In Australia the current provisions allow an initial eight years of exclusive protection, where this can be extended up to a maximum protection period of 11 years, where the registration of five minor uses are required for each additional year.

A detailed description of most facets of the Canadian program is given in Appendix 5. It is this program that is seen as the most appropriate model for development of future minor use crop protection policy in Australia. A key factor in the success of the Canadian *Minor Use Pesticides* and *Pesticide Risk Reduction Programs* has been the participation of stakeholders, including growers, in the priority setting process. This has resulted in a list of national minor use priorities divided into those with solutions, and those without solutions, among the disciplines of weeds and growth regulators, entomology (insect & mite pests) and pathology (diseases). In addition a number of regional and organic priorities are selected. When determining the solutions for each problem, products which minimise the potential impacts on the environment and human health are considered. These then become projects within the *Minor Use Pesticides Program* for the upcoming growing season. The *Pesticide Risk Reduction Program* creates a framework through which growers develop and implement pesticide risk reduction strategies, focussed on selected crops and priority pest management issues that are determined through stakeholder consultations at a national level.

There are four subprograms. Details are available in Appendix 5:

- Implementation program
- Biopesticides
- Strategies
- Crop profiles

The result has been a substantial increase in minor use registrations in Canada. Since its inception in 2003, the PMC has made over 275 minor use submissions to PMRA on behalf of growers, resulting in more than 165 registrations and 540 new registered label uses. Under the *Pesticide Risk Reduction Program*, in addition to 13 new biopesticide registrations representing over 114 new registered uses, numerous tools, technologies, and techniques have been developed for grower use, that encompass a strategy to reduce the risk to human health and the environment associated with pesticide use. Besides pesticides, identification guides of pesticides and mechanical tools have also been developed and used by growers. Along with the reduced risk pesticides, these tools have great potential to reduce pesticide use in addition to contributing to a slow-down in the development of pest resistance to pesticides.

However, new uses of pesticides are still required and PMC staff work with stakeholders to prioritise projects and generate the data required supporting the registration of grower priorities (pesticide use). The PMC works closely with PMRA, thus providing a dedicated stream of data, issue data requirements, review regulatory submissions (data packages) and issue registrations. From priority setting to registration it can take approximately 36 months if all works well (trials are successful and residue analysis is without problems). The regulatory review and registration takes at least eight months.

The funding cycle is five years for the *Minor Use Pesticides Program*, while it is indeterminate for the *Pesticide Risk Reduction Program* (\$2.5 M per year). A second 5 year funding cycle for the period 2008-13 is shown (Table 1).

Table 1. Second round of government funding for the Canadian Minor Use Pesticides Program, 2008-13.

	2008-09	2009-10	2010-11	2011-12	2012-13	Total
						(\$mn)
Pest Management Centre (AAFC)	\$8.5	\$9.97	\$9.97	\$9.97	\$9.97	\$39.89
Pest Management Regulatory Agency (HC)	\$4.5	\$3.99	\$3.99	\$3.98	\$3.98	\$15.95
Total		\$13.96	\$13.96	\$13.96	\$13.96	\$55.84

Recommendations for Reforming Pesticide Regulatory Policy to Address Minor Use Inequities and to Develop Sustainable Crop Protection Programs

Horticulture is a vital supplier of quality, fresh produce in Australia, and as such, is an important contributor to the Australian economy. In 2008, ABS statistics showed that horticulture had 25,000 to 30,000 businesses nationally (Appendix 6), while in 2009/10, an ABARE survey gave it an annual farm gate value of \$8 billion (Appendix 7), making it the third largest agricultural sector behind meat and grains by value. However, to achieve this, horticultural producers must have guaranteed access to export and domestic markets. To this end, continuing access to effective and environmentally acceptable crop protection products, including providing appropriate responses to biosecurity threats and enhancing access to export markets, is an important requirement. Horticulture though, is comprised of a large number of different crops that are non-broad acre in cultivation and are of major importance for the food industry and consumers. There are in excess of 50 individual horticultural industries in Australia, with some, such as vegetables, embracing almost as many crops again. Horticultural industries are relatively minor, both in scale of production and in use of plant protection products, when compared to total agricultural production. This list includes products regularly purchased by consumers, including what some may mistakenly perceive as major due to the regularity and reliance of those within the diet of most Australians. These include bananas, onions, peas, carrots, tomatoes, leafy & Asian vegetables, mushrooms, pineapples, mandarins, lemons, cherries, herbs & spices, nuts and brassica vegetables (cabbage, cauliflower and broccoli) to name just a few. While the magnitude of pest problems faced in these crops is similar to major crops, many newer and more efficient plant protection solutions are often unavailable to producers, mostly for economic reasons, where the returns on the cost of regulatory approval is not considered sufficiently profitable to justify investment by the private sector. Generally speaking, the approval and maintenance of crop protection products available to Australian agricultural industries is undertaken by the private sector, and typically that sector focuses on the major market opportunities (*major crops*) with the likely greatest return on the investment required to achieve regulatory approval.

It is important to recognise that government has a key role to play in ensuring the necessary delivery of appropriate crop protection solutions and influencing that delivery through policy development. This involves the role and type of crop protection mechanisms that Australia's agricultural industries adopt, including mechanisms to encourage and adopt softer or newer technologies that reduce pesticide risk and enhance practices such as IPM, such as those developed and implemented under the Canadian program.

Internationally, many governments are adopting new approaches that are focusing on delivering such objectives. These include policies and support for R&D, encouraging private investment via targeted incentives, developing targeted programs to provide agricultural industries with assistance in meeting regulations, whilst maintaining an appropriate level of regulatory oversight. Whilst such actions and support can come at some cost, it has been demonstrated that the cost of these actions provides a high rate of return (see p13), while meeting the objectives outlined (Miller 2007).

The current reviews being undertaken by COAG for a single national regulatory framework for AgVet chemicals, and the more recently released *Better Regulation of Agricultural and Veterinary Chemicals* policy discussion paper, provide a unique and timely opportunity to develop a reform agenda that would establish a framework that sets the direction and enhances the future approval, delivery and adoption of crop protection solutions within Australian agriculture. In particular, reforms should address the problems confronted by horticultural producers, most of which are

minor users of pesticides, as a matter of priority. Of course these comments equally apply to other agricultural production stakeholders such as the goat industry impacted upon by the minor use issue. It is interesting to note the comments made by the following key industry organisations on the minor use issue in response to these reviews. They highlight the anxiety felt by their industries over this issue and support the need for a comprehensive proposal on a new sustainable approach to delivering effective crop protection solutions for minor use producers. In the responses to the COAG Consultant's Discussion Paper (<http://www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/domestic-policy/psic/responses-to-discussion-paper>), attention is drawn to the comments made by the Mushroom, Olive, Pulse, Biological Farmers and Cherry industries and to those from the VFF, HAL and CropLife, and significantly to the valuable contribution made by the US IR-4 Project. In the responses to the Better Regulation of Agvet Chemicals Review (<http://www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/responses-to-the-discussion-paper>) the following extracts on the issue are provided:

AUSVEG said

'One aspect that is not explicit in the discussion paper is that of providing regulatory reform that can facilitate registrations of agvet chemicals for minor or specialty crops. AUSVEG believes that a more efficient assessment and registration process, while desirable, is unlikely to substantially alter the current minor use situation i.e. process changes as outlined are unlikely to alter the current market failure where economic return does not justify the pursuit of registration. Therefore, AUSVEG would be supportive of reforms where enhanced chemical access for minor uses was a stated outcome. To this end AUSVEG believes that consideration should be given to exploring initiatives in the areas of process efficiency, data protection and fees, which would improve chemical access by facilitating minor uses onto label registrations.'

The NFF said

'In general terms the discussion paper does not recognize the key regulatory outcomes required by farmers as chemical users. These outcomes include how to ensure safe and effective chemicals remain available to chemical users whilst minimizing the cost of regulation, and ensuring that effective mechanisms exist which allow small agricultural industries (i.e. 'minor-uses') to access the chemicals when there is a market failure and chemical registrants do not have the incentive to register chemicals for these 'minor-uses'. Chemicals are an important tool in underpinning the productivity of many farming systems and it is also important to ensure there is a suite of chemicals available for different purposes to avoid chemical resistance in pests and weeds.'

AMGA said

'As indicated the mushroom industry suffers from a lack of pest management options. To fill these gaps AMGA has sought minor use permits. To have these permits granted, data on residues and or efficacy have had to be submitted by AMGA to enable the APVMA to undertake its risk assessments. The industry has been prepared to accept the responsibility of carrying the load as it was seen as its obligation to the supply chain. Currently, the AMGA holds three minor use permits and is in the process of preparing applications for an additional two agvet chemicals. While gaining minor use permits has assisted the industry, the preference is to have such uses moved directly onto labels. Having uses on labels overcomes a number of potential pitfalls, when seen from a whole supply chain perspective, e.g., issues of confidence in the use, liability and permit renewal.'

APAL said

'APAL notes that the discussion paper is silent on possible reforms to the registration process for 'minor use' chemicals. The 'minor use' issue has arisen because of market failures whereby the economic return from a market as small as Australia does not justify the pursuit of registration for application to many agricultural commodities. However the 'minor use' issue is a contentious one, even within the apple and pear industry where sectors have differing views. APAL looks forward to a high degree of industry consultation on this matter whilst the COAG single national framework regulatory impact statement is being developed. In the mean time, an assessment is required of what impact the reform detailed in the current discussion paper will have on the registration and assessment of chemicals for 'minor use.'

NSW Farmers said

'...improved access to chemicals by small agricultural industries is required and the minor use permit system should be considered as part of the reforms'.

The proposed new approach to addressing minor use-risk reduction issues outlined below will require a budgetary allocation by the federal government. There is no avoiding this conclusion. The myriad of horticultural industries, despite their combined value, are in no position to individually meet the financial demands of pesticide registration to enable industry to meet its obligations and to remain competitive. The fundamental aim of this legislative reform process, aside from developing a single, national regulatory framework for the assessment, registration and control of use of Agvet chemicals, is to reduce the cost burden on industry and this should apply equally to the end user as well as to chemical manufacturers.

The proposal addresses the key objectives stated in the preamble to the Agricultural & Veterinary Chemicals Act 1994. These recognise the importance of protecting the health and safety of human beings, animals and the environment as essential to the well-being of society and of the demands of ecologically sustainable development in a regulatory system. In addition, we firmly believe that the proposal meets the required policy outcomes for three key elements of the proposed national policy framework for assessment, registration and control of use of Agvet chemicals (Anon. 2010a).

