Review of pesticide investment in the vegetable industry

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Project Number: VG12105

VG12105

This report is published by Horticulture Australia Ltd to pass on information concerning horticultural research and development undertaken for the vegetables industry.

The research contained in this report was funded by Horticulture Australia Ltd with the financial support of the vegetables industry.

ISBN 0 7341 3204 2

Published and distributed by:
Horticulture Australia Ltd
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179 Elizabeth Street
Sydney NSW 2000
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Horticulture Australia

Project Number	**VG12105 (September 2013)**
Project Title	**Review of pesticide investment in the vegetable industry**
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Research Provider	**Scholefield Robinson Horticultural Services Pty Ltd**

VG12105 - Review of pesticide investment in the vegetable industry –

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September 2013

This project has been funded by HAL using the vegetable industry levy and matched funds from the Australian Government.

Purpose of Report:

This review has revealed a complex but functional Minor Use system in place for vegetables. It has multiple stakeholders and relies on the industry-government partnership for funding. Many industry stakeholders are not aware of how the system operates and how their input to it could improve timeframes and responsiveness to industry needs. Registrants find insufficient commercial incentives in the process to drive regular participation, but national regulatory incentives that offer value to registrants have been identified. The minor use programme requires significant funds for management and data generation and the recommended introduction of a formal prioritisation process will allow investment on industry's behalf to be more objective. Increased engagement, industry ownership, communication, prioritisation, refined timelines and incentives the minor use programme could become streamlined and more cost-effective.

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GLOSSARY

APVMA	Australian Pesticides & Veterinary Medicines Authority
AUSVEG	Peak industry body representing the vegetable industry
CCPR	Codex Committee on Pesticide Residues
CODEX	CODEX alimentarius (international food standards, guidelines and codes of practice)
CRDC	Cotton Research and Development Corporation
DAFF	Department of Agriculture, Fisheries and Forestry
FSANZ	Food Standards Australia New Zealand
GLP	Good Laboratory Practices
GRDC	Grains Research and Development Corporation
HAL	Horticulture Australia Ltd
IAC	Industry Advisory Committee
IPM	Integrated Pest Management
IR-4	Inter-regional Project #4
JMPR	Joint Meeting on Pesticide Residues
MRL	Maximum Residue Limit
MU	Minor Use
MUP	Minor Use Program (Canada)
NAFTA	North American Free Trade Agreement
OECD	Organisation for Economic Co-operation and Development
PMUC	Pesticide Minor Use Coordinator (HAL project)
R&D	Research and development
RDC	Research and Development Corporation
SARP	Strategic Agrochemical Review Process
US-EPA	United States – Environmental Protection Agency
VTAG	Vegetable Technical Advisory Group

MEDIA SUMMARY

Vegetable producers are aware of the small range of crop protection products and herbicides products available to them for efficient crop production. Many are aware that to achieve a wider range of products through permits or label extensions, passage through an expensive, time-consuming and complex minor use programme, is necessary. In the foreseeable future, no alternative programme is likely and it is presumed that the vegetable industry will continue to direct levy funds to it.

The review has considered system improvements and the potential for better informing and streamlining the system, increasing industry ownership of it and formalising the investment decision-making steps.

A revised compartmentalised minor use system would see:

- the vegetable industry appoint an AUSVEG minor use leader with responsibility for:
  - Industry requests prioritisation process
  - Industry education and engagement
  - Communication

- Horticulture Australia Limited (HAL) manage:
  - Data acquisition and generation
  - Submissions and permit management
  - Strategic and tactical development

More specifically the recommendations include:

- A formal prioritisation process and Prioritisation Workshop
- Five defined, levy-funded projects
- Increased industry education and engagement
- Tighter timelines and consequences
- Revised key roles
- Structured decision-making
- Required communication and feedback loops
- Required consultation with registrants and the national regulator, APVMA
- Increased strategic awareness in prioritisation and funding
- Investment in resistance management

Recommendations relevant to the national regulator are also made.

TECHNICAL SUMMARY

The minor use programme is Australia is functional and providing benefit to many growers of minor vegetable crops. Sustainable vegetable production relies upon the continued availability of safe, efficient and cost-effective products that ensure the supply of a volume, diversity and quality of produce, that consumers demand. The minor use programme does not however have an 'end point' as the market failure for access to chemical crop protection products for use on minor crops, is unlikely to diminish.

This review considered limitations in the current programme and has recommended revised and new steps for the system. Until a national minor use system is developed, it is recommended that the current vegetable minor use system be revised to address industry ownership, engagement of stakeholders, informed participation, strategic awareness and responsiveness, goal-focussed and structured decision-making, and documented consultation. Registrant disincentives were identified, international schemes reviewed, and potential incentives for consideration by the regulator, are discussed.

The implications of some limitations in the current vegetable minor use programme are:

- Industry engagement and ownership is minimal
- Third parties, rather than end users drive the programme
- Renewals maintenance is a focus rather than introductions of newer, softer chemistry
- Reliance on old generic chemistry is on-going
- Tactical rather than strategic decision-making
- Registrants are neither fully utilised nor engaged, due to commercial realities
- Limited registrant and cross-industry co-funding

Key activities to drive process awareness and outputs are recommended. The appointment of an AUSVEG Minor Use leader would give industry stakeholders and Horticulture Australia Limited (HAL) a much-needed central contact point. Two key responsibilities of this position are recommended: the development and implementation of an education campaign and the introduction of a formal industry request prioritisation process. The nationally prioritised list of researchable projects with industry, regulator and registrant approval would become the starting point for the HAL data generation and permit management project, each year. Industry funding would be allocated after formal agreement on industry goals and a structured decision-making process.

Other HAL projects required within the minor use scheme would continue to be those focussed on desktop submission preparation and the holding of permits. A cross-industry strategic expert would have responsibility for updating the vegetable and other industry Strategic Agrochemical Review Process (SARPs) documents and informing both the prioritisation and funding processes with relevant input from other annual industry priority lists, the national regulator and international schemes and authorities.

Other recommendations for the revised process include:

- Requirements for registrant engagement and documented approval of proposed solutions
- Documentation of regulator consultation
- No acceptance of uninformed or unsupported pest solution requests, e.g. requests not accompanied by information and crop group (or other) endorsement
- Tighter timelines and consequences
- Tasks compartmentalised in five projects and revised key roles
- Funding considerations on emergency and formally-prioritised researchable projects
- Transparent funding decisions that reflect industry minor use goals, e.g., more low, risk proprietary chemistry
- Industry feedback requirements to justify continuation of permits (renewals)
- Increased commitment to resistance management initiatives

Immediate investment in stakeholder education, the appointment of the AUSVEG Minor Use leader, and a review of all existing vegetable permits, were recommended.

The review found the tendering processes within HAL to be suitable and effective. It has recommended that the regulator adopt new crop groupings and the 'representative crop' arrangements when international decisions are finalised. Co-funding projects with international schemes is recognised as being difficult and no authority exists, or is recommended to exist, for project leaders to commit funding in this area. It is suggested that engagement with New Zealand authorities by the regulator, could deliver more benefit.

Other recommendations relevant to the regulator, but considered as beneficial to the minor use process, are given:

- an APVMA minor use database open for stakeholder access
- fee incentives and priority fast tracks within APVMA and the scheduling of submission periods

1 INTRODUCTION

The vegetable industry is a collective of small disparate industries producing 50-60 different crops across Australia. Vegetable production is important to our communities and well-being, and economically as a provider of employment. Sustainable vegetable production relies upon the continued availability of safe, efficient and cost-effective products that ensure the supply of a volume, diversity and quality of produce, that consumers demand. End users, chemical registrants, regulatory authorities, service providers and researchers, are each invested in the array of programmes that interact to determine approved chemical use.

It is not surprising that in practice the individual components of the vegetable industry do not act or respond in concert, have the same product needs, or capacity and capabilities to evaluate pest management options, current and future resistance issues, or preparedness for emerging threats. The Horticulture Australia Limited (HAL) Minor Use programme facilitates for minor crop producers access to crop protection and herbicidal chemistry that would not otherwise be legally available to them. The HAL 'programme' includes various projects and service providers, and requires interaction with the national regulator, permit holders, vegetable and chemical industry representatives.

Before an agricultural pesticide (agrichemical) may legally be used or sold in Australia, the Agricultural Pesticides and Veterinary Medicine Authority (APVMA) must register it. A registered product has an official label that identifies the crops on which it may legally be used and the manner in which it may legally be applied. The data requirements in support of a registration (or permitted off-label use) are extensive and expensive to generate and collate.

Minor crops, new and emerging crops, and genetically modified crops do not often meet, in terms of acreage or volume of use, the expectations of manufacturers on likely financial returns on investment in product registration. There are numerous horticultural crops including vegetables, tree fruit and nuts, grown across Australia, but the acreage of each is fragmented and widely distributed, and small in total when compared to broad acre grain acreage. As a result horticulturists, despite their more extensive range of problem weeds, pests and diseases, have a limited range of registered, effective crop protection products to access. In addition, horticultural produce is often consumed fresh and its quality and safety are critical to meeting consumer expectations.

Added to these challenges for fresh vegetable and fruit producers, is the loss of once-approved chemicals. Some chemicals have been removed from the APVMA-approved lists after reviews; others have lost efficacy due to the development of resistance to them by the target pest. Others have voluntarily been replaced by newer chemistry. In general, strategic review and proactive awareness of pesticide status and needs have not been extensive in the Australian vegetable industries.

A minor use programme in some form will, for the foreseeable future, be necessary and it is presumed that the vegetable industry will continue to service its stakeholders, through direction of levy funds to it. There is no indication of diminished support for its existence, or demand for approved minor uses, under current legislation. The market failure in access to crop protection products for minor crops will continue nationally. It is important to highlight that the issuance of permits was not designed to "fix minor use". The original aim was to overcome a short-term need that today is reflected only in the emergency permits issued. Vegetable grower reliance on permits is an unintended outcome of the minor use projects and chemical use approval system, but it is noted that the Victorian legislation, were it to be applied nationally, would greatly reduce the number of permits needed. The broader implications of this state's liberal approval of off-label access to chemistry however are not necessarily desirable or advocated, but they are drivers in the system and growers in all states recognise their influence.

Recently proposed regulatory and APVMA cost-recovery reforms are likely to have a negative impact on all minor use programme costs and timeframes, and on minor crop industries that could lose access to generic chemistry not subjected to 5-7 year reviews.

The progress since 2000 from uncoordinated grower wish lists and APVMA log jams, to the more strategic process implemented and driven by Horticulture Australia Limited (HAL), today is to be commended.

2 MATERIALS AND METHODS

This review by Scholefield Robinson has been structured around the provided Brief (Appendix 1). It has required extensive consultation with stakeholders and informants of each step in the current minor use process. The consultation list is included in Appendix 2. The review has considered current weaknesses and the potential for streamlining the system, increasing the industry 'ownership' within the system, and formalising the investment decision-making steps. The minor use 'system' (or programme) incorporates a wide range of stakeholders, jurisdictions and authorities, HAL projects and personnel.

2.1 Review – Minor Use outputs

In Australia, there is no single national programme with capacity to deliver crop protection options to all plant industries that require minor use approvals. The horticulture minor use system is complex and costly. It is primarily managed as a number of HAL projects, in which the majority of beneficiaries appear not to be fully engaged.

The current horticulture minor use projects and activities are the mechanism by which effective crop management products that do not negatively impact on the environment or human health, are approved for legal use on minor crops (and minor use on major crops), including vegetables.

The outputs of the HAL minor use projects include:

- *Label extensions* – registered product label may be amended to include a new use pattern, new crop or changed withholding period. Additional data is needed to support such changes. The APVMA advises applicants on data requirements for registrations and permits.
- *New permits* - data requirements for efficacy, crop and food safety may be sourced from overseas to support the initial request. Data submitted for permits is not 'protected' (retained for exclusive use). Local residue trials must be undertaken for the specific use pattern to support permit renewals. Some new permits are issued in direct response to an 'emergency'.
- *Renewed existing permits* – permits have a finite life, but may be renewed with some additional data supplied from data generation trials, manufacturers, desktop research or via APVMA. The approval is officially a 'new' permit, but it is often referred to as a 'renewal'.
- *New chemistry registration* – new chemistry is rarely introduced via HAL minor use projects. Registrants make such submissions with data protection for 5-10 years afforded. Rarely are minor crops included on new chemistry label submissions. Efficacy and crop safety data may be developed 'in house' by the manufacturer but residue data must be carried out on target crops by independent service providers and accredited laboratories, under Good Laboratory Practices (GLP).