Firstly, that the *'Access to Chemicals - Operating Environment* (shall ensure that)

1. Effective regulation manages the risks while minimising costs for businesses
2. Users in all jurisdictions have the same right of access to Agvet chemicals unless regional risk management measures require otherwise
3. An internationally competitive scheme that does not unduly constrain access to new and existing Agvet chemicals
4. Regulation of Agvet chemicals that does not unduly constrain industry development particularly for
 - industries with minor use demands for Agvet chemicals
 - developing chemical industries.

Secondly, under *Access to Chemicals - Assessment and Registration*, in accordance with Policy Principle Number 4, it meets the outcome of (Registration of) Agvet chemicals available for use on as wide a range of host/pest combinations as possible.

Thirdly, under *Access to Chemicals – Permits and Permissible Uses*, that access to chemicals (is available) for minor industries and minor uses in larger industries.

Aside from the submission delivering meaningful outcomes to minor use producers, it also fulfils legislative goals, plus policy outcomes in the current COAG review.

It is important to recognise that government has a key role to play in ensuring the necessary delivery of appropriate crop protection solutions and influencing that delivery through policy development as to the type of crop protection mechanisms Australia's agricultural industries adopt.

In the light of this, it is recommended that reforms develop a number of interrelated measures to improve the level of registration approval of crop protection products, with a focus on addressing those uses that are affected by a lack of private investment, and to make a budgetary allocation for the needs of data generation to support registration submissions from annualised national priority targets and the expanded demands of the APVMA. This should include an examination and possible mirroring of approaches adopted by other countries in particular the *Canadian Minor Use Pesticides and Pesticide Risk Reduction Program* to serve as a model to enhance more registration outcomes and that new regulatory incentives also be implemented to facilitate more interest and investment by the private sector in that process.

In meeting these goals it is recommended that two fundamental and interrelated approaches are required. Firstly the establishment of a *National Sustainable Minor Use Crop Protection Program* and secondly for that program to be complemented with appropriately tailored *Regulatory Processes and Incentives*.

Creation of a National Sustainable Minor Use Crop Protection Program

Need for improvements

The current model for Australian pesticide regulation, outside that provided by *minor use* permits, does not provide for the needs of user industries. It is designed primarily to address the private sector's (product registrants) market opportunities, where those are determined principally on the level of economic return from product sales. Alternative processes are therefore required to address chemical access issues for all uses, where the regulatory system contains components that specifically recognise user needs and provides incentives and mechanisms for the user sector, in order to have those needs addressed.

End users are best suited to determine their needs although they need specialist knowledge in the form of a program that provides regulatory assistance in determining data requirements, finding and generating data and solving problems in the most cost effective, efficient and timely manner. Such a program needs to be developed in a national context and structured to bring benefits to all industries by enhancing collaboration between similar industries and to maximise efficiency in effort and data generation where required.

Improving the legal options for *minor uses* could involve a number of enhancements to current approaches, plus the implementation of new approaches involving active participation and contributions from the user industry, product registrants, regulators and government, similar to those operating in countries such as Canada and the United States. The development of a new nationally coordinated program servicing all industries is considered a critical component for success.

Function of the new program

The program should be the national focal point and vehicle for establishing and progressing solutions to priority crop protection gaps identified by, and on behalf of, users, with active participation by the private sector (product registrants) and regulators, in addressing those needs in

the most cost efficient and timely manner. The program, with direct input from users, should annually establish a list of crop protection priorities drawn from commodity annual priorities and with a higher focus placed on priorities that address issues associated with *minor uses*. These identified annualised priorities should be complemented by specific regulatory incentives that are designed to enhance and facilitate their regulatory approval in an expedited manner and through the use of international data where appropriate.

The program should contain a number of 'officers' with specific responsibilities attached to the aims of the program. These officers and the program should be independent of the national regulator. Officers of the program could be established based upon various commodity (crop) groups or by geographical regions. The program would be responsible for conducting an ongoing and annualised process of establishing lists of priority crop protection needs (gaps) that are recognised by the NRS (APVMA and States) to further enhance and facilitate their regulatory approval via complementary regulatory incentives. This would be via agreed mechanisms that are designed to deliver the following suggested general aims of the Program with a particular focus on addressing issues associated with *minor uses* and in doing so;

- meet on a nominated basis with affected industries to identify priority gaps and possible crop protection solutions including identification of future gaps that may arise due to chemical reviews undertaken by the regulator of older chemistry, and issues associated with industry biosecurity and market access (trade)
- assist user industries in compiling regulatory proposals for approval, and where required, assist user industries in the conduct of trials for those uses requiring further data,
- work collaboratively with all rural development corporations (HAL, GRDC, RIRDC etc.) to facilitate regulatory approvals and industry uptake of R&D,
- engage with registrants in facilitating the registration of crop protection products for priority gaps,
- seek access to all available data (including international data) to support the approval of crop protection uses and products within Australia and to reduce costs and time required to address needs where similar solutions are required or have already been addressed,
- engage with other international minor use programs to undertake joint R&D,
- engage with the NRS to;
 - determine data requirements, suitability of international data and new risk assessment guidelines or standards for crop protection products, and
 - provide guidance and input into the appropriate arrangement for access to legal off-label uses (i.e. those uses determined to be of low risk and not requiring regulatory approval via registration or permit).
- establish agreed priorities that focus attention on reducing the environmental risks of chemical products by seeking solutions such as biopesticides and softer chemistry that enhance facilitation and adoption of IPM and resistance management by user industries.
- maximise, where possible, collaborative efforts in data generation and sharing with other international minor use programs and seek to channel submissions through regulatory assessment mechanisms such as OECD Worksharing and Global Joint Reviews.
- deliver regulatory approvals via a number of interrelated mechanisms. These should include a first priority of working with the private sector to have uses registered and on product labels. In situations where registration may not be feasible, and as a last resort, the program may seek approvals via permit and also include the provision of national

advice on behalf of user industries on the possible and appropriate arrangements for legal off-label uses.

- seek funding from government (State and/or Federal).

It is suggested that specific priority aims/goals (or sub-programs) of the program should include:

1. Creation of a **National Sustainable Minor Use Crop Protection Program** by the Australian Government to improve access to new and effective tools and technologies for minor crops and minor uses in major crops through a process of registration. Research trials and laboratory analyses to be commissioned to generate necessary data to support the development of submissions to the APVMA for the registration of new minor uses and reduced-risk chemistry.
2. Creation of a **Pesticide Risk Reduction Initiative** to facilitate the development, regulatory approval (where required) and adoption of pesticide risk reduction strategies. The focus being on improving access to low-risk, environmentally-sustainable, IPM compatible and economically competitive crop protection tools and practices, including biopesticides. The initiative should be enhanced by the program's interaction with international counterparts where such technologies may have already been developed and approved. A component of this initiative would also be the development of **Pesticide Risk Reduction Strategies** to identify gaps and barriers in current pest management approaches, defining realistic and measurable goals to bridge these gaps and to specify the expertise, actions and resources to achieve these goals. The initiative should be overseen by a **Pesticide Risk Reduction Technical Working Group** including representatives of government departments and non-governmental organisations, grower associations and commodity groups to review the activities of the *Pesticide Risk Reduction Initiative* and provide advice and technical assistance.
3. Creation of **Crop Profiles** to provide crop production and pest management information, in particular IPM strategies on a commodity basis, nationally, and for these profiles to be used in identifying crop protection gaps in the annual priority setting process.
4. Creation of a **National Crop Protection Technical Working Group** comprised of growers, pesticide manufacturers and representatives of grower associations, to provide advice to the *National Sustainable Minor Use Crop Protection Program* on issues such as the process used for the identification of crop protection priorities and in the setting of annual national crop protection priorities, trial protocol development, the drafting of registration submissions, submission mechanics and collaborative projects with the private sector and other similar international minor use programs. National priorities to become projects within the *National Sustainable Minor Use Crop Protection Program* for the following funding year or period to be determined. This working group should also provide advice to PSIC and the APVMA, in areas of regulatory requirements, chemical reviews and *control-of-use* (including options for legal off-label uses without recourse to a permit).
5. Creation of **Commodity Stakeholder Working Groups** to identify crop/pest problems and potential solutions for these problems and set annual commodity crop/pest priorities. These groups would meet regularly and representatives would attend the annual national priority setting process of the *National Crop Protection Technical Working Group*. They should also provide input into the *Pesticide Risk Reduction Initiative* in the context of developing reduced-risk solutions including the development of IPM strategies, as outlined previously. These working groups would serve as a vehicle for the provision of regulatory advice to industry groups in areas such as new crop protection approvals, issues those industries may face in response to chemical reviews

being undertaken by the national regulator and any actions that may need to be taken in addressing review outcomes, including identification of alternative options.

6. Creation of a **Biosecurity and Market Access Technical Working Group** to identify and consult (as required) with other organisations such as the OCPPO and PHA on the provision of advice to those organisations on regulatory matters for the use of crop protection products. Also for managing the expedient approval of crop protection solutions, where required, in response to exotic pest/disease incursions. To identify trade barriers from the use of crop protection products in both a national and international context. The working group would provide advice to the *National Sustainable Minor Use Crop Protection Program* on biosecurity and trade barrier matters and any options that may be considered and/or pursued to overcome those barriers. This could include discussing local issues with the IPHRWG or for international market access where the *National Sustainable Minor Use Crop Protection Program* could make submissions for the establishment of CODEX MRLs or country specific import tolerances.
7. Provision of a **budgetary allocation by Government** on a 5 year cycle, administered by DAFF, to fund the activities of the *National Sustainable Minor Use Crop Protection Program* and *Pesticide Risk Reduction Initiative*. Disbursement to be made to research agencies through an application process to undertake field and greenhouse trial projects on targeted commodity and national priorities identified annually by *Commodity Stakeholder Working Groups* and the *National Crop Protection Technical Working Group*, and to the APVMA, to increase its capacity to review submissions and to provide shorter timelines for registration of new minor use and reduced-risk products and uses. Funding also to be made available for the activities of the various working groups identified previously.

Regulatory Processes and Incentives

Incentives need to be developed that 'lift' the value of, and interest in, registering minor uses. Whilst this value will not come directly from the registration of a minor use, it could be realised via alternative 'values' that registrants may recognise and where these could be provided in other areas and for other uses or products.

The *National Sustainable Minor Use Crop Protection Program* and its aims and goals should be closely linked to, and underpinned by, a range of regulatory processes and incentives developed and implemented to facilitate and enhance regulatory support in the approval of priority crop protection gaps. Such an approach could enhance the 'value' of registering those uses and increase registrants' interest in, and interaction with, the *National Sustainable Minor Use Crop Protection Program* and its associated industries.

Key incentives, linked to the *National Sustainable Minor Use Crop Protection Programs*, could include areas such as:

- Data protection
- Expedited reviews and accelerated assessment
- Fee waivers
- Conditional registration
- Data waivers
- International collaboration
- User requested and supported registrations

Data protection

Existing data protection provisions should be enhanced for both new active ingredients and also existing registered products. Some possible options could include the following considerations.

New active ingredients – new products

Currently an initial eight years of exclusive protection is provided for the registration of products which contain a new active ingredient. Provisions are available to extend the length of this period for a further 3 years up to a maximum of 11 years. Each additional year of data protection is provided for the registration of five minor uses. The scheme was developed and implemented in 2005 to encourage the registration of more minor uses, although few if any applications are known to have utilised the scheme. Change is therefore required.

Options for consideration are:

- Review existing procedures to enhance interest in and value of the registration of crop groups by assigning a minimum data protection value/period for crop groups. Weightings could be established for crop groups relative to the number of associated minor use commodities within each crop group and data required to achieve that crop group registration compared to likely economic return. For example crops such as cereals, Brassica vegetables, Allium vegetables, herbs and spices, pome fruit, tropical fruit etc., could be classified into either;
 - Major Crop Groups (i.e. cereals, pome fruit),
 - Major-Minor Crop Groups (i.e. Brassica vegetables, Allium vegetables) and
 - Minor Crop Groups (herbs & spices, tropical fruit),

with data protection values of 1, 1.5 and 2 years respectively for registrations in those crop groups.

- Increase the length of data protection from the current maximum of 11 years to 15 years, consistent with provisions available in Canada (page 26).
- Reduce the number of minor uses from the existing five minor uses in order to achieve one year's additional protection to either four or three minor uses. Canada currently requires three minor uses for each additional year's protection (page 26). Different values could be assigned to crops from within Major Crop Groups (five crops required), Major-Minor Crop Groups (four crops required) and Minor Crop Groups (three crops required).
- Increasing the unit value for the registration of a priority crop protection gap identified by the *National Sustainable Minor Use Crop Protection Program*. Values up to twice their current value could be considered for registrants who registered priority crop protection gaps.

Existing active constituents – already registered products

As with new active ingredients, data protection was implemented in 2005 for the registration of new use patterns involving an already registered product, where five years protection (exclusivity to labels with that use) is provided to the registrant. Although there is little 'real life' or likely incentive provided for the registration of uses in products that are generically marketed and freely available where end users may, and will most likely, choose to use similarly registered products off-label for otherwise protected uses. Whilst illegal, it is questionable if current compliance and enforcement activities would sufficiently protect these data protection uses negating the exclusivity intended by

legislation. This situation hinders the data protection incentives available for currently registered products where similarly registered generic alternatives exist.

Options for consideration could include one or a combination of the following;

- A new data protection initiative allowing the transfer of data protection 'credits' from one product to another product for registrants who register minor uses. The value attributed could be considered at a lower/reduced value than standard data protection provisions such as 50% reduction value (years or additional years).
- Similar to the first option, although with a prerequisite that the registration would need to have addressed a priority crop protection gap identified by the *National Sustainable Minor Use Crop Protection Program*.

In both options, considerations should allow the transfer of the credit to another product of the registrant's choosing, including those marketed by other registrants and new active ingredients. In all cases, however, the data submitted would not be afforded protection in the sense of exclusive rights to label that use pattern, but rather only the 'credit' afforded would be recognised and the use would therefore be open to all similarly registered products. The option should also consider allowing a registrant to 'bank' data protection credits gained and enable credits achieved through other submissions to be combined and redeemed at a later date and perhaps within a given period i.e. 3-5 years. For example, where a registrant addressed an identified/agreed priority minor use involving a generic product, the credit could be transferred to another product of their choice, be that a product they may have registered or to be exchanged with another registrant's registered product.

- As an alternative option, an economic or timeframe 'value' could be assigned for the registration of uses, where those 'credits' could be redeemed for other incentives such as fee waivers or expedited reviews on other submissions. Consideration could be provided to increasing the value where the product was subject to competition from other generic products in the market, or for registrations of uses that were a priority crop protection gap identified by the *National Sustainable Minor Use Crop Protection Program*.

Expedited reviews / accelerated assessment

The *Better Regulation of Agricultural and Veterinary Chemicals* policy discussion paper has suggested a possible provision for an accelerated assessment process being provided in cases where a registrant may pay a fee set at full cost-recovery. It is suggested that consideration should also be provided for accelerated assessment (expedited reviews) being provided to registrants who register minor uses, and in particular a priority crop protection gap identified by the *National Sustainable Minor Use Crop Protection Program*. It is suggested that the accelerated assessment could be established at approximately 50% of the otherwise registration assessment timeframe. For example, for new active ingredients where the registration timeframe is currently 15 months, this could be reduced to less than 10 months, or for extensions of use for existing registered products where timeframes are usually either five, eight or 12 months timeframes, could be reduced to between three and six months.

Fee waivers, reductions and/or debits

Fee waivers/reductions could be provided for applications that are either identified as:

- a priority crop protection gap identified by the *National Sustainable Minor Use Crop Protection Program* and/or
- demonstrated by the registrant (or user industry) to only be in minor markets (low volume/niche products) where the cost of registration is sufficiently small to justify registration as is available in Canada.

Options for consideration could include:

- A set 'credit' of monetary value assigned to the *National Sustainable Minor Use Crop Protection Program*, where the program could provide an allocation of fee credits in support of a registrant's registration application. Essentially this would be equivalent to establishing a 'priority crop protection regulatory fee fund'. For example for new use patterns for existing registered products where average registration costs are estimated at approximately \$10-20,000, a fund of approximately \$250-750,000/annum could be utilised for the regulatory assessment costs for the registration of priority crop protection gaps identified by the *National Sustainable Minor Use Crop Protection Program*. This could be limited to between 25-50 registration submissions/annum. Such a fund could be established through the allocation of specifically dedicated funds to the *National Sustainable Minor Use Crop Protection Program*, for part disbursement to the APVMA to enhance its effectiveness in this program.
- A scheme similar to that adopted in Canada could be established where a registrant could seek a fee reduction for low sales volume uses and niche products. In Canada the fee reduction is set at a maximum of 10% of the revenue from sales of the product registered during the sales verification period of three years. For example if a product had an estimated sales value over the three-year verification period of \$100,000 the maximum registration assessment fee payable would be \$10,000. Considerations could also be provided for different levels depending upon the predicted sales volume over 3 yrs, i.e. less than \$100,000 ~ 5%, 100-250,000 ~ 7.5% and >250,000 ~ 10%.
- Similar to the issues with the registration of low sales volume uses and niche products, consideration could be given for a fee debt to be accrued by a registrant for the registration of a low sales volume and niche product. A minimal fee could be initially established or a set % required as an up-front payment, whilst the remainder of the regulatory fee would be payable on an annualised basis for the remainder of the three years sales period. This mechanism would possibly enhance registration of low volume products where it would provide the registrant an initial level of return while still paying the required (or perhaps reduced) regulatory fee over a given sales period (suggested at three years).

Conditional registrations

The *Better Regulation of Agricultural and Veterinary Chemicals* policy discussion paper has a section titled; *Using overseas assessments to their full extent*. It is suggested that specific provisions be included to enable conditional registrations to be provided for priority crop protection gaps identified by the *National Sustainable Minor Use Crop Protection Program*. In these cases, as a pre-requisite, eligible submissions would need to contain a priority crop protection gap identified as determined and supported by the *National Sustainable Minor Use Crop Protection Program*. The

regulator would provide conditional registration based upon registration in another OECD member country (the process may require the assessment of the same data package and/or provision of the other country's regulatory assessment report). The registration would be conditional upon the provision of local residue and/or efficacy data within a period of approximately 3-5 years. The registration submission and its assessment may still be subject to complete regulatory risk assessments in the areas of human health (toxicology) and environment.

Additional pre-requisites could be established where the *National Sustainable Minor Use Crop Protection Program* would be required to identify a certain percentage of its support for conditional registrations for those uses that addressed objectives of the program's *Pesticide Risk Reduction Initiative*. An allocation of conditional registrations provided per annum may need to be determined, but initially, it is suggested that the target could be set at approximately ≤ 20 conditional registrations per annum (approximately one per crop group) with the number subject to further review over time.

Data waivers

The *Better Regulation of Agricultural and Veterinary Chemicals* policy discussion paper suggests that efficacy data may be waived where there is a low risk from excluding the assessment and for certain classes of applications. It is suggested that consideration should also be provided for waiving efficacy data requirements for uses that are priority crop protection gap identified and supported by the *National Sustainable Minor Use Crop Protection Program* as efficacious to a level satisfactory for end users' purposes. Also that efficacy data are provided to satisfy consumers that the product will be effective according to the claims of the registrant. Currently this is independently determined by the regulator, on behalf of the user/consumer. The proposal in this case would see the determination of efficacy and its ability to waiver the regulatory assessment determined by the end users via the *National Sustainable Minor Use Crop Protection Program*. In these cases it should perhaps still remain a legislative requirement that the registrant should have available for review, sufficient data to support its safety and efficacy, and if requested, be able to demonstrate this to the regulator (i.e. in cases of adverse reports being received and where those are deemed to require further investigation).

Alternatively or additionally;

- For conditional registrations discussed previously, data waivers could be provided in areas like residues and/or efficacy, provided the use was a priority crop protection gap, identified and supported by the *National Sustainable Minor Use Crop Protection Program*, and was supported by a given amount of data (possibly international). It could similarly be a requirement that over a period of nominated time, additional data be generated to fill these gaps.

and/or

- Explicit data waivers could be established for certain classes of minor uses, such as those that involve uses where the efficacy and/or crop safety has already been demonstrated in a related major crop, negating the need for data to be generated in all crops of a particular crop group (or class). This concept would enforce the provisions of data extrapolation between related pests, diseases and commodities in areas of efficacy and crop safety. Good examples of the provisions possible in this area could be enhanced via examination of the LTAEU system that was previously in place in the UK, and more recent efficacy and crop safety extrapolation tables, as developed and published by the EPPO.

International collaboration

A registration initiative could be established between the regulator and user groups, through the *National Sustainable Minor Use Crop Protection Program* to identify an annualised set of minor use priorities where new chemistry, including biopesticides, and new use patterns are registered internationally and to have these uses registered in Australia. The initiative would involve the regulator providing assistance via accessing and engaging with its international counterpart (overseas regulator) and between registrants and international minor use programs.

The initiative should also seek to maximise efficiencies and outcomes from the regulatory assessment of Global Joint Reviews undertaken by OECD and where Australia is included in the joint assessment of those submissions. Global Joint Reviews involve the simultaneous submission by a registrant to multiple OECD countries' regulatory authorities and where those regulators share the workload in undertaking that assessment. The initiative should maximise minor use approvals where those uses may have otherwise not been submitted as part of the Australian submission.

The initiatives should also be considered alongside other complementary incentives outlined such as the use of *Conditional Registrations / Use of international data* discussed above.