2.2 *Review - Steps within t*he current minor use vegetable projects

The vegetable industry is the major funding contributor to the horticulture minor use programme. The project MT10029 *Managing pesticide access in horticulture* is funded by HAL using the vegetable industry levy and across industry funds with matched funds from the Australian government. This project at present has a principle investigator contracted to coordinate aspects of the HAL minor use programme. The project leader is often referred to as the Pesticide Minor Use Co-ordinator (PMUC). The composition of contributions at present to the primary minor use project is: 50% vegetable levy and 50% across industry funds (all matched). Other related minor use projects are also contracted by HAL to carry out specific aspects of the programme, e.g. permit holder and data generation.

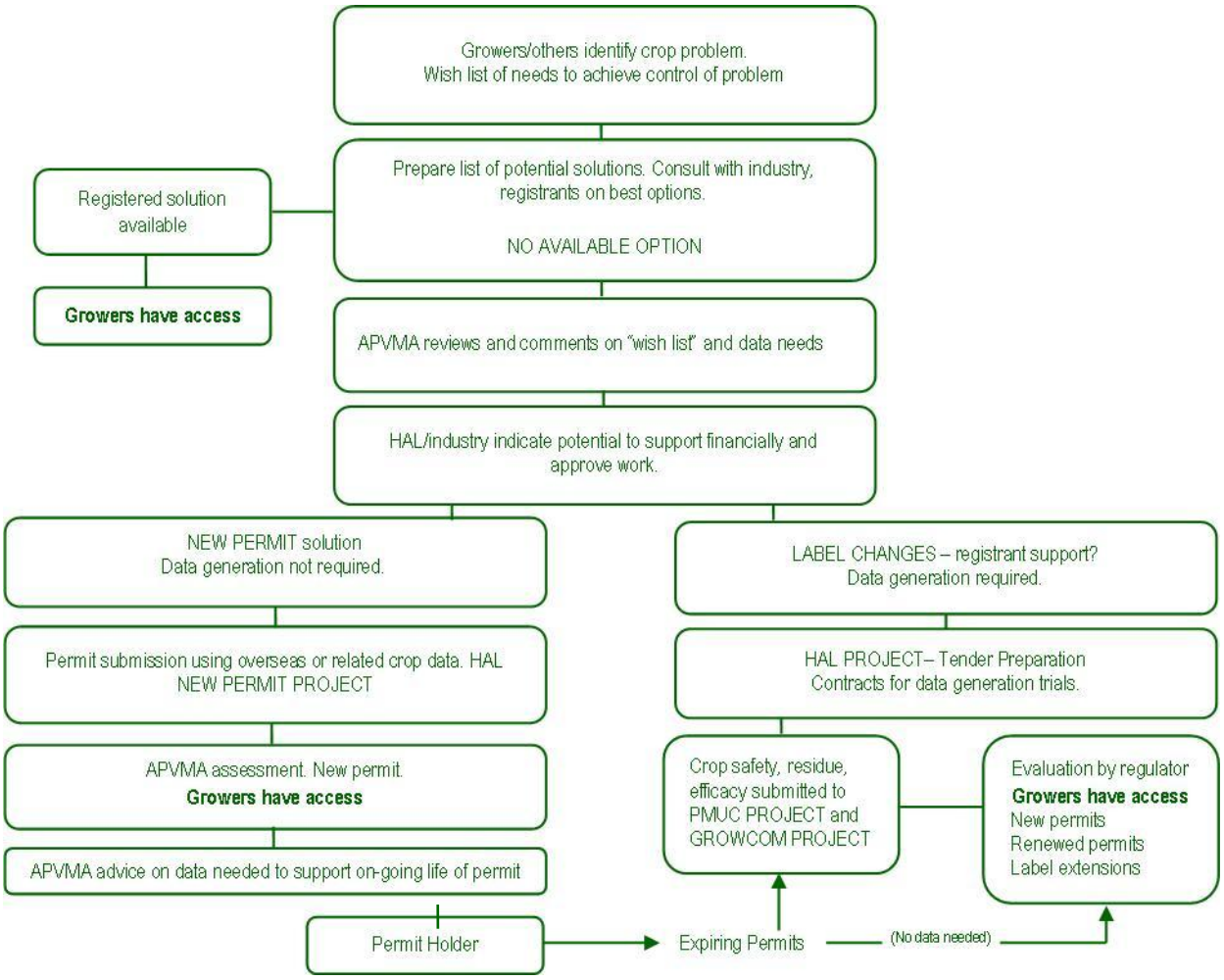
Various steps in the HAL minor use projects are managed and overseen by individuals contracted by HAL. Other important participants are the State governments, the APVMA as the national regulator, and registrants. Technical input is variously sourced from end users, consultants, product manufacturers and registrants, researchers and crop specialists, and international chemical committees and programmes.

The general steps in the project MT10029 *Managing pesticide access in horticulture*, as understood, are shown in Figure 1. This simplified structure of the project identifies key steps, rather than relationships and assigned responsibilities that inform them.

The general steps toward minor use access, regardless of the intended output, require contributions on:

- Crop problem
- Solution alternatives
- Packaged data in support
- Regulatory assessment
- Regulatory approval

Figure 1 : General steps in the current Minor Use system



The on-going and specific actions within the MT10029 project as documented by the contracted project leader (PMUC), relate to many crops. The main steps are identified in Tables 1-5.

Although the steps and activities are those largely of this service provider, it is noted that each minor use project step has:

- Requirements for input from stakeholders
- More than one invested and interested party
- Activities that inform and underpin future steps, outcomes and timeframes
- Different costs and contributors
- Requirements for third party and/or industry decisions

Table 1 : Activity informing the current MT10029 project steps

On-going steps	Informing data/activity/evidence
Crop protection solutions and needs awareness	SARPs updating by industry Reference group input International consultation Registrant consultation
Solution status and programme awareness	Project monitoring On-going status checks by project leader PMUC Database updates, copies distributed to HAL Awareness - strategies, technologies in pest management Correspondence - Notifications – requested, new, expiring, renewed, retired permits - Requests, permit consolidations - Industry due diligence - Industry feedback on use, need Industry, APVMA, HAL regular contact HAL Milestone and Final reports

Several of the HAL minor use projects relevant to the vegetable industry reflect efforts since year 2000 to increase strategic input, transparency and registrant engagement in minor use. The APVMA similarly has increased its contact with industry via the MT10029 project. HAL project MT10029 includes a strategic agrochemical review process (SARP) for each vegetable commodity group. In theory, each SARP document is informed by relevant industry input, and identifies endemic threats to production, and solutions and technologies effective against them.

In practice, the industry input to inform the SARPs has not always been timely or sufficiently specific and finalisation of SARPs has not been consistently achieved. SARP preparation and finalisation are critical to the minor use system and they demand tactical and strategic input, awareness of industry practices, pest threats and regional differences.

Efficacious solutions that are/are not suitable to address an identified vegetable industry problem are noted in SARPs as are problems that do not have a known solution. Solutions that need to be legalised for their use on vegetables become entries on the industry's 'wish list' for new access. The route taken thereafter depends on the availability of suitable data to support the request – be it for another use on an existing label, a new use addressed by a permit, or an emergency use.

The MT10029 project leader (PMUC), with the benefit of registrant and APVMA advice, decides on the solutions that could meet industry needs. These are presented to industry representatives for approval. Consultation with APVMA identifies the data gaps and requirements to support the requested off-label uses. Data requirements vary for different host crops, products of different nature, prior registration or permitted status, as will be discussed in more detail. The background data available on requests and proposed solutions is captured and ultimately packaged for the service providers contracted for data generation trials.

Table 2 : Informing steps in current determination of an off-label need

Process steps/action	Informing data/activity
Identified crop problem	Requests made by any party Completed New Permit Questionnaire (NPQ) Reference group input SARPs
HAL database includes requests	MT10029 project leader (PMUC) input from NPQs
Solutions lists	APVMA discussion of proposed solutions with PMUC Permit holder clarified
HAL and industry review	Project costs estimated Funding availability from industry - via IAC
Approved pursuit of solutions for legal use	Industry approval of suggested projects

Table 3 : Informing steps toward a new desktop permit in current minor use projects

Solutions requiring new permit	
Data collated	Requests collated by active ingredient Data accessed by PMUC from local R&D, registrants, APVMA, international public domain Registrants support sought
Submission of data in support	Tendering (Table 4) for submission preparation DESKTOP PROJECT (Growcom from 2013; other consultant) Data for submissions from PMUC, or sourced directly
Assessment by APVMA	Submissions accepted Contact with applicant (Growcom, as permit holder and approved vegetable industry contact)
Permit decision known	APVMA informs applicant of decision Applicant/Growcom advises HAL, PMUC New permit issued Key industry reps, VTAG, AUSVEG informed in 1-3 days by PMUC of new permit Project leaders advise re-sellers, wider industry
Data generation obligations known	APVMA advises applicant of data needed in next 2-3 years Industry reps sent data generation requirements (Permit renewal – Table 5)

Table 4 : Informing steps towards label extensions in the current minor use projects

Solution requiring change to existing product label	
Local data gaps known	APVMA-agreed trial number, crops and locations PMUC advises industry reps Consultation with registrant re financial support, data
Researchable projects approved	PMUC estimates project costs VTAG review
Tender preparation	Same pesticides grouped for tendering PMUC provides list of approved data generation and desktop projects HAL drafts tenders from PMUC information PMUC reviews draft tenders HAL releases tenders to GLP-accredited service providers Background data collated by PMUC
Service providers approved	HAL review quotes from service providers HAL recommends service providers Service providers approved by sub-committee of IAC Service providers contracted by HAL through HAL projects
Data generation trials	Service providers receive background data from PMUC (original request, existing permits and available data) Service providers seek and generate new data in support Service provider project status monitored; milestone, final reports Confidential GLP data sent to HAL only (and registrant if co-funded) GLP data summaries to PMUC, APVMA, and in HAL reports
APVMA assessment and decisions	APVMA discussions with applicant only APVMA alerts applicant of outcome* *Note: if *unsuccessful, path to resolution is not defined* Project leader advises commodity industry via key contacts, VTAG HAL database updated Project leader advises re-sellers, wider industry

Table 5 : Informing steps toward permit renewal in the current minor use projects

Solution requiring permit renewal	
Permit expiring within 12 months	PMUC alerts industry of expiries within 12 months *For industry-held permits, Growcom alerts PMUC and HAL of forth-coming expirations so they could be transfered into project system* Permit holder alerted by APVMA – 3 months before expiration of permits
Industry support for renewal	PMUC distributes due diligence forms on adverse experiences, use, efficacy to industry reference groups HAL distributes forms to VTAG VTAG comments consolidated by HAL, forwarded to PMUC Growcom sees industry feedback APVMA advised of feedback HAL (with PMUC) approve 'go-ahead' based on feedback o No feedback – assumed permit need, effectiveness
Permit data – a) no data needed	No data necesary – HAL approves Growcom action (as 2013 contracted project leader for desktops) Growcom recevies old data, original permit details from PMUC Growcom prepares submissions Growcom submits 'straight' renewals to APVMA (unless collated)
Permit data – b) data needed Permit data – c) lack of required data	Data generated over 2-3 years (for renewals and data generation projects) Service providers prepare submissions with generated data PMUC approves data generation reports before Growcom *Data needed - but little/none generated* *APVMA advised*
Consolidated permit renewals	Permit submissions consolidated
Renewal submissions	Growcom submits packages 3 months before expiry
APVMA extensions	Renewals lacking data can request extensions
Awareness of renewal status	APVMA communicates with applicant/permit holder Outcome is reported to PMUC HAL database updated

2.3 Review - Current roles and responsibilities

The duties carried out by current 'main players' in the vegetable minor use system are described below, and in Tables 1-5. Confidential HAL documents outline more specific tasks that are known to the contracted project leaders and service providers. This review has allowed consideration of the roles and responsibilities with evidence of fulfilment, rather than those contracted and left unattended.

2.3.1 Horticulture Australia Limited (HAL)

With advice from the Vegetable Industry Advisory Committee (IAC) and the Vegetable Technical Advisory Committee (VTAG), HAL tenders, reviews and contracts research and development (R&D) required to populate the minor use submissions. Two full-time HAL employees have direct roles in managing the HAL minor use projects – Industry Services Manager (Mr W Gordon) and Portfolio Manager-IPM & Chemicals (Ms J Pedrana).

HAL's roles include:

- Management of multiple specific projects (MT10029, permit holder, data generation and desktop projects), one cross-industry project and several related crop protection and integrated pest management (IPM) projects and cross-industry pest resistance projects.
    - Tender preparation and evaluation
    - Allocation of project funding
    - Time and resource investment in project oversight
    - Accountability of projects and service providers through required reporting, communication and database managed on HAL's behalf.

The 2012-13, the data generation budget for minor use in vegetables was approximately $1million, with the costs of each trial (and submission) varying from approximately $7,000 (efficacy, crop safety, minimum 2 trials/crop) to $8,000 for GLP residue trials of which 2-4 are needed for each crop. Permit submission preparations cost in total approximately $2,000 with the fee of the regulator ($350) also included.

2.3.2 HAL PMUC Project MT10029

The leader of HAL project MT10029 has a national role that encompasses many duties and responsibilities. Some are included in Table 1-5. The goal of the contracted project leader, referred to as the pesticide minor use coordinator (PMUC), is to:

- Deliver appropriate minor use permits and label outcomes that meet industry needs, in a timely and cost efficient manner

Implicit in this are requirements for the PMUC to maintain awareness of:

- New, effective crop protection products and technologies
- Industry threats, needs, solutions, data and knowledge gaps
- Status of products in the minor use system at various stages
- The effectiveness, suitability and use of products delivered as outputs
- Mechanisms to drive efficiencies in the minor use system

To fulfil these requirements it is apparent that the PMUC needs to:

- Have/develop extensive networks and relationships
- Consult registrants, the regulator, technical experts, crop experts, international minor use schemes
- Communicate regularly with HAL, commodity and wider industry, the regulator, other industries with minor use access needs
- Base decisions on strategic and tactical input and awareness
- Provide input to project tasks and service provider selections
- Understand and convey legislative, regulatory reforms and changes that affect product use and trade

- Consolidate permit requests and renewals, ensure compete data packages, seek co-investment opportunities
- Facilitate the pursuit of registrations for newer chemistry with registrants
- Serve as the horticulture minor use project focal point and main resource
- Keep industry stakeholders informed – due diligence
- Keep extensive records - all requests, solutions, data generation outputs, regulatory approvals e.g. HAL database

It has been confirmed that the PMUC has extensive and specific tasks in strategic reviews (SARPs), communication with industry, regulator and registrants, product awareness, data packaging, tender submission development, data generation and submission collation, outcome advice to industry via a representative group, database maintenance (Tables 1-5) and international global reviews and regulatory engagement. To successfully carry out the PMUC role, cooperation and timely engagement with many other stakeholders has therefore been essential. Direct contact of the PMUC with the APVMA, registrants, permit holder, industries undertaking SARP reviews, HAL and some data generators, has been confirmed. Attendance at international inter-regional project 4 (IR-4) meetings has been confirmed. AUSVEG and the PMUC in recent years have had limited direct communication, with HAL required to be the conduit at times.

The PMUC reports directly to HAL through milestone and final reports, and indirectly to the vegetable industry via Vegetable Technical Advisory Group (VTAG) and HAL.

2.3.3 Growcom

Growcom has roles:

- as the vegetable industry 'approved person' and official holder of vegetable permits on behalf of the vegetable industry
- in preparation of some new permits and renewals.

As the permit holder Growcom incurs a legal responsibility, but it is well-compensated for this. In addition to this role, but separated from it, Growcom has sometimes been contracted by HAL for the desktop preparation of some new permits and renewal submissions.

Under instructions from the APVMA and HAL, the PMUC and Growcom have consolidated permits for renewal. This has delivered some minor cost savings, but there appears to be potential for more. Permits have a finite life and in recent years, permit renewals have far outnumbered new permit or label extension requests.

The APVMA alerts the permit holder of expiry dates within the forth-coming three months, but prior to that, the PMUC alerts industry to expirations due within the forth-coming 12 months. Based on industry feedback to due diligence forms, HAL approves Growcom to prepare renewal submissions. Industry input that would justify continued permit status without adjustment (i.e. changed use pattern, withholding period), verify the continued need for the permit, or its relative strategic benefit over other alternatives, has not always been documented.

APVMA receives submissions for renewals that required additional data, 3-5 months before expiry of the permit. Growcom is the permit holder and approved person (applicant) for vegetables and as such they make relevant submissions (after data review by the PMUC) and have direct contact with APVMA. Growcom, like other service providers are approved for some but not all, minor use submissions. Growcom was not the service provider for the 2013 vegetable desktop projects, but they remain a 'HAL minor use project leader' due to their other roles.

Growcom, like AgAware, also carries out some private consultancies in the same work. Growcom is a member of AUSVEG.

2.3.4 Service providers

Tenders for data generation to support label extensions and permits renewals, are developed by HAL with the assistance of information from the PMUC. Although registrant data on efficacy and crop safety are accepted by regulators, independent third parties must carry out residue trials under Good Laboratory Practices (GLP) to fill data gaps and establish a tolerance for the pesticide.

Independent service providers are contracted each year to:

- Undertake data generation field work in support of vegetable industries.

At present four independent contractors are usually assigned HAL vegetable data generation projects each year and this is likely to continue as a mechanism to maintain capacity in this area of expertise.

I am informed that successful service providers on contracting, approach the PMUC for background data relevant to the forth-coming trials, and they independently seek additional information. The information may include background on the original request and need, solution, existing status of the solution, data available, and registrant and/or APVMA input. Ideally the background information informed the tender document.

The contracted data generation service providers are an essential component of the minor use system and in my opinion they are also 'HAL minor use project leaders'. They find suitable sites and co-operators to satisfy the geographic spread and GLP requirements of field trials. To protect the confidential data generated, summaries are submitted with reports to the PMUC for review and for consolidation by PMUC and Growcom where appropriate. Growcom makes the submission to APVMA. The intellectual property is protected by HAL and HAL is the only recipient of the full data sets (other than registrants that have co-funded the work). Final reports comprise two documents - one containing a summary of GLP reports; the other, the full GLP reports that are not published.

HAL requires that minor use data generators:

- Prepare quotations for each trial
- Find appropriate trial sites
- Carry out the GLP trials as per the tender – use pattern, crops, harvest time, residue analysis (with accredited laboratory), geographical spread
- Prepare summaries of the confidential GLP residue data for submission packages
- Submit packages to the PMUC (or relevant contracted project leader) for review (with APVMA fee for renewals)
- Understand their reviewed submission is then forwarded to Growcom (renewals and data generation projects) before submission by them to APVMA
- Submit milestone and final reports to HAL.

Vegetable industries and AUSVEG

- Levied vegetable growers are the major contributors (with the Australian government) of funds to the HAL project MT10029 and to each of the HAL data generation vegetable projects*.
- Growers are the primary beneficiaries of each of the projects in the integrated minor use programme.

The vegetable industry is important financially to horticulture minor use programmes but in practice the vegetable industry is not an actively engaged participant. The returns on vegetable investment in minor use have not been specifically enumerated, but are assumed to be significant in terms of access to chemistry.

* Not all "vegetable industries" are levied or represented by the peak industry body AUSVEG. However all vegetable industries at times and regardless of their representation, have sought and carried out required activities to access off-label chemicals. In each case efforts have been funded via industry funds (levies or voluntary contributions) and the potential to share data, and resistance management efforts across all the vegetable industries, appears a worthwhile pursuit and worthy of further discussion. See Section 9.4.

2.3.5 Registrants and chemical manufacturers

- Production and development of crop protection chemistry
- Owners of products sought for minor use (solutions); product intellectual property (IP)
- Product stewardship leaders
- Programme participants at various levels – willing to reluctant
- Essential resource – chemistry advice, data-sharing, data generation, co-funding and financial assistance, international strategic awareness, in principle approval for pursuit of off label use

There are four main registrants in Australia that are investing in innovative technology and new crop protection chemistry in Australia – Dow, Bayer, DuPont, Syngenta, and resuming this role again in Australia is BASF/FMC. These companies, and also formulators and re-packers, have an important position in the minor use system, regardless of their stance on registration of their products for use on minor crops (or minor use in major crops). With legal applications of their products via registrations or minor use permits, the manufacturers and re-packers may gain economic returns but also liabilities.

The costs and time committed to generating, preparing and collating data packages for registration of products are substantial (Appendix 3). Registrants make investment decisions on active participation in the registration or minor use projects, on the basis of likely commercial returns. The nature and size of the targeted marketplace for each product, in addition to perceived risk associated with the product's use, therefore underpin most investment decisions. They also consider trade implications that may change the demand for their product.

Product use in minor crops is neither a strategic nor commercial imperative of manufacturers as the control of use in such markets is limited and as a result product (and environmental) stewardship becomes more complicated. Product use in vegetables has been identified as a disincentive for registrants to actively engage in the minor use projects, but their role in the minor use programme as a whole, remains a key one.

The majority of permits within the vegetable minor use projects approve use of generic chemistry - products with expired intellectual property (IP) that are packaged by numerous suppliers. The business models and drivers of local companies packaging generic products are quite different to those of multi-national manufacturers developing and marketing new chemistry. The latter are protective of their IP, data, budgets for development, and they have 5-7 year targets for returns on investment.

Registrants have roles also in identifying and/or approving solutions in response to industry needs. Several proactive registrants have focus groups that include growers and technical experts, through whom they learn of needs and opportunities. There is no obligation for registrants to provide financial support for permit pursuits for their products.

2.3.6 APVMA

APVMA has a legislated role as the national regulator of registered and minor uses of pesticides. It has been reported that the APVMA receives about 250 permit applications each year and also submissions in support of new labels and label extensions for a wide range of crops. In recent years, permit renewals have accounted for 40 percent of permit applications and 42 percent of

permit applications have been submitted on behalf of minor crop industries. Ninety percent of permit applications are for generic products and 85 percent of minor use applications require residue data to be developed in support.

In the current HAL MT10029 project, the APVMA is engaged by the PMUC to:

- Review requested solutions
- Consider appropriate solutions including new technologies, products, use patterns
- Provide data requirements for approved projects
- Consider timeframes and passage log jams in APVMA
- Review how data submitted can satisfy requirements – e.g. edited, improved, or retrofitted (not preferred)
- Provide advice on increasing permitted uses (permits) becoming registered uses (on labels).

In its legislated role, the APVMA is required to address and review all submissions. There is no priority/fast track, except for submissions identified as being for an emergency use. There is no apparent formal link of APVMA to the vegetable industries, yet the industry generally perceives APVMA is the cause of delays in the approval process for minor use permits. While log jams do account for some delays, it has been reported to me that most result from the submission of incomplete data, or late submissions that force a permit extension at short notice before its expiry.

The APVMA operations may change under the proposed legislative and cost-recovery reforms. The principle of 'user pays' will result in higher costs for submission reviews. Incomplete submissions will no longer be accepted into the system. The proposed review every 5-7 years of registered products is likely to affect vegetable crop alternatives, slow the whole approval process, and it may require increased investment by minor industries to support reviews of old chemistry that is still needed by minor crops.