User Requested/Supported Registrations

Incentives should be developed for the registration of user requested or sponsored needs. This may encompass user industries being able to seek regulatory assessment of needs and be utilised as one mechanism to overcome user issues associated with product label discrepancies and adoption of new application technologies. For example, as noted in both Canada and the US, minor use submissions may be submitted directly by the user industry to the regulator, where the regulatory outcome is approval of uses on label (registration). It is suggested that a specific regulatory approval process be established for the regulator to assess industry submissions for the registration of minor uses and to utilise this process in place of the current off-label permit process. Some responses to Rose and Sheppard (2009) and the more recent consultation paper on Better Regulation of AgVet Chemicals have specifically quoted successes utilised by Pulse Australia in such a way, and others have also expressed an interest in having such a mechanism available as an alternative to permits. Such a process may also provide an avenue for user groups to have existing labels rectified (updated to contemporary use practices) where manufacturers do not see any economic interest to do so. This could work particularly well in addressing issues noted by Rose and Sheppard (2009) concerning user groups' complaints about out-dated product labels and confusing label statements by enabling varied agronomic practices and new application technologies to be approved.

Consideration could include applications lodged directly with the regulator for priority crop protection gaps identified by the program. The process would work particularly well for generically registered products, where those competing registrants of similarly registered products do not see any economic value in registering certain minor uses. The process would see the *National Sustainable Minor Use Crop Protection Program* lodge regulatory submissions, and following assessment by the APVMA and if supported, all registrants of products included could seek to have their product labels updated with the new use pattern. Such submissions could be complemented by other suggested incentives such as accelerated assessment, data and fee waivers.

References

- Anon. 2005. Agvet chemicals minor use initiatives, Product Safety and Integrity Committee Stakeholder Workshop, 2005, 27 pages.
- Anon. 2007. http://www.daff.gov.au/data/assets/pdf_file/0006/374721/discussion-paper.pdf
The Specialty Crops Unit Discussion Paper – 24 August 2007. Drafted by the Minor Use Liaison Office – a joint initiative of the Australian Government Department of Agriculture, Fisheries & Forestry and the Australian Pesticides and Veterinary Medicines Authority, 33 pages.
- Anon. 2009a. Article 51, Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, European Parliament, Council. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R1107:EN:NOT>
- Anon. 2009b. Report on Specialty Crop and “Minor Uses” Conference, 4 November 2009, 3pp.
- Anon. 2009c. *OECD Guidance on Defining Minor Uses of Pesticides*, OECD Environment Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, 23 October 2009, 26 pages.
- Anon. 2009d. http://www.oecd.org/department/0,3355,en_2649_34383_1_1_1_1_1,00.html, OECD Strategic Approach in Pesticide Risk reduction, OECD Pesticide Risk Reduction Steering Group, OECD Environment Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, 23 October 2009, 18 pages.
- Anon. 2010a. A national policy framework for the assessment, registration and control of use of agricultural and veterinary chemicals. Attachment A(vii), pp. 1-21, Council of Australian Governments Report.
http://www.coag.gov.au/reports/docs/agricult_veterinary_chemical_framework.pdf.
- Anon. 2010b. Fascinated by pesticides. Vegetables Australia September/October 2010, pp44-45, a magazine of AUSVEG for national vegetable levy contributors.
- Anon. 2010c. Registration division’s conventional new chemical decisions in FY2010, Report of Registration Activities in the Office of Pesticide Programs, 4 October 2010, pp11
- Greaves, J. 2007. Do we need regulatory changes to make biopesticides a mainstream solution? RELU Conference, 'Unlocking Change in the Food Chain', Congress Centre, London, 7th November 2007).
- Ludwig, J. 2010. Better regulation of agricultural and veterinary chemicals – policy discussion paper, Minister for Agriculture, Fisheries & Forestry, November 2010, 11 pages.
- Miller, SR. 2007. National economic analysis of the IR-4 Project. Center for Economic Analysis, Michigan State University, May 25 2007, 25pp. <http://ir4.rutgers.edu/Other/IR4EconomicImpact.pdf>.
- Rose, R. and Sheppard, N. 2009. A national scheme for assessment, registration and control of use of agricultural and veterinary chemicals – Discussion paper, December 2009, 77 pages.

Appendices

Appendix 1. History of national activities in minor use in Australia

Year	Activity	Comments
1995	National minor use permit scheme established	Continuing.
1998	National minor use workshop	Produced national minor use pesticide program for horticulture in 1999. Currently operating through Peter Dal Santo, AgAware Ltd.
2003	Minor Use Forum, Canberra	APVMA convened stakeholders meeting. Resulted in formation of Minor Use Task Force ¹ to progress issues.
2003	OECD seminar, Canberra	OECD pesticide risk reduction group conducted seminar on minor uses and pesticide risk.
2005	PSIC Stakeholder Workshop and Minor Use Task Force actions	First action was to propose a Strategic Framework (5 strategies) and development of Minor Use and SCDU
2006	APVMA Product Safety and Integrity Committee meeting	Approved Minor Use Task Force proposal. SCDU, renamed MULO. Two positions appointed.
2007	National minor use forum, Canberra	Organised by MULO. Comprehensive discussion paper available at http://www.daff.gov.au/_data/assets/pdf_file/0006/374721/discussion-paper.pdf
2007	OECD Expert Group on Minor Uses	Established with Australia appointed Chair. http://www.oecd.org/document/50/0,3746,en_2649_34383_40759026_1_1_1_1,00.html
2007	FAO Global Minor Use Summit, Rome, December	Hoping for strong Australian representation http://www.ir4.rutgers.edu/gmus/index.html
2009	Codex Electronic Working Group on Minor Uses and Specialty Crops	Established with US appointed Chair and Australia and Kenya appointed Co-chairs.

¹ Minor Use Task Force comprised representatives of the chemical industry, agricultural users, agricultural consultants and the APVMA.

Appendix 2: New use registrations for agricultural purposes granted by the APVMA in 2010.

Note: information obtained from the APVMA website of advice summaries issued in 2010 at: <http://www.apvma.gov.au/registration/assessment/advice/2010.php>. The list includes only those registrations granted that involve the approval of novel/new use patterns in agricultural cropping situations.

Description of registration granted	Product No.	Application No.	Product Name
control of downy mildew and powdery mildew on grapevines	64640	48831	Melpat Mildex WG Fungicide (PDF, 42kb) (RTF, 304kb)
establish a grazing withholding period (WHP) in peanuts	53884	50029	Crop Care Barrack 720 Fungicide (PDF, 40kb) (RTF, 298kb)
reduce rates for use on, vines to control downy mildew, potatoes to control target spot and Irish blight, and on tomatoes to control target spot/early blight, septoria leaf spot and Irish blight/late blight	59375	47848	Neoram 375 WG Fungicide (PDF, 48kb) (RTF, 311kb)
extend the label claims to include control of ectotrophic root infecting (ERI) fungi, couch grass decline, spring dead spot and take-all patch	63615	50232	Headway Maxx Turf Fungicide (PDF, 37kb) (RTF, 177kb)
change the instructions for use following application to turf	59696	50036	Merit Turf and Ornamental Insecticide (PDF, 41kb) (RTF, 301kb)
extend the use to growth regulation of cherries	53027	48532	Progibb SG Plant Growth Regulator (PDF, 45kb) (RTF, 306kb)
extend the use to include control of insect pests on fruit crops and for the control of adult mosquitoes, midges and flies in outdoor situations	60610	49130	Py-Zap Insecticide With Natural Pyrethrum (PDF, 36kb) (RTF, 301kb)
extend the use to include bio-regulation of shoot growth in cherries	61570	46883	Nufarm Regalis Plant Growth Regulator (PDF, 53kb) (RTF, 220kb)
extend the directions for use to include early post-emergence use on triazine tolerant canola for the control and suppression of various broadleaf and grass weeds	56973	49110	Terbyne 750WG Herbicide (PDF, 46kb) (RTF, 319kb)
seed treatment for control of various diseases in barley and prevention of spread of barley yellow dwarf virus	64690	48981	Arrow Plus Seed Treatment (PDF, 37kb) (RTF, 303kb)
extend the use to include the control of helminthosporium disease (<i>Bipolaris</i> spp, <i>Drechslera</i> spp, <i>Exserohilum</i> spp) and winter fusarium (<i>Microdochium patch</i>) (<i>Fusarium nivale</i>) in lawns and turf, and extend the use for control of grey leaf spot (<i>Pyricularia grisea</i>) to WA and NT	56777	49522	Daconil Weather Stik Turf Fungicide (PDF, 39kb) (RTF, 307kb)

to accelerate or increase the red colouration in grape berries and bunches in conjunction with the approval of Abscisic acid (application 45408)	63314	45309	Protone SG Plant Growth Regulator Soluble Granule (PDF, 128kb) (RTF, 327kb)
for the control of cockroaches, ants, spiders, flies and fleas inside and outside of domestic, commercial, industrial and public service buildings including factories, hospitals, homes, retail outlets, and farm buildings	64396	48224	Dupont Arilon Insecticide (PDF, 73kb) (RTF, 378kb)
to enhance the performance of Vivus Max	64627	48808	Optimol Biological Insecticide Optimiser (PDF, 40kb) (RTF, 311 kb)
extend the use to an additional minor food crop (olives), reduce rates and add pest for citrus, extend claims for cotton and grapes, change rates for bananas, extension of claims for mango and amendment to precaution and application information	54179	45163	Sacoa Biopest Paraffin Oil (PDF, 43kb) (RTF, 314kb)
for the control of codling moth in apples	63025	44536	Madex Biological Insecticide (PDF, 119kb) (RTF, 476kb)
extend the use to include an additional pest in cotton, use in soybeans and use in additional minor crops	61311	47530	Vantal 18 EW Miticide/Insecticide (PDF, 35kb) (RTF, 297kb)
extend the use to include the control of husk spot in macadamia and rust in almonds	49315	58900	Nufarm Cabrio Fungicide (PDF, 50kb) (RTF, 324kb)
extend registration to all states and include use on turf for the control of Anthracnose, Brown Patch, Helminthosporium, Winter Fusarium.	49511	54360	Banner Maxx Turf Fungicide (PDF, 43kb) (RTF, 314kb)
extend the use to include control of French's Cane Grub in sugarcane	61591	47852	Ospray Couraze Classic Insecticide (PDF, 35kb) (RTF, 181kb)
extend the label claims to include control of the Ectotrophic Root Infecting (ERI) fungi Couchgrass Decline and Take-all Patch	54360	50321	Banner Maxx Turf Fungicide (PDF, 33kb) (RTF, 296kb)
extend the use to include fireweed in the weeds controlled list (existing situations) and to amend label directions in relation to mulch, animal waste and export	59173	45335	Hotshot Herbicide (PDF, 29kb) (RTF, 297kb)
for use on vegetable seedlings for the control of early season sucking and chewing pests	63936	46959	Durivo Insecticide (PDF, 347kb) (RTF, 814kb)
extend the use to include the control of cane grubs in sugarcane	60689	42490	Sumitomo Shield Systemic Insecticide (PDF, 105 kb) (RTF, 336kb)
extend uses to include use on barley to control barley leaf scald, powdery mildew and to suppress net form net blotch, use on wheat to suppress glume blotch, reduce rate for use on wheat to control stripe rust, reduce withholding period, and add an export slaughter interval	61019	48000	Crop Care Jockey Systemic Seed Treatment (PDF, 53kb) (RTF, 207kb)
for use in native pastures, rights of way, non-agricultural areas, commercial and industrial areas for the control of certain brush species	62431	43106	Ultimate Brushweed Herbicide (PDF, 50kb) (RTF, 318kb)
for the control of marshmallow and annual nettles in rough grass and turf areas; in the control of marshmallow and certain	64135	47634	Turf Culture Smackdown Herbicide (PDF,