2.3.7 State governments

The Australian states have oversight of, and power to control the use of chemicals in their jurisdiction. Chemical use regulation is not uniform across the states. The variation relates primarily to the approved use of registered products on other crops for which a maximum residue limit (MRL) exists. The Victorian legislation (and also the Queensland legislation which allows 'like use') has a direct impact on the potential for production of some vegetables in that state. It gives some producers a commercial advantage not shared by growers of the same crop, in other states. It also limits the need for permits in that state, while increasing the incentive to register proprietary products for use in the state.

2.4 Review - Strengths of the current Australian minor use vegetable projects

2.4.1 General strengths of the system

It is agreed that the strengths of the current minor use vegetable projects are the:

- Sound aims and purpose
- Co-ordinated data generation
- High number of beneficiaries
- Efficient responses to emergencies
- Experienced HAL minor use project leaders with extensive networks

- Detailed tasks and success parameters identified for projects
- Delivery of outputs with public good – risk-assessed, safe, high quality, diverse range of produce
- Consideration of environmental health in solution choices
- In principle support of registrants, national regulator
- Government-industry partnership (both being co-investors)
- Strong HAL commitment to management and accountability for allocated resources
- Processes that include representative growers in decision-making
- Transparent tendering process for projects

2.4.2 Tendering for R&D

The tendering process has been successful, and is a current strength of the HAL minor use projects. The HAL audit of tender briefs and responses, and allocation of funds to service providers on the basis of price, methodology, geographic coverage, and proponent merit are evidence of good corporate governance in this area. The comprehensive feedback given to service providers has resulted in more consistent and comparable tender responses, which has delivered some efficiency within HAL, and assurances to the entire minor use programme.

It is sensible capacity building to allocate data generation research to multiple service providers. However some service providers have reported they would reconsider such work if their allocation resulted in income below a self-determined threshold. This is because the work entails both field trials for which they are well-established and prepared, and also report preparation. Some complete the report component with the assistance of employed administrative staff or personnel they sub-contract casually. When the contracted HAL project is for less trial work than expected, the employment of administrative staff is considered a risk that the service provider may not always be willing to accept. Despite this acknowledgment (of an undefined acceptable 'minimum workload') by some service providers, and the risk associated with spreading the data generation work further, it is my opinion that HAL's reliance on only four service providers, is in itself, a threat to the minor use programme.

There are qualified and experienced service providers who are GLP-accredited, but work solely for registrants. Some technical staff members within universities, research stations and state departments are capable of report/submission preparation and could become GLP-accredited for minor use trial work. Their lack of involvement in HAL minor use projects appears to reflect a lack of institutional and government support for servicing such practical research at the given prices.

It is noted that double handling of the APVMA fee between data generation service providers and the applicants and PMUC occurs. The reason for this is unclear.

This review acknowledges these minor use programme strengths. The brief requires recommendations on areas of improvement in the system, and therefore discussion hereafter is focussed on perceived or reported weaknesses and inefficiencies in the system itself, in projects and in interactions, be they founded in design and/or implementation.

3 RESULTS – REVIEW OF INTERNATIONAL SCHEMES

3.1 International schemes for Minor Use

Successful international minor use schemes have some common features, being:

- Integrated systems responsive to clear, prioritised grower needs
- Systems founded on collective regional then national prioritisation
- Systems that integrate strategic problem and solution review, and science
- Systems that offer some incentives for solutions that reduce reliance on pesticides
- National minor use system and national regulator
- National co-ordination to achieve product registration for crop groups
- Systems operating on a pre-determined budget that dictates the number of priorities (and therefore projects) addressed each year
- Systems with structures and technology that allow stakeholders to find the position of a permit or registration package within the system
- National systems that are government- and industry-supported with large budgets

3.1.1 USA – Interregional Project 4 (IR-4)

There are several United States groups that facilitate access to products for minor speciality crops, but only one national scheme. The Minor Crop Farmer Alliance maintains a grower request database and is establishing links beyond the US and Canada, into the Asia-Pacific region. The IR-4 system however is the most extensive minor use scheme and it responds to the needs of growers of minor crops and more recently, also transgenic horticultural crops. Transgenic horticultural crops and speciality minor crops grown on small acreages are similarly encumbered by a limited array of registered crop protection products.

The IR-4 programme is a well-established, stream-lined system enhanced by collective expertise, purpose and resources provided by, land grant universities, in addition to support from government agencies and crop industries. The IR-4 programme balances:

- Regulatory requirements
- Regional needs
- Multiple requests
- Budget and resource limitations -50-70 trials/year
- Scientific merit
- Focus on reduced-risk/safer chemistries

The programme is a structured and selective response to regional requests made initially on-line by growers, grower groups, and research or extension personnel, primarily for residue trials. The trials are necessary to establish a tolerance for the proposed product and use pattern, because registration (rather than short-term exceptions) is the goal. Not all requests can be accepted. They are prioritised at a regional level and then nationally at the annual IR-4 Food Use workshop. The IR-4 *Minor Use Project Clearance Request Forms* are collated and previewed to expose any direct or accumulated risks associated with the proposed use, or a low potential for product registration. IR-4 receives feedback and removes those crop/pest/solution combinations that are not suitable for further consideration.

Prioritisation is based on many criteria, including:

- Availability and efficacy of alternative pest management tools
- Pest damage potential of target pest/s

- Performance and crop safety
- IPM compatibility
- Uses currently covered by other temporary or emergency exemptions
- Harmonization implications due to lack of international MRLs

The national decision-making process uses the Priority Setting Tool (PST) which collates all input on relevant requests and potential projects. This process relies on stakeholder input to drive prioritisation within clear guidelines. Growers from four regions compete to see their priority projects on the final national list of 50-70 projects for the year.

Once the data generation projects are assigned, the US-EPA schedules the registration package submission periods, thereby managing the volume of submissions and review, with 30 months allowed for submission of new labels.

The Australian PMUC has been given authority to engage in and learn from this programme but not to commit funds to it.

More details of the IR-4 program are included in the following links and in Appendix 4.

http://www.apsnet.org/publications/apsnetfeatures/Pages/TheIR4Project.aspx - overview

http://wrir4.ucdavis.edu/pst/ - Priority setting tools IR-4 Western Region

http://www.uscanadagrowerprioritydatabase.com/databaseinformation.pdf - US-Canada Grower Priority Database

http://ir4.rutgers.edu/Other/AnnualReports/StrategicPlanFinal.pdf - Strategic Plan 2009-2014

3.1.2 Canada - Minor Use Pesticide Program (MUP)

The Canadian system is modelled on the IR-4 programme and it works closely with the IR-4 programme. Both have the goal of increasing grower access to reduced-risk products. The stakeholders of MUP are growers, minor use coordinators in each province, manufacturers, registrants, provincial and federal pest management regulators, crop consultants, CropLife and IR-4. The Pest Management Center develops efficacy and residue data and crop tolerances.

Priority setting commences at the provincial level with the identification of provincial pest priorities for major and minor crops. After registrant input on the status of identified solutions (registered, not registered, no known solution), provincial lists of the top three priorities for each crop/pest combination are compiled by discipline (weeds, diseases, and insects). The provincial priority lists are submitted to the national Minor Use Priority Setting meeting. The 200 participants at this meeting rank the pest priorities nationally. For each discipline, a 'top 10' priority list is reached by consensus, providing a total of up to 40 priorities (including some specific regional and organic priorities) in weed, disease and insect control. For each top 10 priority there is discussion of the highest priority potential solutions which may be pesticides or other alternatives. When no adequate solution is known, the crop/pest priority becomes identified as "'*A' priority without solution*" and it is included in screening trials for the current year.

When the 'top two' solutions are agreed for each crop/pest priority, the relevant commodity and registrant representatives for each pest/solution combination, CropLife and IR-4 and are asked for input. Wherever possible, those solutions with potential joint registration prospects (with IR-4) are chosen as the final top pest/solution priority. Researchable, high priority projects are constructed, with the effective number of new research priorities addressed each year to the benefit of Canadian growers, further increased by joint submissions with the IR-4 scheme.

There are very clear roles for the Minor Use Priority Setting Meeting participants. These have been reviewed as a basis for proposed roles within an Australian prioritisation process. The following links provide access to more details on the Canadian system:

http://www.agr.gc.ca/eng/?id=1286197216280 – Minor use pesticide program

http://www.agr.gc.ca/eng/?id=1289590771112 – Priority setting workshop 2013

http://www.agr.gc.ca/eng/?id=1307567081498 – Biopesticide priority setting

http://www.agr.gc.ca/eng/about-us/offices-and-locations/pest-management-centre/?id=1176486531148 – Pest Management Center

3.1.3 New Zealand

New Zealand (NZ) minor crop growers have access to a wider range of newer chemistry for pest and disease control, than Australian growers of the same crops. NZ growers have a competitive advantage that serves them well in export markets, without compromising environmental or human health, or food safety. It appears that if the product is registered in NZ, all growers have access to it if an MRL has been established.

Being a hazard-based scheme, the regulatory burden appears to be less than in Australia. It is understood that the NZ registration process does not demand efficacy data. New Zealand also has very few trials required for a registration package. NZ requires four trials for a comprehensive registration package while Australia often requires eight.

3.2 Other International Initiatives

There are several international approaches to supporting minor crop growers. They include: temporary approvals (e.g. permits, off-label, emergency uses); data generation assistance plans that bring growers and registrants together usually with government funding (as in Australia); plans that deliberately favour and provide incentives for safer and low risk chemistry and biopesticides. The incentives include fee reductions, extended data protection and fast-tracked reviews.

The United States Environmental Protection Agency (US-EPA) offers fee waivers for submissions 'in the public interest' that have been developed via the IR-4 program. An application is in the public interest if it is for a biopesticide or if it has specific, nominated criteria, including: previous registration on a food crop; use is for a minor crop or niche pest on a major crop; it is a pesticide with new mode of action, part of a pesticide/crop combination with exemptions but no registrant incentive to generate data; and controls a pest for which there are no efficacious alternatives. The full list of criteria may be found at: http://www.epa.gov/pesticides/fees/questions/factors-for-public-interest-finding.pdf.

Other initiatives have been designed to increase the 'value' of registration to the registrant. In some cases reducing the regulatory time and cost, or accepting representative crop data to achieve whole crop group label, is sufficient to increase the 'value' to the registrant. Data protection and data acceptance for extrapolation however are considered the main mechanisms for increasing value. The US offers 'exclusive use of data' extensions of one year for labels that include three minor crops, two years for six crops and three years for nine minor crops.

Sharing or reducing liability adds 'value' in some cases. Liability transfers can be useful when a registrant does not support a proposed off-label use. The liability associated with use is transferred to the end user, while the registrant retains the liability for product quality. 'Indemnified labels' have been approved in some cases when the crop injury potential is unacceptable to the registrant but growers are prepared to accept the injury liability in exchange for having the product available for their critical use.

3.2.1 Global joint reviews and other committees

The output of global joint reviews is the Joint Meeting on Pesticide Residues (JMPR) monograph. The benefits of these global reviews are harmonised maximum residue limits (MRLs). Countries can adopt the harmonised MRLs for their country's produce, thereby reducing existing trade barriers. Growers in theory gain access faster to lower risk chemicals for use on exported commodities.

The Residue Chemistry Expert Group (of the Organisation for Economic Co-operation and Development - OECD) has proposed that field trials required may decrease by 40 percent when applications are made via global joint reviews. This could mean the eight trials required in Australia could become five if 'commodity MRLs' were accepted here and internationally (by trading partners). Work is being undertaken by a range of international committees including CODEX, to advance the single harmonized crop classification system that uses crop groupings and representative crops.

3.2.2 Crop groupings

The concept of crop groupings was established in the USA in 1983 to reduce the need for residue tests on every crop. By grouping like commodities, residue tests on 'representative' crops can establish a pesticide tolerance for all crops in the group, delivering cost savings. In the current USA system one residue test can provide support for more than five new uses.

There has been international activity on revising crop groupings and adding many new crops in recognition of the increased global foods and markets. It has been proposed that the new US groupings would allow one residue test to support more than 10 new uses in the USA. The US-EPA crop group regulations enable the establishment of tolerances for a group of crops based on residue data for certain crops that are representative of the group. The fruiting vegetable group for example in 2005 comprised six crops and the revised one includes 21crops (and three sub-groups); the bulb vegetable group has increased from seven to 25 crops.

Concurrently there are efforts to resolve the differences that exist between North America Free Trade Agreement (NAFTA) and CODEX crop groupings, and between CODEX and country/national MRLs for specific pesticide/crop combinations. Harmonised MRLs cost effectively but safely, reduce some trade limitations. Australia should adopt the modified crop groupings in support of global trade and the data extrapolation opportunities they can provide.

Relevant draft groupings are shown in Appendix 5 as a tabulated extract from the table in document: http://ir4.rutgers.edu/other/CropGroup.htm

The IR-4 crop grouping brochure is also included in Appendix 5 and is available at:
http://ir4.rutgers.edu//NewsItems/crop%20grouping%20brochure_crop%20grouping%20brochure.qxd.pdf

Other information on the current revision of crop groupings is available at:
http://www.epa.gov/pesticides/minoruse/cropgrouping.html

4 RESULTS – LIMITATIONS IN THE CURRENT AUSTRALIAN MINOR USE SYSTEMS

In contrast to other reviewed schemes, Australia has a national registration system for pesticides but no national minor use programme. There is however collaborative and coordinated data generation within some industries (horticulture, grains).

Industry funds are invested on behalf of industry to ensure producers are not disadvantaged in their potential to produce high-yielding, high quality crops. The vegetable minor use projects are functional and comprehensive in design, and productive. They are however not well-understood. Within project MT10029 there are various levels of expectation, leadership and capacity to accept responsibility; engagement, strategic awareness and collaboration. Growers are the primary beneficiaries of the project but their expectations regarding timeframes for permits are not realistic, and the reliance on permits and on-going renewal of permits, is not desirable or in line with the original purpose of granting permits.

Although the introduction of new chemistry is not meeting expectations, there are agreed reasons why the minor use off-label requests have not diminished in volume or demand. There has been no appreciable decline in the needs of industry or regular progression of permits onto labels. The programme is likely to remain for the foreseeable future, because:

- The current market failure has no foreseeable end (lack of, or inequitable, access to effective chemistry)
- Registrants have few incentives to register products for minor use, or for minor crops
- On-going maintenance of generic chemistry is a dominant activity
- State control of use legislations are not harmonised
- Data demands and costs for permits are significantly less than those for registration
- Emergencies and new threats will continue to arise.

The system efficiency is limited by inadequate industry ownership and responsiveness, which in turn has made investment decision-making difficult. Partnerships and co-investment in the system have been limited because registrant engagement has understandably been and remains, driven by commercial imperatives and product stewardship, not industry needs. There are also external influences on the minor use system as a whole: different ‘control of use’ regulations across states, the limited interaction between vegetable industries due to distance, cohesion and resources; and the insignificant position of Australia in the global pesticide marketplace makes international collaboration difficult.

The minor use system has identified limitations in practice. These are not in most cases a reflection of the design of the HAL minor use projects, but rather of inconsistent or untimely implementation, complexity and missing or overlapping roles. The limitations identified or brought to my attention, are shown in Table 6. The implications of the inefficiencies and limitations are noted in Table 7.

Table 6: Current minor use programme limitations

Structural limitations	Operational limitations
• Programme complexity • Not a national scheme • No central industry focal point or 'clearing house' person • Industry fragmentation • Unclear leadership and roles • Engagement not formalised • No formal industry prioritisation • Inflexible regulatory system • Few partnerships • Legislation not harmonised	• No 'first point of contact' in vegetable industry • Understanding of programme and roles • Multiple permit holders, but not industry • Programme costs high; resource intensive • Timelines too flexible – inaction accommodated? • Renewals cheaper/easier than registration • Few roles in engagement and education • Commercial disincentives for registrants • Few incentives within APVMA to register products for minor use • Few service providers

Table 7 : Implications of the current minor use programme limitations

Implications of minor use programme limitations
• Third party drivers; end users do not drive the programme • Renewals/maintenance focus • Too few entries of new chemistry and technologies and soft solutions • Reliance on old chemistry on-going • Industry engagement and ownership is minimal • Inequities across states in outcomes and investment • Limited proactive, strategic input and response • Tactical not strategic decision-making • No resource allocation to national environmental pests, weeds, biosecurity • Registrants not fully utilised or engaged • Limited cross industry co-investment and collaborative opportunities

The minor use system limitations are explained and considered in more detail, specifically: project ownership; engagement; strategic awareness and prioritisation; system responsiveness; incentives; and timeframes.

4.1 Limitation - Programme ownership

Most vegetable growers are not familiar with the operational steps within the MT10029 project, nor are they aware of the importance of their input to it and other steps in the minor use system. It is clear that some growers are frustrated by the time taken for data generation, review and approval of label extensions, permits and renewals. It has been reported also that growers do not understand why:

- new uses (permits/labels) are expensive
- permits do not proceed automatically to registration
- levy investment supports more existing permits than new labels
- New Zealand growers can apply (and export the crop) chemicals not registered in Australia
- some growers have access to a greater range of chemical options than others

Most Victorian minor crop growers and some in South Australian and Queensland, have a competitive advantage, thus highlighting state legislation as an external influence on grower understanding and appreciation of 'minor use' as a complex system, rather than an isolated project.

Industry ownership of the minor use projects is minimal, because end users/beneficiaries are neither project nor system drivers. Project leaders have reported insufficient industry input and responsiveness, and resultant inefficiencies. At present the industry members appear unaware of the efficiencies to be gained via active industry participation and prioritisation.

Inefficiencies and risk may result from the current informal justification of 'needs'. At present a single grower may nominate a new or continued use request. This minimum threshold is not an appropriate determinant of 'industry need' and should not be a sufficient basis on which to enter the minor use pathway.

The liability associated with holding permits is untested but it is known that advice given to HAL suggested it should not be the holder of permits. Until a national scheme is available HAL is likely to be required to fund a permit holder, but the vegetable industry may wish to consider their capacity to hold vegetable permits and maintain the vegetable database. It is possible this role could be both a cost-saving measure and an industry education and engagement mechanism.

The HAL minor use projects and the system as a whole at present lack a mechanism that forces the industry/end users to engage collectively and competitively in prioritisation and justification of their requests. This process would drive industry ownership of the minor use projects and would better inform all steps in the process.

4.2 Limitation - Engagement

4.2.1 Industry engagement

The vegetable producing stakeholders are difficult to co-ordinate and actively engage in all minor use steps. Communication with industry at present is largely one-way and there is little evidence of industry input to the process other than via permit requests. Although commodity groups do nominate two or three informed growers to work with the MT10029 project leader (PMUC), the preparation of vegetable industry strategic agrochemical review process (SARPs) documents have not necessarily been populated with direct industry input. Their completion is an identified PMUC task and the resources and expertise in that position and a reference group, have largely populated the vegetable industry SARPs.

SARPs are valuable industry documents but it is my opinion that few growers consult them, actively commit to their development, or reference them in making requests for new minor off-label uses. Strategic awareness of alternatives to chemicals remains limited. A process of prioritisation by industry could demand this in the future.

Vegetable producers today are less engaged also in practical field research and development (R&D), than in the past when departmental researchers and extension officers worked closely with growers in problem-solving and on practical production advancements. The decline in field data captured and technical input has been attributed in part to the loss of institutional commitment to applied research and the loss of regional industry development officers. The gaps have been filled by private consultants, resellers and technical officers of registrant companies, all of whom have a commercial interest in protecting the data they develop.

Industry engagement in resistance management strategies has also been limited by the absence of state department and extension personnel. The vegetable industry is viewed by some as a risk creator, with concerns based on perceptions of growers having low awareness of chemical regulations, and the implications of chemical mis-use, including over-use. Industry engagement through education on strategic chemical and biological use, and resistance management, is

essential if the minor use projects relevant to vegetable producers, are to be sustained with the confidence of all stakeholders.

4.2.2 Registrant engagement

The supply of new chemistry entering the marketplace is not endless. Although, most new proprietary chemistry is not readily made available for use on minor crops, registrants support the principles of approved minor use. The MT10029 project states that PMUC consultation with registrants is expected. It is an undefined task, but registrants consulted in this review reported they were engaged in the process and confirmed that the PMUC has been their main and usually earliest contact with the vegetable minor use project. The level, timing, nature and frequency of their engagement have not been documented to my knowledge.

Early engagement of registrants is essential if the minor use system is to address the highest priorities of industry with registrant support, be it in-kind or financial. Corporate registrants prioritise their new chemistry/product development budgets, often at a global level in multinational companies. Once agreed, there is little leeway for the local branch to manoeuvre in terms of product development priorities, budget allocations or minor use pursuits requiring data generation. Approval within both local and international corporate budgets is usually necessary.

Registrants have reported that early awareness of SARPs, industry crop protection needs, and the provision of accurate crop statistics, would be valuable. It would allow many companies to evaluate their products as potential solutions, the industries in which they might be used, and the benefits of sharing data generation costs in pursuit of a new or off label use. When asked to consider potential uses on minor crops, registrants usually provide a response that includes consideration of commercial knowledge of the product, its efficacy and safety, its status in their corporate plans, and of the proposed end user industry.

Registrants usually provide one of the following responses:

- Registration of this product is not being pursued by the company
- Registration is being pursued, but not in minor crops; data cannot be shared
- We have data that supports this proposed use and provide in principle support for a minor use to be pursued by others

Less often, other responses may be given:

- We are willing to share data generation costs as a service to industry
- We have data that does not support this proposed use and could not support a permit application

The last response reflects concern that registrants have not always been asked for their approval or otherwise of proposed minor use patterns and test protocols. Two registrants reported that data generation field work had been undertaken against the expressed advice of the product's manufacturer. Since registrants incur a liability for both registered and off-label uses of their products, lack of approval should be a sufficient basis for removal of a product from an industry wish list and from the investment decision-making process. The programme should require HAL be advised of registrant support or rejection of any proposed minor uses, before investment is agreed.

4.2.3 APVMA engagement

Early APVMA engagement is essential to preview the industry's wish list, or preferably in future, its prioritised list. With early APVMA engagement, the risk of investment in data generation for priorities unlikely to succeed, or unlikely to satisfy many growers, can be minimised. Previews and documented data gaps will increase the likelihood that the generated data will satisfy industry and APVMA's requirements. Examples of submitted data packages that have not matched the APVMA requirements for geographical spread, sampling time, or

residue analysis exist and can explain some of the long delays reported for permit renewals and new label extensions.

Early engagement and negotiation with APVMA could reveal different routes to approvals, data protection extensions, and/or the potential for data to satisfy label rather than permit requirements. It is understood that APVMA given time, may also consider fee reductions in some circumstances. APVMA's engagement is important in strengthening the industry-regulatory understanding, maximising investment returns by limiting the potential for wasted time and funds.

4.3 Limitation - Strategic awareness and prioritisation

At present, the strategic evaluation of industry needs and solutions is minimal. The current system places responsibility for this within the HAL project MT10029. Individual requests however cannot be considered representative of, or of equal merit to, requests made after strategic review, with regional or national crop group support. One grower's unsupported request may reflect a management problem, rather than a strategic or true 'need'.

Some tools that assist industry in due diligence exist in the current minor use project. The SARPs in particular, are an excellent basis of strategic evaluations of stated needs and solution options. However industry reference to them has been limited, with the current permit list showing the domination of old, generic chemistry.

Strategic review by industry has been limited in part by the ease with which casual, partially-informed requests can be made and accepted into the MT10029 project. The finalisation of SARPs has also contributed. SARPs have not always included current details on export/trade; international maximum residue limits (MRLs), chemical and management alternatives in pest/disease control, and chemicals under review, reported resistance, and chemistry that is the subject of Global Joint Reviews. The data that SARPs routinely include are noted in Table 8. A cross industry HAL project by AKC Consulting has the potential to provide more strategic input to SARPs, and for the vegetable industry to benefit further from this project leader's knowledge of Australian and international regulatory matters, pesticide reviews, liaison with CODEX, international chemical committees, and other minor use schemes that strategically prioritise industry needs.