other broadleaf weeds, in commercial, industrial and public service areas, and around buildings and yards, in tank mixture with knockdown herbicides			39kb (RTF, 308kb)
for the control of White Rot in onions and Powdery Mildew in Grapevines	63023	44533	Allitron Systemic Fungicide (PDF, 50kb) (RTF 322kb)
extend the use to include pyrethrum crops	59148	48374	Baron 400 WP Selective Herbicide (PDF, 38kb) (RTF 305kb)
extend use into potatoes, capsicum, eggplant, peppers and tomatoes and for the control of powdery mildew in grapevines, and to allow a rate range to control <i>Botrytis cinerea</i> in grapevines	59032	42941	Nufarm Filan Fungicide (PDF, 170kb) (RTF, 412kb)
for control of powdery mildew in cucurbits	62695	43749	Colliss Fungicide (PDF, 176kb) (RTF, 494kb)
extend the use to include additional pests in existing crops including canola, field peas lentils, lucerne, lupins, pastures and cereal crops, and the addition of the crops, grapes and faba beans	53047	42747	Sumi-Alpha Flex Insecticide (PDF, 97kb) (RTF, 399kb)
include the control of various diseases in apples and pears and to reduce the WHP for apples from 4 weeks to 14 days	62974	47275	Nufarm Pristine Fungicide (PDF, 37kb) (RTF, 347kb)
include control of annual ryegrass, wild oats and annual phalaris in barley	61992	47504	Hussar OD Selective Herbicide (PDF, 37kb) (RTF, 369kb)
for post harvest treatment of citrus, pome fruit, stone fruit and kiwi fruit	63391	45488	Scholar Fungicide (PDF, 44kb) (RTF, 417kb)
for control of smut and bunt diseases in cereals, in conjunction with the approval of new active ipconazole	63309	45294	Rancona C Seed Treatment (PDF, 71kb) (RTF, 604kb)
include the control of early blight in capsicum, eggplant, peppers and tomatoes, downy mildew in poppies and various diseases in mangos	61186	43371	Nufarm Aero Fungicide (PDF, 83kb) (RTF, 378kb)
extend the use of Belt 240 WG Insecticide to tomatoes, capsicums, green beans and lettuce for the control of various diseases	61224	43381	Belt 240 WG Insecticide (PDF, 69kb) (RTF, 242kb)
extend the use to include bananas, mangoes, poppies, onions, capsicum, eggplant, peppers, chickpeas, lentils, field peas and faba beans; to extend the use on grapevines to include control of downy mildew and phomopsis and to amend the rate on tomatoes	58901	42954	Nufarm Polyram Df Fungicide Spray (PDF, 32kb) (RTF, 346kb)
extend the use to include specified pests in cotton	61864	47640	Movento 240 SC Insecticide (PDF, 66kb) (RTF, 355kb)
extend the use to include the control of stripe rust on wheat	54526	45757	Indar Fungicide (PDF, 34kb) (RTF, 247kb)
For the control of various fungal diseases on potatoes and	63898	46862	Amistar Top Fungicide (PDF, 39kb) (RTF,

tomatoes			360kb
for the control of botrytis in grape vines	63223	45050	Ecoprotector Fungicidal Potassium Soap (PDF, 26kb) (RTF, 310kb)
to include higher application rates for the control of red legged earth mite in cereals and pasture	56454	47346	Danadim Insecticide (PDF, 25kb) (RTF, 298kb)
for the control of various diseases in cereals	62753	43929	Opera Fungicide (PDF, 126kb) (RTF, 467kb)
include pulses	46226	47540	Gaucho 350 Flowable Seed Dressing Insecticide (PDF, 38kb) (RTF, 335kb)
to reduce rate for control of specified annual weeds prior to sowing winter cereal, oilseed, pulse crops and pastures	62042	48123	Crop Care Alliance Herbicide (PDF, 52kb) (RTF, 318kb)
extend the use to include the control of volunteer canola including Roundup Ready varieties	52904	47758	Nufarm Amicide 625 Selective Herbicide (PDF, 24kb) (RTF, 300kb)
extend use to control prickly lettuce and Shepherd's purse in wheat, barley, cereal rye and triticale and to include additional compatibility statements	62444	46338	Velocity Selective Herbicide (PDF, 34kb) (RTF, 351kb)
for the control of existing infestations of insects and related pest species and rodents in various situations and control of post-harvest insect and rodent pests in structures such as grain silos or other grain storages, mills, warehouses, stationary transportation vehicles (excluding aircraft and passenger railcars), temporary and permanent fumigation chambers and commodity storage structures only containing specified commodities	59952	37112	Profume Gas Fumigant (PDF, 72kb) (RTF, 530kb)
extend the use to include post emergent use in TT Canola	55187	47660	Rallis Metribuzin 750 Wg Herbicide (PDF, 26kb) (RTF, 306kb)
to add new weeds to Clearfield canola use pattern, update adjuvant recommendation and other various label changes	60683	46550	Nufarm Intervix Herbicide (PDF, 28kb) (RTF, 330kb)
extend the use as an additive to glyphosate herbicides for the post-emergence control of certain summer weeds in Southern Australia, prior to sowing broadacre crops or starting a fallow	61328	45686	Pyresta LV Herbicide (PDF, 51kb) (RTF, 316kb)
extend use to include suppression and seedhead control of bahia grass, and include catsear, chickweed, cotula, creeping oxalis, curled dock and milk thistle	62571	47562	Monument Liquid Turf Herbicide (PDF, 29kb) (RTF, 323kb)
extend the use to include the control of powdery mildew in wheat	63243	48111	Prosaro 420 Sc Foliar Fungicide (PDF, 26kb) (RTF, 305kb)

for the control of certain weeds in chickpeas, faba beans, field peas, lupins and triazine tolerant canola	56973	40585	Terbyne 750wg Herbicide (PDF, 65kb) (RTF, 572kb)
add additional crop/weeds, modify application rates for certain crops and to update the WHP and ESI statements	40714	46522	Broadstrike Herbicide (PDF, 31kb) (RTF, 325kb)
approval to shorten the Withholding Period (WHP) for mangoes from 8 weeks to 4 weeks, and to set a new Maximum Residue Limit (MRL) of 0.05 mg/kg for mangoes (current MRL is *0.01).	60997	47857	Admiral Insect Growth Regulator (PDF, 27kb) (RTF, 302kb)
extend use to canola for reduced tillage situations, various tank mixes and to extend state use	56421	45871	Nufarm Triflurx Selective Herbicide (PDF, 31kb) RTF, 339kb)
extend the use to include a higher use rate on avocados for mature and late season fruit	56467	45909	Smartfresh (PDF, 24kb) (RTF, 183kb)

Appendix 3. New use permits granted for agricultural purposes by the APVMA during 2010.

Note: information obtained from the APVMA website at; <http://www.apvma.gov.au/permits/search.php>.

Note: this list only includes permits approved that involved new use patterns for agricultural crops.

Permit #	Description of permit approved (product/situation/purpose)	Date Issued	Expiry Date
PER10422	Methidathion / Lychees / Mango planthopper	30-Jun-10	30-Jun-13
PER10748	Tilt 250 EC Systemic Fungicide and all other 250g/L formulations of propiconazole / Silverbeet / Various fungi	12-Aug-10	30-Jun-12
PER10784	Ultimate (metsulfuron methyl) / Oilseed Poppy / Growth regulator	10-Sep-10	31-Dec-13
PER10800	Bayfidan 250 EC Fungicide / Chillies and Paprika / Powdery Mildew	02-Feb-10	30-Jun-13
PER10851	Amicide 625 / Pastures / Fireweed	12-Jan-10	31-Mar-12
PER10903	Flint 500 WG Fungicide / Cucumbers and capsicums (protected) / Powdery mildew	18-Aug-10	31-May-13
PER10908	Tebuconazole / Beetroot, chicory, endive, radish, silverbeet and spinach / Sclerotonia rot	09-Jun-10	30-Jun-13
PER11148	Thiram / Sunflower seed (export) / Fusarium, Rhizoctonia & other seed-borne diseases	17-Mar-10	31-Jan-13
PER11221	Various products / Forestry nursery	15-Oct-10	30-Jun-15
PER11355	Abamectin / Sweet Corn	19-Jan-10	30-Sep-12
PER11421	Glyphosate / Hardwood plantations / Annual and perennial weeds	21-May-10	30-Jun-12
PER11482	Pyraclostrobin / Pawpaw and Papaya / Black spot & Brown spot	05-Jan-10	31-Jul-13
PER11483	Phosphorous acid / Tomatoes / Phytophthora root rot	13-Jan-10	30-Jun-13
PER11553	Applaud Insecticide (buprofezin) / Nursery Stock (Non Food) / Mealybug, Leafhoppers, Scale and Whitefly	24-Feb-10	30-Nov-14
PER11560	Suscon Maxi Insecticide / Nursery stock / Various insects	28-Jan-10	31-Jan-13
PER11572	Chlorothalonil / Spinach & Silverbeet / Downy Mildew, Alternaria Leaf Blight & Grey Mould	23-Feb-10	31-Mar-13
PER11618	Fenbutatin oxide and abamectin / Papaya (Pawpaw) / Two-spotted or Spider mites	08-Apr-10	30-Jun-13
PER11651	Acramite Miticide / Lettuce / Two-Spotted (Red Spider) Mite	22-Jan-10	31-Dec-12
PER11669	Amicide 625 / Pastures / Fireweed	14-Jan-10	31-Mar-12