Informed, transparent prioritisation of industry needs, solutions and investment would re-fresh the permit list with newer chemistry, technologies and more solutions considered low risk. In its absence, the 'wish list' will not end, and the IAC and VTAG will be unable to evaluate the relative merit of projects and investments.

Table 8 : The content of SARPs

Current SARP content	
• Diseases, pests, weeds • Their incidence and severity – regional, national • Registered products/chemistry for control • Permits available, changing status • Use pattern – rates; applications/season? • Summaries of available products • Current solution status – suitable, unsuitable • Priority pests • Activity needed to meet the industry objectives • New pests/diseases – mites, insects, quarantine, fungal, bacterial, post-harvest	• Disorders • Weeds • Other – birds and parasitic, exotic plants **Deficiencies of some SARPs** • Resistance alerts • Potential chemical alternatives – new, existing • Global MRLs • Chemicals under review • Trade issues

4.4 Limitation - System responsiveness

Some elements of current minor use activities do not ensure it is an inclusive and responsive industry programme. Communications regarding minor uses, with and between the various stakeholders, have not always been documented. The vegetable industry, through AUSVEG, is not at present the central hub for communication about minor uses. The PMUC has due diligence and communication tasks that include informing and alerting industry, e.g. SARPs, minor use advice and outcomes, and feedback forms.

Industry feedback is a responsibility of the relevant industries, and it should be the basis of any activity in permit or label pursuit. Inconsistent industry and programme responsiveness appears to be founded in three key areas: consultation and communication, incentives, and timeframes.

4.4.1 Communication and consultation

Consultations and communication at present are not formalised by documented timetables and outcomes. This has limited the capacity of:

- Industry to adequately inform and refine wish lists (into prioritised lists)
- Permit renewal activity to be adequately justified
- Industry and PMUC to formally agree on reference group composition
- HAL to preferentially prepare tenders for data generation projects that have documented registrant support
- APVMA to schedule the receipt and review of highest priority submissions
- HAL and industry members to learn of delays in approvals, inadequate data submissions, rejected submissions etc.
- Industry to adequately consider and address non-compliance

Steps in the programme are underpinned by specific input from several stakeholders, and therefore a stream-lined minor use system that is responsive to industry needs, must include regular consultation between industry members, regulators, registrants, project managers, annual crop industries and service providers. Industry consultation must inform all minor use requests, the prioritisation process and the SARPs.

Industry consultation is required as evidence of support for permit renewal. In the current minor use project MT10029, industry input is requested via distributed due diligence forms. Industry responsiveness as assessed from returned, completed forms, has been minimal and slow. At present a lack of feedback is interpreted as supportive of the *status quo* (e.g. no adverse experiences, use pattern still effective, efficacy maintained). This is unlikely to always be the case. An on-line system that allows electronic input may increase industry feedback, but it is possible it will remain weak until there is industry ownership of the minor use system, and consequences for missing evidence of industry support, e.g. Go/No Go points in the system.

Registrant and regulator input to project leaders have been acknowledged, but it is not documented. Service providers also consult with registrants, PMUC and HAL, but rarely with the APVMA.

4.4.2 Project interactions

Both the PMUC and Growcom are in my opinion HAL minor use ‘project leaders’ or principle investigators. Both are contracted by HAL and engaged in direct communication with APVMA and in the preparation of minor use data. Both the PMUC and Growcom have due diligence requirements in their contracted projects, and Growcom is the vegetable permit holder. It has not been common practice to document the relevant liaison between the leaders of HAL minor use

projects, but double-handling of some activities has been acknowledged. The overlapping Growcom and PMUC roles and communication gaps have resulted in some delayed permit renewals, and confusion. The PMUC and Growcom responsibilities have been previously discussed (Section 2.3).

Some permit requests assessed to require only 'desktop' preparation have required data generation. This has resulted in some double-handling, waste of funds and loss of time depending on the position in the funding cycle. Responsibility for background data that informs all off-label requests and activity is at present assigned within the MT10029 project but this appears inefficient, and a limiting factor in project interaction. Others have roles in data acquisition. Industry members should inform all requests after consideration of SARPs and data available to them from multiple sources, including researchers. On contracting, service providers receive background data but are also expected to access new data. Industry is expected to provide feedback on due diligence forms to inform renewal requests. At times those preparing submissions and conducting data generation trials have been unaware of the industry justification for their preparation. This is not necessarily required, but there is an assumption that all work undertaken has been justified by the industry, registrants or others and that the contracted trial work is aligned with approved industry use patterns for the requested solution.

Some stakeholders have not been informed of the status of permits requests within the minor use system. APVMA, Growcom and PMUC have roles that directly or indirectly, require awareness of the status of submissions. There are efficiencies to be gained from clear roles, mandatory steps within the minor use programme and two-way communication that informs all minor use activity. In the event a permit submission is denied due to lack of data or inappropriate data, the service providers, tender documents and background data need immediate review and a resolution pathway mapped. This would demand interaction between several HAL minor use project leaders/service providers, applicant, HAL and the APVMA.

AUSVEG and PMUC communication expectations have not been clearly defined. An extensive industry and registrant reference group is utilised by the PMUC to inform project decisions, but consultation with it has not always been documented, nor accepted by AUSVEG, as fully representative of the vegetable industry. AUSVEG also engages growers to acquire industry feedback but it is apparent that grower understanding of the necessity for informed and timely grower input to the minor use consultation process, is insufficient. This deficiency combined with a lack of direct AUSVEG and PMUC communication, has resulted in justification for some projects being less than desired.

The Growcom and PMUC roles are co-dependent in the following areas:

- Consolidation of permits
- Permit notifications
- APVMA liaison – PMUC holds most information but APVMA must communicate with applicant (Growcom)
- PMUC reviews data generation reports from service providers, before applicant submits them
- Preparation of some renewals and new permits
  - Renewals - Growcom advised by PMUC of expiry dates 12 months in advance
    Growcom advised by APVMA 3 months before expiry
    PMUC advises reference group of expirations within 12months
    PMUC distributes due diligence forms to industry reference group
    HAL distributes forms to VTAG
    HAL gives 'go-ahead' to Growcom based on industry (VTAG) feedback

Growcom receives PMUC reference group feedback

PMUC receives data summaries and draft submissions from data generation project leaders/service providers

Growcom submits renewal applications to APVMA

- New permits - Contracted desktop project leader (not Growcom in 2013)

  Data in support provided by PMUC occasionally

  PMUC reviews draft applications

  Applicant submits to APVMA

4.5 Limitation – Registration disincentives

It is not clear to industry stakeholders why the registration of products for use on vegetables is not routine. In simple terms, a primary reason is that the commercial disincentives outweigh the commercial incentives for registrant investment in data generation for minor uses. For generic chemistry with no remaining intellectual property (IP) and potentially 20 or more packers, it appears that there is no specific incentive to drive investment in minor use, other than 'serving the industry'. It is acknowledged that some registrant initiatives (e.g. Bayer Crop Science's "MUSCLE" - *Minor Use, Screening Products, Co-funding opportunities and Label Extensions*) do consider the 'service to industry' role through minor use, and the potential to share data generation costs, seriously. Through the MUSCLE initiative, Bayer Crop Science resources have been allocated to collaborative work with some horticultural industries, with the aim of achieving registrations to avoid on-going permit needs. Other registrants find it difficult to justify investment in projects that do not encompass crop groups, reduced data requirements, data protection or financial incentives (e.g. fee waivers, data protection). The result in total is low level registrant investment in minor use, on-going demand for permits, a minor use scheme dominated by permit maintenance, and the rare introduction of new chemistries and technologies.

Risk of product mis-use or over-use is also a disincentive for registrants, especially if the proprietary product has high resistance potential, and the intended end users are in an industry known for non-compliance.

Registrants have also reported the disconnect they experience with supermarket quality assurance (QA) programmes, and its influence on the pursuit of approved minor uses. Some supermarket chains dictate to suppliers their 'preferred spray programme'. A grower's acceptance of the preferred spray schedule underpins (with residue testing) acceptance of the grower's produce, by the supermarket. Supermarkets include in their preferred spray programme registered products only. Registrants with food chain awareness and proprietary chemistry suitable for use on minor crops, therefore have incentive to establish MRLs and pursue registrations for particular minor crop uses, in order to appear on the supermarket programme.

4.5.1 APVMA

There are several areas in which the APVMA adds to the existing disincentives reported by registrants. Lack of data protection makes some submissions more difficult to co-fund, and it discourages the sharing of data on product-crop combinations for which there is future registration potential. Adding a crop to an existing label or changing the use pattern on a label requires considerable additional data, half of which must be generated in Australia. Proprietary data is protected for 5-10 years but data generated for a generic chemistry permit cannot be protected from other packers of the active constituent. The registrant is provided therefore with no assured return on investment.

There are suggestions APVMA should accept more overseas data, accept New Zealand registrations, the concept of representative crops (levied or not), and offer more incentives for minor crop access to new low-risk chemistry. From an industry perspective, it appears the APVMA has resisted the potential to accept NZ data and registrations, despite the two countries accepting common conditions of food trade and food safety through Food Standards Australia and New Zealand (FSANZ). This needs more investigation.

The time for passage through the APVMA remains a disincentive, albeit somewhat unjustified. The APVMA may have means to more strategically schedule their reviews and submission evaluations, and to provide insight to their system and timelines via an open-access (for industry stakeholders) database.

4.6 Limitation - Timeframes

It is a general belief of all stakeholders with an interest in minor use of chemicals, that the time taken in Australia to gain minor use approval (be it for label extensions, permits or permit renewals), is too long. Comparison with other schemes in NZ and the USA would suggest this sentiment is based in fact. Emergency permits however are often addressed very efficiently by APVMA and this has been recognised.

Throughout the minor use process, timelines appear flexible because they are not specifically defined. The collective flexibility however has resulted at times in unacceptable delays, insufficient consultation, and the late submission of data packages. In most cases, slow approvals have not been caused by APVMA, but rather the number and completeness of submissions.

There is evidence that the industry reference and consultation groups of the PMUC and AUSVEG do not at present, act in concert, or provide documented feedback that underpins all permit renewal activity. In the past, slow and late industry input has caused delays in the permit renewal projects and review system. HAL now demands the process commences 12 months before permits expire. The assigned life of a new permit (usually 1-3 years) is intended to provide sufficient time for data generation to support its renewal (or future registration).

While most approvals proceed as expected, there is evidence of data remaining incomplete for as long as nine years. Incomplete data packages that require revision and sometimes attempted retro-fitting of data are demanding of time and resources. Some cannot be ‘fixed’ because the original data generated was not appropriate. Regardless of the cause, submissions that do not clear APVMA, fail to serve the industry, deliver returns on their investment, and waste industry resources.

When data has not been generated over the 2-3 year period of the original permit, APVMA often prepares at short notice, an extension of the permit. This interrupts the system, but occurs to support permit users. The relative ease of obtaining an extension should be reviewed. APVMA diversion to unproductive double handling of submissions is not desirable use of government or industry resources, and HAL and the industry should be made aware of failures to accurately address data generation obligations, and the implications. Resolution pathways and timeframes should be defined.

5 RECOMMENDATIONS - REVISED PROCESS

The review has revealed areas in which the process and steps within it, might be improved. In brief it is recommended that the system be compartmentalised to allow,

- the Vegetable industry through AUSVEG, to drive:
  - industry prioritisation process
  - industry education and engagement
  - communication

- HAL the resources and roles to manage:
  - data generation projects
  - submission and permit management
  - strategic and tactical development

- the national Regulator (APVMA) to:
  - engage with authorities to introduce incentives
  - timely evalutations through scheduling and prioritisation of submissions

There are various duties that are required to inform industry (Table 9) and develop a Prioritisation process (Table 10). New steps or those that appear to be have been inconsistently addressed in the current process are shown in red in Tables 9-13. The HAL projects would commence with a list of approved, prioritised pest/crop solutions. The revised process is explained in more detail as categorised recommendations in the following text and Tables 9-13.

Table 9 : Informing industry awareness in a revised process

On-going steps/action	Informing data/activity
Budget for minor use projects in vegetables	*Pre-determined budget or agreed max number per crop group or max active permits per crop group*
Industry awareness – Crop protection and needs	SARPs *New threat alerts* *SARPs updated each year by HAL strategic project leader* *Regular strategic and international input to SARPs* *Facilitated registrant access and formal review of SARPs annually*
Industry awareness – Permits and label	Identification and checking of status by *AUSVEG minor use and permit holder* Permit correspondence - Combined hort and industry-specific permit lists - Industry due diligence documents - Industry feedback requests - Notifications – requested, new, expiring, renewed, retired permits Due diligence forms and response HAL database input and maintenance; copies sent monthly Milestone and final HAL reports *APVMA open access database- position of permit within system* *Direct communication: APVMA/permit holder/applicant; industry/AUSVEG minor use leader/HAL*

Table 10 : Informing activity in Prioritisation of industry needs

Process steps/action	Informing data/activity - AUSVEG Project
Identified crop problem	Requests made by any party New Permit Questionnaire (NPQ) - revised Current SARPs *AUSVEG minor use leader receives informed requests on-line (ideally)* (Appendix 6) *AUSVEG minor use leader facilitates industry investigations/crop group support in regions* *Crop group/ 'sponsored/supported' requests accepted*
HAL database up to date on requests	*AUSVEG minor use leader updates database*
Potential Solution lists - *Available solutions – use, no further action* - *Unavailable solutions - not suitable? not legal?*	Permit holder clarified Funding available – ***pre-determined annual budget*** *for new chemistry, renewals, new permits, emergencies* *AUSVEG minor use leader collates solutions from crop group, registrants, other industries* ***Registrant comments*** *on proposed solutions documented* ***APVMA reviews potential solutions*** ***APVMA identifies data gaps*** *Industry reference group reviews solutions* ***Priority solutions*** *– criteria – eg. replace old chemistry, introduce newer/soft/compatible chemistry; export suitable* ***Prioritisation of requests/solutions – Prioritisation Workshop***
HAL and industry review	Project costs estimated
Approved pursuit of solutions - **New permit** - **Label change**	Industry review and approval –VTAG; *wider industry?* ***Cross-industry review of priorities*** ***Sign-off by registrants*** *in support of high priority solutions* **HAL minor use PROJECTS COMMENCE**

6 RECOMMENDATIONS - PRIORITISATION OF INDUSTRY REQUESTS

6.1 Introducing a prioritisation process

Formal and inclusive prioritisation of industry needs is the most important operational change recommended for a revised minor use (MU) process. It is strongly recommended that a prioritisation process be in place before the proposed regulatory changes to APVMA come into being in 2014.

Implementation of a prioritisation process will allow industry to:

- Lead the vegetable minor use programme (with HAL projects commencing post-prioritisation)
- Request and respond early to registrants and regulator input (and previews)

- Reliably invest in both tactical and strategic needs with industry approval
- Set appropriate and firm timelines
- Share informed priorities across industries.

It is recommended the driver of the prioritisation process be an AUSVEG-appointed minor use leader and the goal be to increase the introductions of new chemistry, while continuing to meet grower needs in other respects.

Prioritisation should at the first step accommodate requests from two regions that cover the vegetable production areas. The two regional sources recommended, are tropical/sub-tropical and Mediterranean/cool zones. In practice the recommendation is for vegetable permit requests from Queensland, Northern Territory, NSW and northern Western Australia (WA) to be initially collated and distinguished from those submitted from Victoria, Tasmania, South Australia (SA) and central-southern WA. The current vegetable crop groupings are suitable for each region.

Step 1 Reviewing Requests

- Accept requests from both regions with industry support/'sponsors' and adequate background data (revised request form, Appendix 6).
- Collate requests by crop group, pest category (weed, disease, insects)
- Identify potential chemical and soft solutions (from SARPs) and circulate the combined list from each region, to registrants and APVMA
- Summarise requests lacking known solutions and provide to HAL for cross industry review and input
- APVMA asked to indicate the number of trials needed to support a permit or label extension for the combinations
- Request for the crop/pest/solution combinations, APVMA- and registrant-signed feedback, and indicative support (financial, in-kind, none)
- Collate feedback for the crop/pest/solution combinations receiving registrant and/or APVMA in principle approval to pursue
- Remove from lists all crop/pest/solution not receiving registrant or APVMA approval
- Retain combinations with proposed solutions ranked 1 or 2 by registrants or APVMA and biopesticides or other soft, IPM compatible solutions
- Highlight requests with potential for whole crop group label or permit
- Recognising regional differences in efficacy, epidemiology, target crop sensitivities, the Prioritisation Workshop should address a rationalised list from each region initially.

Step 2 Prioritisation workshop logistics

Participation

- Extend invitations for the one-day Prioritisation Workshop, to informed growers from each crop group in each region, SARP authors and strategic knowledge experts, technical field personnel and consultants, registrants, the regulator, and HAL. No more than 60 people should be in attendance.
- Prepare clear guidelines on the prioritisation process and criteria (preferences for replacement of old chemistry)

Prioritisation

- Collectively prioritise the top 25-50 national researchable industry needs (labels, permits)
- Allow up to three specific regional requests to be included
- Allow up to two requests suited for organic production to be included
- Representatives for the high priority commodity/solutions must sign approval for pursuit of this combination before the end of the Prioritisation Workshop

Timing

- Vegetable Technical Advisory Group (VTAG) and the Industry Advisory Committee (IAC) meeting schedules and funding cycles determine the timing of the Workshop (and receipt of requests)
- The priority lists should be reviewed by VTAG and IAC within one month of the Prioritisation Workshop
- Priority list for researchable projects circulated to HAL's cross industry coordinator, to canvass opportunities for co-investment or consolidated R&D with other annual crop industries
- Priority list circulated to the HAL's project leaders and APVMA for input on data gaps and trial requirements.
- Decision–making on investment simplified by industry-led prioritisation

The completion of Step 2 in the revised process is the recommended starting point for HAL's minor use data generation/coordination project. It is anticipated that the project leader at this stage would have sufficient information (from the vegetable industry and prioritisation process) to:

- Engage with other annual industries and non-levied vegetable industries to maximise sharing and co-funding of data generation research
- Negotiate data sharing and/or voluntary contributions when appropriate from non-levied industries that may assist or benefit from proposed data generation
- Prepare data generation tenders
- Prepare background information packages (for service providers on contracting)
- Request registrant input on trial protocols
- Request from APVMA a scheduled permit/label submission time – to be provided to service providers on contracting.

The revised minor use structure that incorporates the proposed prioritisation process is shown in Figure 2. The industry drives the process to the green line and HAL projects commence below it.

Figure 2 : Revised Minor Use Steps

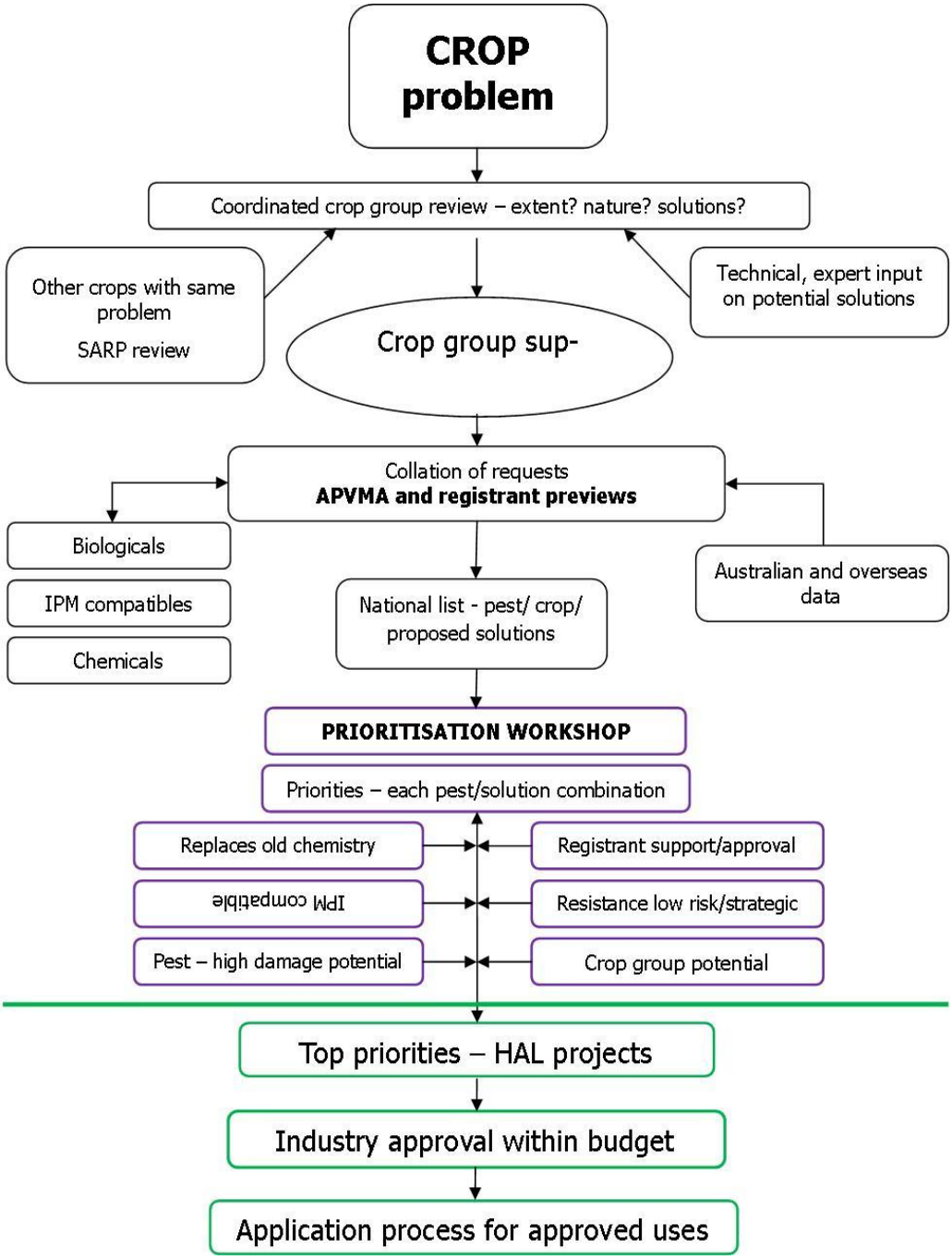


Table 11 : Informing steps towards new permit in revised system

Solutions requiring New permit – HAL PROJECT	
Approved projects	See Section 10 - investment decisions
Data collated	Data accessed by PMUC project from AUSVEG minor use leader (industry informed requests) and others
Submission of data in support	Desktop project leader ***Emergency requests addressed first*** *High priorities addressed* ***Notify industry (via AUSVEG minor use leader and established networks/reference groups) of submission date***
Assessment by APVMA	Submission accepted Contact with applicant ***Open access database*** *showing position in APVMA system*
Permit decision known	APVMA briefs applicant Industry informed in 1-3 days by *AUSVEG minor use leader* and PMUC email Wider industry, re-sellers informed *(by AUSVEG minor use leader and networks)* *Direct communication: APVMA→permit holder→*PMUC, HAL; *APVMA→AUSVEG minor use leader→to industry stakeholders* *Permit includes CropLife advice* *Unsuccessful permit application – resolution pathway and review within 6 months. Coordinated by Applicant and APVMA, with AUSVEG minor use leader* APVMA advice on data needed in next 2-3 years → PERMIT RENEWAL project

Table 12 : Informing steps toward a label extension in a revised minor use project