PER11707	Payback Plant Growth Regulator (paclobutrazol) / Ornamental and amenity trees / Excessive plant growth regulation	30-Jun-10	30-Apr-13
PER11753	Unleaded Petrol / Hives of European Honey Bees / Varroa, Tropilaelaps & Tracheal Mites	12-Jan-10	30-Sep-15
PER11763	Pirimicarb / Spring Onions / Aphids	06-Jan-10	31-Dec-12
PER11765	Etoxazole / Snow or Sugar Snap Peas / Two Spotted Mite	06-Jan-10	31-Dec-12
PER11766	Sumi-alpha Flex insecticide / Farm dams / Yabbies	15-Jan-10	31-Dec-10
PER11775	Movento / Seed sunflower, Seed sorghum, Seed corn, Seed sweet corn / Green Peach Aphid, Cotton Aphid, Western Flower Thrip	19-Jan-10	31-Dec-11
PER11798	Tebuconazole / Garlic / Orange Rust	08-Apr-10	31-Mar-13
PER11800	Pirimicarb / Garlic / Bulb aphid and other aphid species	01-Sep-10	31-Aug-13
PER11801	Lambda-cyhalothrin / Garlic / Bulb aphid redlegged earth mite	20-Aug-10	31-May-13
PER11803	Clethodim / Garlic / Winter Grass	16-Aug-10	31-May-13
PER11831	Various products / Pyrethrum crops / Various pests	21-Dec-10	30-Apr-15
PER11832	Bioglobal Carpophilus Monitoring System / Specified fruits / Carpophilus Beetle (monitoring)	15-Dec-10	30-Jun-11
PER11839	Movento 240 SC Insecticide / Sorghum and Maize (seed crops only) / Green Peach Aphid & Maize Thrip	26-Feb-10	31-May-12
PER11852	Fenhexamid / Greenhouse and Protected Cropping (GHPC) Peppers and GHPC lettuce (head & leafy) / Grey Mould	17-Aug-10	31-Jan-13
PER11865	Glufosinate ammonium (Basta) / Pongamia tree plantation / Weed control	05-Mar-10	31-Mar-15
PER11866	Haloxyfop (Verdict 520 Herbicide) / Pongamia Tree Plantation / Grass Weeds	05-Mar-10	31-Mar-15
PER11966	Various Fipronil products / Custard Apple / Ants	11-Aug-10	30-Jun-13
PER11969	Sunny Plant Growth Regulator / Custard Apple / Plant Growth Regulation	08-Apr-10	31-Mar-13
PER11971	Pegasus insecticide / Nursery stock / Aphids, mites and whitefly	12-Aug-10	31-May-15
PER11972	Acramite Miticide (Bifenazate) / Nursery stock / Mites	13-Aug-10	31-May-15
PER11973	Chess Insecticide & Fulfill Insecticide (pymetrozine) / Nursery stock (non-food) / Aphids and whitefly	30-Jun-10	30-Jun-15
PER11977	Endosulfan / Sunflower and Sorghum Seed Crops / Rutherglen bugs	10-Feb-10	30-Jun-15
PER11989	Tramat 500 SC Selective Herbicide / Spinach, Silverbeet, Onions / Various Weeds	18-Aug-10	31-Jul-13
PER12001	K-Obiol Combi / Seed for sowing of sunflower and canola / Various pests	29-Sep-10	31-Aug-15

PER12002	Ecocarb Fungicide / Parsnip, radish, snow peas, sugar snap peas, swede and turnip / Powdery mildew	15-Jul-10	05-Sep-12
PER12007	Apithor Hive Beetle Harborage / Bee Hives / Small Hive Beetle	29-Sep-10	30-Jun-12
PER12014	Metsulfuron - methyl / Pastures, Roadsides, Non-crop areas, Rights of way, Forests, Reserves and Bushland / Bahia Grass and Fireweed	15-Jul-10	30-Sep-13
PER12019	MouseOff Zinc Phosphide Bait / Tomato and immediately adjacent crops / House mouse	18-Feb-10	31-May-10
PER12026	Phosphine / In -transit Fumigation / Wood chips & Cereal grain	16-Apr-10	30-Sep-10
PER12037	Sumagic Plant Growth Regulator (uniconazole-P) / Pyrethrum / Plant Growth Regulation	10-Jun-10	31-May-15
PER12054	Propiconazole / Brassica leafy vegetables, chicory, endive, radicchio / Cercospora leaf spot, rust, Septoria leaf spot	22-Oct-10	31-Aug-14
PER12056	Pulse Penetrant / Cotton Crop Machinery / Solenopsis Mealybug	12-Mar-10	31-Aug-10
PER12065	Maldison / Pasture / Wingless grasshopper	08-Apr-10	31-Mar-15
PER12100	Fastac Duo (alpha-cypermethrin) / Softwood plantations / Army worm	30-Mar-10	31-Aug-12
PER12120	Scholar (fludioxonil) / Mangoes (post-harvest) / Anthracnose, Stem end rot & Dendritic spot	26-Jul-10	30-Jun-13
PER12125	Confidor Guard (imidacloprid) / Non-bearing Blueberry / Scarab beetle larvae	05-May-10	30-Jun-13
PER12130	Propyzamide / Oilseed Poppies / Ryegrass	22-Oct-10	30-Nov-15
PER12135	Caltex & Prospect Post Harvest Fruit Treatment / Citrus (post-harvest) / Lightbrown apple moth	24-Jun-10	30-Jun-11
PER12141	Benzalkonium Chloride / Infected Materials / Decontamination	03-May-10	31-May-20
PER12147	Tilt (propiconazole) / Ornamental Plants / Myrtle rust (Uredo rangelii)	07-May-10	31-May-11
PER12156	Triadimenol, Triforine, Mancozeb, Azoxystrobin, Copper oxychloride, oxycarboxin and propiconazole / Nursery stock (non-food), ornamentals and cut flowers / Myrtle Rust (Uredo rangelii)	09-Sep-10	30-Jun-11
PER12157	Dynasty PD Fungicide / Peanuts / Aspergillus crown rot	15-Jul-10	31-Jul-11
PER12179	Hotshot / Cereal crops & Grass pasture / Three-horned bedstraw	12-Aug-10	30-Nov-15
PER12185	Dichlorvos & Maldison / Lures for fruit fly trapping / Fruit Flies	17-Aug-10	31-Mar-15
PER12196	Eco2Fume (phosphine) / Viterra Bunker Grain Storages / Mouse	11-Jun-10	31-Jan-11
PER12225	Various / Cotton and Pigeon pea / Australian plague locust	01-Oct-10	31-Dec-10
PER12250	Phosphine / Wood Chips & Cereal Grains in Ship Holds / Insect Infestation	10-Nov-10	30-Sep-11

PER12255	Maldison & Chlorpyrifos / Crops as described on the registered labels / Australian Plague Locust (<i>Chortoicetes terminifera</i>)	01-Jul-10	30-Jun-11
PER12293	Zinc phosphide (MouseOff ZP Econobait) / Eyre Peninsular / Mouse plague	08-Sep-10	31-Jan-11
PER12297	Affirm (emamectin) / Canola / Diamond Back Moth Larvae	25-Aug-10	31-Oct-10
PER12307	Taktic EC (Amitraz) / infested sites (stockyards) / Cattle ticks	29-Jul-10	30-Sep-10
PER12318	Triadimenol, Triforine, Propiconazole & Azoxystrobin / Myrtaceae quarantine movement / Myrtle Rust (<i>Uredo rangellii</i>)	05-Aug-10	30-Aug-13
PER12319	Triadimenol, Triforine, Propiconazole & Azoxystrobin / Hosts at Infected premises / Myrtle Rust (<i>Uredo rangellii</i>)	05-Aug-10	30-Aug-13
PER12329	Various synthetic pyrethroids / Adzuki beans / Australian Plague Locust	02-Sep-10	30-Jun-11
PER12332	Chlorpyrifos & Maldison / Tree nuts / Australian plague locust	24-Sep-10	31-Aug-11
PER12336	Maldison / Fruit trees and fly traps / Asian papaya fruitfly, melon fly and other fruit flies	31-Oct-10	31-Oct-15
PER12338	Phosphine / Cereals / In-Transit Fumigation	12-Aug-10	30-Sep-10
PER12364	BASF Pyramin WG Selective Herbicide / Fodder Beet, Red Beet, Silver Beet / Various Weeds & Grasses	30-Sep-10	30-Sep-11
PER12388	Phosphine / Cereals & Wood chips / In-Transit Fumigation	10-Nov-10	30-Sep-11
PER12389	Methyl Bromide / Post harvest fumigation / Fruit fly, whiteflies, thrips	01-Sep-10	31-Aug-15
PER12393	Chlorothalonil / Chickpeas & Lentils / Ascochyta blight & Grey mould	10-Sep-10	31-Dec-10
PER12429	Caltex Organic Summer Oil / Agricultural areas, pasture, crop and non-crop areas / Australian Plague Locust	08-Oct-10	30-Jun-11
PER12456	Amistar (azoxystrobin) / Chick peas and lentils / Ascochyta blight	20-Oct-10	31-Mar-11
PER12458	Procymidone / Chickpeas / Botrytis grey mould	12-Oct-10	31-Mar-11
PER12459	Prosaro (prothioconazole + tebuconazole) / Chick peas and lentils / Ascochyta blight	20-Oct-10	31-Mar-11
PER12460	Amistar Xtra (azoxystrobin + cyproconazole) / Chick peas and lentils / Ascochyta blight	21-Oct-10	31-Mar-11
PER12480	Captan / Chick peas and lentils / Chocolate spot, Ascochyta blight & Grey mould	11-Oct-10	31-Mar-11
PER12511	Prosaro 420 Foliar Fungicide / Wheat and barley / Fusarium head blight	15-Oct-10	31-Dec-11
PER12559	Glyphosate / Lupins / Pre-harvest desiccation and weed control.	11-Nov-10	31-Jan-11
PER12588	Ridomil Gold 480 EC Systemic Fungicide, Country Metalaxyl 250 EC Systemic Fungicide / Grapevines / Downy Mildew	01-Dec-10	30-Apr-11

PER12596	Copper present as Cupric hydroxide / Chestnuts / Chestnut Blight	06-Dec-10	31-Mar-12
PER12605	Max MZ Fungicide (metalaxyl + mancozeb) / Grapes / Downy Mildew	07-Dec-10	30-Apr-11
PER12606	Methomyl/ Specified Annual green leafy herbs / Heliothis, Green Vegetable Bug & Grasshoppers	07-Dec-10	31-Dec-12
PER12610	Amistar WG & Amistar 250 SC (azoxystrobin) / Olives / Anthracnose	17-Dec-10	30-Jun-11
PER12618	Tebuconazole / Mung beans / Powdery Mildew	23-Dec-10	31-May-11
PER12619	Sulphur / Mungbean / Powdery Mildew	16-Dec-10	31-May-12
PER12620	Bollgard II Cotton Event 15985/ Variation to condition of registration / Alton Downs, Clermont to Belyando (north) and Mackenzie (QLD only)	15-Dec-10	31-Dec-10

Appendix 4. Summary of Victorian pesticide residue survey results 2002-08

	2007/08	2006	2005	2004	2003	2002
Total samples	457	420	391	405	309	329
No. samples of fruit	296	153	80	97	207	87
No. samples of vegetables	161	212	271	270	83	227
No. samples of nuts	0	5	9	0	0	0
No. samples of herbs	0	50	19	20	19	0
No. samples of green tea	0	0	5	0	0	0
No. samples of grain	0	0	0	18	0	15
Total pesticide tests	32, 314	21, 986	16, 260	10, 772	6, 381	7221
No. tests > MRL	21	11	3	9	11	11
No. tests where residues >MRL or with no MRL	39	48 (+2 ERL)	34	18	16	12
% tests where violations >MRL	0.065	0.05	0.018	0.08	0.17	0.15
% tests where violations >MRL or with no MRL	0.12	0.22	2.1	0.17	0.25	0.17
% samples where violations >MRL	4.6	2.6	0.77	2.2	3.6	3.3
% samples where violations >MRL or with no MRL	8.5	11.4	8.7	4.4	5.2	3.6
Number of chemicals involved in violations	15	22	13	8	10	7
Number of chemicals involved in violations when no MRL present	8	17	9	4	4	1
% chemicals involved in violations when no MRL present	53.3	77.3	69.2	50	40	14

- Analysis based on tests and samples.

Appendix 5. The Canadian Minor Use Pesticides and Pesticide Risk Reduction Programs

(Details taken from the Canadian PMC web site - [Directive 2001-01](#))

The two programs at AAFC's PMC support the goals of the [Growing Forward Framework](#) - to contribute to innovation and competitiveness while encouraging environmentally friendly and cost-effective food production.

They are:

- Minor Use Pesticides Program
- Pesticide Risk Reduction Program

1. Minor Use Pesticides program

The Minor Use Pesticides Program was launched in June 2002 as a joint initiative between AAFC and Health Canada's PMRA. The Program, which has been fortified under the Federal Agricultural Regulatory Action Plan of the Growing Forward policy initiative, aims to increase grower competitiveness by improving access to new and effective crop protection tools and technologies.

The Minor Use Pesticides Program works with growers, the Provinces, manufacturers and the U.S. IR-4 Specialty Crops program to establish grower-selected crop/pest needs, and match them with potential solutions, particularly reduced risk products. As the front-line guardians against pest issues, growers know from experience the types of persistent and emerging pest problems that can have serious effects on their operations. It is for that reason that growers select priorities at an annual priority-setting workshop.

AAFC then conducts field and greenhouse trials and commissions laboratory analyses to collect the required data, including efficacy and residue information, before drafting regulatory submissions to PMRA for the registration of new minor uses. Many of these new uses replace older chemistries and formulations which have been taken off the market.

There is a two-fold process:

Grower-determined Crop/Pest Problems

Each year in winter, growers and other stakeholders work with Provincial minor use coordinators to identify crop/pest problems and potential solutions for these problems. These problems are grouped into three disciplines: weeds and growth regulators, insects (entomology) and diseases (pathology). The Provincial lists are compiled by the PMC and integrated into a national priority list for each discipline that serves as the working document for the Canadian Minor Use Pesticide Priority Setting Workshop. The last workshop took place March 23 - 25, 2010, in Ottawa.

Selected National Priorities

During the 2010 Canadian Minor Use Pesticide Priority Setting Workshop, the national priorities were selected. Thirty (30) "A" Priorities with potential solutions and seven "A" Priorities without solution were determined. They were divided among the three disciplines (weeds and growth regulators, entomology and pathology). In addition, five regional priorities and two organic priorities were also selected. When determining the solutions for each pest problem, products which minimize the potential impacts on the environment and human health were considered. These selected priorities will become projects within the Minor Use Pesticides Program for the 2011 growing season. The 2010 national priority list is given in the Table 2 as an example.

Table 2. A selection of 'A' entomology priorities for 2010

AAFC #	Crop Group	Crop	Target Pest (common name)	Target Pest (scientific name)	National Pest Priority Rank	Solution ranking	Potential Solution (active ingredient)	Potential Solution (product)	Registrant
11-017	4	Lettuce, leaf (GH)	Whiteflies	<i>Trialeurodes vaporariorum</i>	A	1	pyrifluquinazon	NNI-0101	Nichino
	4	Lettuce, leaf (GH)	Whiteflies	<i>Trialeurodes vaporariorum</i>	A	2	pymetrozine	Endeavor	Syngenta
11-018	6	Chickpea	Cutworms	<i>Euxoa ochrogaster, Agrotis orthogonia</i>	A	1	chlorantraniliprole	Coragen	DuPont
	6	Chickpea	Cutworms	<i>Euxoa ochrogaster, Agrotis orthogonia</i>	A	2	cyantraniliprole	Cyazypyr	DuPont

AAFC #	Crop Group	Crop	Target Pest (common name)	Target Pest (scientific name)	National Pest Priority Rank	Solution ranking	Potential Solution (active ingredient)	Potential Solution (product)	Registrant
11-019	8-09	Pepper (GH)	Mealybug	<i>Pseudococcus citri</i>	A	1	pyrifluquinazon	NAI-0101	Nichino
	8-09	Pepper (GH)	Mealybug	<i>Pseudococcus citri</i>	A	2	flonicamid	Beleaf	ISK
11-020	8-09	Tomato (GH)	Thrips	<i>Frankliniella occidentalis</i>	A	1	tolfenpyrad	NAI-2302	Nichino
	8-09	Tomato (GH)	Thrips	<i>Frankliniella occidentalis</i>	A	2	<i>Chenopodium ambrosioides</i>	Requiem (Facin)	AgraQuest

2. Pesticide Risk Reduction Program

The Pesticide Risk Reduction Program, a joint initiative of AAFC and the PMRA, works to reduce the risks from pesticides used in the agriculture and agri-food industry. These include risks to human health, risks to biodiversity resulting from impacts on non-target organisms, and risks to air, water and soil. The Canadian program differs from the US EPA program in that it does not simply rely on a comparison with conventional organophosphate chemistry as the basis for qualification.

The Pesticide Risk Reduction Program creates a framework through which growers develop and implement pesticide risk reduction strategies. It focuses on selected crops and priority pest management issues that are determined through stakeholder consultations at a national level.

The Program provides funding and regulatory support for the implementation of developed strategies. Success of the strategies is measured and the current pest management situation for individual crops is updated in the Crop Profile and Issues section.

There are four sub-programs:

a) Implementation

The PMC provides project funding through the Pesticide Risk Reduction Program to support the development and implementation of reduced risk pest control technologies and practices in order to support growers' efforts to produce crops in more environmentally sustainable ways.

Funding for implementation projects can be accessed in two ways:

- through periodic postings of requests for proposals to conduct work to implement specific aspects of risk reduction strategies; and
- as short term project funding available throughout the year.

Solicitations of bids for specific implementation projects are posted periodically on the government procurement website, MERX, as the requirements are developed by strategy implementation working groups. Emphasis is on projects that will lead to adoption of reduced-risk pest management tools or systems, and can be implemented within a relatively short timeframe of about three years. Postings may include requirements for research and demonstration trials, workshops, strategy support (literature reviews, development of a strategic plan, measurement of risk reduction, etc.), and others for implementation of reduced-risk pest management solutions.

As risk reduction strategies are developed by steering committees and working groups, there may be a need for short term project funding to support immediate strategy development and implementation needs. These needs or gaps and barriers may include the lack of:

- Information on the issue, its status and the potential solutions
- Resources to develop and organize a strategy
- Communication and information resources
- Measurement and tracking of success.

In order to address these gaps and barriers, proposals for projects that address them are accepted on a continual basis throughout the year. These projects are limited to a maximum budget of \$25,000 (GST included), and must be completed by March 31 of the current fiscal year (April to March). Proposals may be submitted by steering committee and working group members (including growers, grower groups and associations, private consultants, researchers and extension specialists).

The 2009 Canadian implementation projects are provided in the Table 3 as an example.

Table 3. Canadian biopesticide implementation projects 2009

Project Code	Project Title	Crop
BPI09-010	<u>Management of lowbush blueberry insect pest (blueberry maggot) with biopesticides</u>	blueberry
BPI09-020	<u>Management of onion thrips with biopesticides</u>	onion
BPI09-030	<u>Management of downy mildew on cucumber with biopesticides</u>	cucumbre
BPI09-040	<u>Efficacy evaluation of the formulated biocontrol strain <i>Clonostachys rosea</i> strain ACM941 for the management of Fusarium Head Blight in wheat</u>	wheat
BPI09-050	<u>Formulation of <i>C. rosea</i> biocontrol agent for efficacy against fusarium disease in wheat and soybean</u>	wheat
BPI09-060	<u>Evaluation of biopesticides for apple scab management in Canada</u>	apple
BPI09-070	<u>Biological control of fusarium root rot and seedling blight of soybean in Ontario</u>	soybean
BPI09-080	<u>Evaluation of biofungicides for management of powdery and downy mildew in grape production</u>	grape

b) Biopesticides

The PMC works closely with the PMRA, the biocontrol industry, grower representatives, and international experts to facilitate the use of biological control products.

To improve access to, and promote adoption of biopesticides by Canadian growers, the PMC:

- Supports projects to facilitate the development of biopesticides and their integration into sustainable pest management systems (see Table 4 for 2009 project list).
- Consults with stakeholders to identify biopesticides priorities.
- Provides regulatory support to priority biopesticides (see below).
- Encourages biopesticides companies worldwide to register their products in Canada.
- Provides advice to biopesticides researchers and industry representatives on scientific and regulatory questions.
- Shares information on new biocontrol tools with growers, researchers and other stakeholders to encourage implementation (see below) .
- Participates in Health Canada working groups to help streamline regulatory efforts.

- Providing advice on regulatory and scientific questions related to biopesticides registration/commercialisation
- Conducting literature surveys and writing scientific rationales to support registration submissions,
- Providing support for supplementary efficacy trials.
- Assisting in assembling and submitting the registration package.

The PMRA has streamlined the registration process for biopesticides to increase their availability in Canada. As part of this initiative, the Agency offers a reduced fee structure for certain biopesticide submissions, and has shortened review timelines for these products.

Since the initiation of biopesticides regulatory support work, the Pesticide Risk Reduction Program has successfully worked with the registrants of the products in Table 4 to facilitate registration submissions to the federal regulator. Many of these products were submitted or registered for the first time in Canada, and the products in Table 4 represent well over 200 new uses. The Pesticide Risk Reduction Program continues to work with growers, researchers and registrants to help make available innovative new products for priority pest issues.

The PMC is committed to improving the access of growers to low-risk, environmentally sustainable and economically competitive pest control tools and practices, including biopesticides.

For the purpose of the PMC's work, biopesticides and other non-conventional pesticides are grouped into the following categories:

- Microbials (relevant [PMRA directive: DIR2001-02](#)): A microorganism (bacteria, alga, fungus, protozoan, virus, mycoplasma or rickettsia and related organisms) and any associated metabolites to which the effects of pest control are attributed.
- Semiochemicals (relevant [PMRA directive: PRO2002-02](#)): A semiochemical is a message-bearing substance produced by a plant or animal, or a functionally identical synthetic analogue of that substance, which evokes a behavioural response in individuals of the same or other species; some examples of semiochemicals are allomonones, kairomones, pheromones, and synomones.

- Biochemicals (excluding semiochemicals; relevant [PMRA directive: PRO2007-02](#)): Biochemical pesticides are naturally occurring substances, derived from naturally-occurring substances by simple processing, or functionally identical synthetic analogues thereof. Biochemicals include natural plant and insect regulators, naturally occurring pest repellents and attractants, enzymes, and certain essential oils and plant extracts. Not included in this category are naturally occurring pesticides which are inherently toxic and as such would be reviewed by PMRA based on requirements and timelines for a conventional pesticide.
- Other non-conventional pest control products (relevant [PMRA directive: PRO2007-02](#)): Other non-conventional pesticides are substances not covered by the above categories which meet some or all of the following criteria: (i) low inherent toxicity to non-target organisms, (ii) low persistence in the environment, (iii) non-toxic mode of action, (iv) low likelihood of pest resistance, and (v) long history of equivalent exposure to humans and the environment with minimal toxicity. Included in this category are common food and feed stuffs, food grade or non-food grade commodity chemicals, and certain mechanically processed natural minerals.

Table 4. New biopesticide products submitted under the Pesticide Risk Reduction Program in Canada, 2009.

Product	Active Ingredient	Registered	Submitted	Phase #	Significant support	Date registered	Date submitted
Agriphage	bacteriophages	FALSE	TRUE	1	TRUE		31-Mar-09
BioSave 10LP	Pseudomonas syringae ESC10	TRUE	TRUE	1	TRUE	29-Jul-10	27-Mar-08
BlightBan A506	Pseudomonas fluorescens A506	TRUE	TRUE	1	TRUE	07-Jul-09	16-Feb-07
BlightBan C9-1	Pantoea agglomerans C9-1	TRUE	TRUE	1	TRUE	01-Aug-06	01-Jan-05
BloomTime	Pantoea agglomerans E325	TRUE	TRUE	1	FALSE	01-Sep-06	01-Jan-05
Botanigard 22WP	Beauveria bassiana GHA	TRUE	TRUE	1	TRUE	23-Jun-09	08-Mar-06
Botanigard ES	Beauveria bassiana GHA	TRUE	TRUE	1	TRUE	23-Jun-09	08-Mar-06
Contans WG	Conithyrium minitans	TRUE	TRUE	1	TRUE	20-May-09	11-Jun-07
Met-52	Metarhizium anisopliae F52	TRUE	TRUE	1	TRUE	06-Feb-09	30-Jun-06
Prestop	Gliocladium catenulatum	TRUE	TRUE	1	TRUE	01-May-08	15-Mar-06
Rhapsody	Bacillus subtilis QST 713	TRUE	TRUE	1	FALSE	01-Aug-07	01-Jan-05
Root Shield Granules	Trichoderma harzianum Rifai strain KRL-AG2	TRUE	TRUE	1	TRUE	23-Dec-09	01-Sep-06
RootShield HC	Trichoderma harzianum Rifai strain KRL-AG2	TRUE	TRUE	1	TRUE	23-Dec-09	10-Apr-06
Serenade Max	Bacillus subtilis QST 713	TRUE	TRUE	1	FALSE	01-Apr-08	01-Jan-06
Serenade Max	Bacillus subtilis QST 713	TRUE	TRUE	2	TRUE	19-May-09	
Timorex Gold	Tea tree oil	FALSE	TRUE	1	TRUE		23-Apr-09
Surround WP Crop Protectant	kaolin clay	TRUE	TRUE	1	TRUE	14-Oct-08	31-Mar-08
Heads Up Plant Protectant	Saponins of Chenopodium quinoa	FALSE	TRUE	1	TRUE		30-Apr-09
Regalia MAX	Giant knotweed extract	FALSE	TRUE	1	TRUE		07-Jul-09
GF-120	spinosad	TRUE	TRUE	1	TRUE	03-Jun-09	16-Apr-08
Milstop	Potassium bicarbonate	TRUE	TRUE	1	TRUE	30-Sep-08	

Table 5. Summary of regulatory support work by the PMRA.

Product	Information / Regulatory status
Agriphage	Status in Pest Management Regulatory Agency (PMRA) public registry
BioSave	Status in PMRA public registry
BlightBan A506	Pest Management Newsletter 02/09, Status in PMRA public registry
BlightBan C9-1	Pest Management Centre (PMC) fact sheet, Status in PMRA public registry
BloomTime	PMC fact sheet, Status in PMRA public registry
Botanigard 22WP	Pest Management Newsletter 02/09, Status in PMRA public registry
Botanigard ES	Pest Management Newsletter 02/09, Status in PMRA public registry
Contans WG	Pest Management Newsletter 02/09, Status in PMRA public registry
GF-120	Status in PMRA public registry
Heads Up Plant Protectant	Status in PMRA public registry
Met-52	Pest Management Newsletter 02/09, Status in PMRA public registry
Milstop	Status in PMRA public registry
Prestop	Status in PMRA public registry
Regalia MAX	Status in PMRA public registry
Rhapsody	Status in PMRA public registry
Root Shield Granules	Status in PMRA public registry
RootShield HC	Status in PMRA public registry
Serenade Max	Status in PMRA public registry
Surround WP Crop Protectant	Status in PMRA public registry
Timorex Gold	Status in PMRA public registry

c) Pesticide risk-reduction strategies

Stakeholders including growers, grower organizations, researchers, extension specialists and others are working in collaboration with the PMC and PMRA, to develop and implement pesticide risk reduction strategies. A pesticide risk reduction strategy is a detailed plan to reduce the risk to human health and the environment associated with pesticide use in agricultural crops. A pesticide risk reduction strategy identifies gaps and barriers in current pest management approaches, defines realistic and measurable goals to bridge these gaps, and specifies the expertise, actions and resources required to achieve these goals. The objective is to develop risk reduction strategies that are economically sound for the grower, beneficial for the environment and have the greatest potential for grower implementation.

Priorities for strategy development are set within the context of the information gathered in national crop profiles, which have been developed for many of the important crops in Canada. Crop profiles document production issues and availability of pest management approaches, and provide the foundation for stakeholder consultations and priority selection.

Through consultations, pest management issues have been identified by stakeholders for a number of crops. While all of these issues are important to growers and government, some provide a greater opportunity for pesticide risk reduction than others when viewed through the lens of pesticide risk. Pesticide risk reduction strategies selected for development are based on identified pest management issues that demonstrate a significant opportunity for pesticide risk reduction.

Program priorities are reviewed annually as new information becomes available. A number of factors are taken into consideration when selecting priorities for action by the program, such as:

- Pesticide risk (pesticide use data, integrated pest management adoption data, risk indicators, environment and health information, product re-evaluation, stakeholder information and recommendation)
- Potential for pesticide risk reduction (availability of reduced risk solutions, stakeholder interest, involvement and willingness)

Many of the pesticide risk reduction strategies being developed under the leadership of AAFC support and complement [transition strategies](#) being developed by the PMRA.

The strategy process involves:

- Engaging stakeholders (establishing a steering committee and/or working groups)
- Setting goals and targets
- Identifying potential solutions/actions (research, extension, education and regulatory support)
- Implementing identified solutions (through research and demonstration projects, outreach, and regulatory activities)
- Establishing performance indicators and measuring success
- Additional information about the process of strategy development under the Pesticide Risk Reduction program can be found on the PMRA website.

d) Crop profiles

Crop profiles are documents that provide crop production and pest management information on a commodity basis. National in scope, they identify gaps in pest management and issues faced by Canadian growers.

The baseline information provided in crop profiles supports the development of pesticide risk reduction strategies as well as the regulatory work of the PMRA. They are a source of current pest management information for AAFC, PMRA, Provinces, industry, growers and grower organizations.

Note that growers are encouraged to consult Provincial crop production guides for detailed information on pest management in their regions.

Crop profiles are developed through an extensive consultative process and are reviewed by industry and provincial specialists prior to publication.

3. PMC: Advisory and Technical Committees

a. PMC Advisory Committee

The PMC consults with a variety of stakeholder organizations through an Advisory Committee that includes representatives from farm and commodity groups, the pest control industry and other groups. It provides AAFC with broad, strategic advice to support the program's goals, and on specific topics such as operational policies and program criteria, approaches to reducing risk, emerging issues, communications activities, leveraging funds, and research needs. The committee is a valuable vehicle to report progress and results to interested stakeholder groups.

b. Minor Use Pesticides Technical Working Group

The Minor Use Pesticides Technical Working Group reports to the PMC Advisory Committee. The group includes representation from growers, pesticide manufacturers and Provincial minor use coordinators. The group provides advice to the Minor Use Pesticides Program on a variety of issues, such as the process used for identifying minor use priorities, protocol development, the drafting of registration submissions, submission mechanics, as well as collaborative projects with companies and with the U.S. IR-4 Minor Use program.

c. Pesticide Risk Reduction Technical Working Group

The Pesticide Risk Reduction Technical Working Group includes representation from provincial governments, other Government of Canada departments, non-governmental organizations, grower associations and commodity group representatives. The group reviews the activities of the Pesticide Risk Reduction Program and provides advice and technical assistance on a variety of issues, such as crop priorities, crop profile development, data collection and IPM adoption.

The group also serves as a means of communication to stakeholders at a regional level and many of the members of the group participate in other working groups and subcommittees involved in the development of risk reduction strategies. The group meets face-to-face once a year in March and conducts other meetings via telephone conference calls throughout the year.

Appendix 6. ABS summary of area of production and number of businesses in horticulture, 2008/09.

Horticultural commodity	Area (ha)	No. agric. businesses
Area of land mainly used for agriculture	33,440,559	71,988
Nursery	5,211	1,985
Cutflowers	5,335	1,083
Vegetables for seed	9,221	930
Vegetables for human consumption	114,982	5,832
All fruit incl. grapes	352,043	16,646
Orchard fruit and nut trees	149,963	8,568

Appendix 7. ABARE summary of value of agricultural production, 2009/10.

Commodity	Value of production 2009/10 (\$mn)	Industry ranking based on value of production
Meat	13,024.6	1
Grains	9,286.7	2
Horticulture	7,921.1	3
Milk	3,365.4	4
Wool	2,109.8	5
Sugar	1,504.8	6
Cotton	876.1	7
Wine grapes	711	8