Solution requiring change to Product label – HAL PROJECT	
Approved projects	See Section 10 - investment decisions
Local data gaps known	APVMA agreed trial number, crops, locations PMUC advises industry *APVMA consideration of NZ, trial reduction for crop group with representative crop* Consultation: Registrants - support? no support? data available, protected? ***Sign-off by registrant** – on use pattern, rates, protocol input.* *(No Go without approval; documented consultation).* ***APVMA sign-off** of residue trials needed* ***HAL – shared priority list cross –industry** co-funding options?* *Background data collated, ready for tenders*
High priority researchable projects approved	***Prioritised projects – co-funded, introduction of new chemistry to industry, low risk product, high number of beneficiaries*** *Non-approved priority projects recorded on request database for following year*
Tender preparation	Same pesticides grouped for tendering PMUC provides approved list and infomration frm which tenders are drafted by HAL *Tenders released same time each year* *Tenders informed by registrant, APVMA and background information* *Packaged background information ready*
Approval of GLP-accredited service providers	HAL recommends apportioned work based on costs, proponent merit etc. Service providers approved by IAC Service providers contracted *Packaged information provided to service providers* ***APVMA provides schedule for future submission** (date to HAL, industry) for each contracted project*
Data generation trials undertaken	***Registrants sign-off protocols**: use pattern, rates, harvest times for residue tests (WHP)* Service providers meet requirements of tender. Once contracted, 18 months for GLP trial work and confidential package submission to HAL project leader/registrant *(Co-funded with registrants - registrants prepare regulatory package)* Service providers submit HAL Milestone and Final reports
Package submitted to APVMA for assessment	GLP reports reviewed by PMUC before going to applicant ***APVMA incentives – e.g. fast tracked new chemistry packages with 3 minor crops on proposed label***
APVMA decisions	APVMA discusses issues with applicant ***Timeframe to respond to APVMA queries – 3 days**,* *Document HAL discussions and delays* *Unsuccessful submissions reviewed within 6 months* APVMA alerts applicant of outcome Applicants via AUSVEG minor use and HAL *advise industry* of label change via email, *published media?*

Table 13 : Informing steps towards permit renewals in a revised minor use project

Permit renewals – HAL PROJECT	
Permit expiring within 12 months	***AUSVEG minor use leader alerted quarterly*** 12 months before expiry APVMA advises permit holder of expiration within 12 months PMUC advises industry of expirations within 12 months
Permit data requirements - status	Data generation over 2-3 years No data needed – desktop submission by contracted service provider Data needed - ***if not generated - default position is 'no further action'*** *Insufficient data – one-off short-term extension by APVMA (with some guidelines for approving extensions, i.e. first time?)*
Industry support for renewal of existing permit	*AUSVEG minor use leader drives industry responsiveness* ***No forms /feedback? default position is 'no further action'*** Industry forms completed- adverse experiences, phytotoxicity, use pattern, efficacy/performance and withholding period. APVMA advised of feedback no *later than 8 months before expiry* SARP confirms on-going suitability/need. *Strategic imperative considered*
Consolidated permit renewal packages	Data collated *no later than* **8** months before expiry Like uses consolidated *Non-levied vegetables included to complete crop group, if data shared, fee/VC negotiated*
Renewal submissions	Packages submitted *no later than* **5** months before expiry ***On-time submissions reviewed on-time*** ***Late submissions*** *moved to next available review date or later* ***Delays and package deficiencies reported to applicant, HAL, and industry*** ***Resolution pathway and review within 6 months*** *Consultation with APVMA documented*
Renewal status	APVMA communicates with permit holder Industry advised by PMUC ***Direct communication to AUSVEG minor use leader*** *for notifications to industry of outcomes – for industry journals etc.* ***APVMA database with open access for applicants*** HAL database updated
Review of outstanding decisions	***Review of HAL permits delayed longer than 6 months – decision criteria for*** *Stop/Go*

7 RECOMMENDATIONS - PROCESS AWARENESS

The current minor use projects and broader system are functional and successful in meeting the expectations of many stakeholders, but not all. Increased process awareness will drive greater industry ownership and responsiveness. This may be achieved through better education and engagement of stakeholders and clear communication pathways that encompass all relevant parties. Suggestions of how these may be achieved are noted below.

7.1 Education

At all levels, the minor use system would benefit from an education plan that outlines the components, participants, roles and responsibilities, required input and interactions, preferred timeframes and targeted outputs. A more informed vegetable industry will be more strategic in assessment of industry requests and proposed solutions, available technology and chemistry; and in determining equitable allocations of funds to industry's highest priority projects.

It is recommended that an education campaign be delivered by AUSVEG as a high profile symposium with subsequent factsheets that outline the minor use steps. The symposium should be one that can attract or include by invitation, growers, consultants, registrants and regulators, and also representatives from international schemes like IR-4. Each stakeholder must become familiar with the drivers, required input, and timeframes for each step within the minor use process, and of the mechanism by which their input to SARPs, assessment of proposed solutions and future strategic needs, can be maximised.

Inclusion of non-levy paying vegetable industries in the education campaign is recommended, so all vegetable industries become aware of the benefits of cross commodity/industry data-sharing and generation, the case for representative crops, and collective prioritisation. Industry collated background and supportive data, by crop group should inform each minor use permit request or requested label change.

7.2 Engagement and leadership

An industry-driven prioritisation process would force both vegetable industry stakeholder and registrant engagement. The AUSVEG communication network is necessary to support this.

It is strongly recommended that the vegetable industry become the informed driver of the minor use process conducted through HAL, and that it assumes the lead role in the prioritisation of requests, justification of renewals, and communication throughout the process.

7.2.1 Vegetable industry leadership

With increased grower understanding and awareness of the steps within the minor use system, the lead role can be anticipated to be one that is proactive rather than reactive. To successfully drive minor use activity and response, the vegetable industry needs a focal point for minor use engagement.

It is recommended that a person with technical and agronomic knowledge be appointed within AUSVEG, to such a position and that the position becomes the 'first point of call' for minor use issues, for industry stakeholders, HAL and APVMA. Opportunity should also exist for the vegetable industry through AUSVEG to work together with HAL to drive cross commodity collaboration and strategic reviews, and to increase the awareness of emerging threats, as was recently demonstrated with green peach aphid resistance. A communication network centred in AUSVEG will be an integral component of effective leadership by the vegetable industry.

7.2.2 Vegetable industry engagement

Communication with industry is the key to increasing industry engagement in the HAL minor use projects and also to increasing awareness of the national requirements. Evidence of improved industry engagement would be regular two-way communication between the vegetable

industry members, their representative bodies, and HAL's minor use project leaders. AUSVEG, as the peak body has successfully developed extensive communication routes through the member industries. Increased communication with non-levied vegetable industries is recommended.

Industry engagement is essential for effective prioritisation of pesticide needs, and for information exchange, e.g. on investment in minor use, resistance management, permit/registration status etc. Formal feedback on minor uses should be required and the feedback loops made readily available (e.g. on-line).

It is recommended that permit requests directed to AUSVEG reflect prior engagement within the relevant commodity/crop groups, AUSVEG, researchers and/or consultants, and SARP knowledge. It is recommended that an individual, personal request for a problem/permit solution not be accepted or approved to consume industry resources, unless accompanied by evidence of broader industry and expert support and contextual information.

It is recommended that the vegetable industry builds on the broader and cross industry engagement currently being shown - with strategic input from registrants and non-vegetable industries alerting the vegetable industry to resistance development, new technologies (iPhone apps for access to permit lists) and potential opportunities to share data generation research, e.g. pesticide screening for *Botrytis* sp. and *Ascochyta* sp. in pulses and vegetables; *Cercospora* sp. in faba beans; and herbicide screening for agronomic *Brassica* spp. (eg. canola) and vegetable Brassica seedlings etc.

7.2.3 Registrant engagement and incentives

The HAL minor use project leader should confirm registrants are formally engaged at least twice each year - through previews of the crop/pest/solution requests and in the prioritisation process (AUSVEG role); and that their approval is given for test protocols prior to data generation.

Registrants are looking to the HAL leadership (HAL-IAC) for evidence that new approaches to pest control are being given priority in solution choices and in investment.

It is recommended that the person appointed by AUSVEG to the minor use position, drive registrant engagement initially through a registrant forum with Department of Agriculture Fisheries and Forestry (DAFF), APVMA and HAL, that outlines the proposed prioritisation process; and data acceptance, generation, protection and sharing that could reduce the disincentives and maximise co-investment and ultimately the number of beneficiaries of approvals. Costs savings in data generation would provide an incentive to invest in minor use permits and label changes. If registrants were allowed to conduct their own Good Laboratory Practices (GLP) residue trials (with independent laboratory analyses), in addition to the efficacy and crop safety trials, the savings would be significant. At present residue trials are required by the regulator to be conducted by a third party. Adoption of representative crops (to give whole crop group registration) would also be a valued incentive.

To advance registrant engagement via the HAL projects and co-investment efforts, it is recommended that HAL secure agreement from each annual crop industry, for formal circulation of high priority researchable minor use projects each year, across industries. These, and SARPS, would be useful to registrants.

It is recommended that registrants and the APVMA be engaged by the AUSVEG minor use leader to clarify the suitability of alternative routes through APVMA for various minor use product categories. Category 25 options are not technically for minor use and they have not previously been pursued for registered products by the vegetable industry. The data requirements for Category 25 approvals are greater, the assessment fee more expensive (than for permits) and the submitted data are not protected (as they have previously been submitted to APVMA to achieve the label). The assessment timeframes are long and the proposed label changes require the support of all registrants of the product. The primary benefit of Category 25

label changes is that all relevant labels change at one time. The data requirements for Category 25 label changes relevant to vegetable crops may be reduced if the APVMA agreed to accept data in the public domain and established MRLs.

7.2.4 APVMA - flexible leadership

It is recommended that APVMA be an active participant in the vegetable industry education campaign on minor use. The current system allows contact with 'applicants' only.

The APVMA would be assisted by the submission of complete packages of appropriate data analysed by correct statistical methods, and presented in consistent formats. This is a current responsibility of both PMUC and Growcom.

Early engagement of APVMA in previewing crop/pest/solution lists is recommended. Their early advice on the recommended approach for cost-effectively and efficiently securing access to solutions by growers is valuable.

It is recommended that registrant representatives also conduct discussions with APVMA, DAFF and the minor use leader in AUSVEG, to formally confirm (or otherwise) the stated views of some registrants that APVMA could more frequently:

- Provide data protection for data submitted for a permit
- Extend data protection for label extensions that include 3 or more minor crops
- Prioritise reviews for label extensions that include 3 or more minor crops
- Prioritise reviews of label extensions or permits adding three minor crops
- Prioritise reviews of label extension packages for low risk, IPM-compatible chemistry
- Minimise or remove fees for permits that progress to labels in a reasonable timeframe
- Review acceptable NZ collaboration on registrations
- Accept more international data that corresponds exactly with the proposed use pattern and target crops
- Consider liability transfer to growers, e.g. Victoria, SA arrangements, indemnity labels US-EPA
- Reject incomplete submissions rather than consume scarce resources trying to retrofit them.

It is also recommended that APVMA be engaged in discussions on the above and following points:

- Agreement to preview regional lists and proposed solutions (including new technologies) before the Prioritisation Workshop
- Equity and risks associated with the current non-harmonised state 'control of use', and implications on permit demand, and resistance management
- Documented approval of registrants in support of a requested permit and use pattern
- Education leadership for regulatory matters and status of on-going reviews
- Fee structures/financial incentives and data protection for permit renewals being used in support of registration (see above)
- Potential to accept other sources of residue data, eg. supermarket quality assurance residue test results in support of some permit applications for very minor specialty crops
- Development of an industry-accessible database that shows the position of an application in the minor use pathway

- The relative risk and benefits associated with GLP residue trials for generics being established by registrants (rather than third parties), and validated by independent NATA-accredited laboratory analyses
- Documentation of communication (on approvals and delays), with applicants and HAL

The APVMA with DAFF engagement are also encouraged to consider approvals in the public interest, like those offered by the US-EPA. See Section 3.

7.3 Communication

The communication required to inform each step has been outlined. In the minor use pathway, information capture and communication of it to the correct stakeholders, can drive or stall the process. Lack of communication may trigger No Go points in the system. If for example, the volume and nature of feedback from industry on permit renewal justification does not reach a pre-determined threshold level of support, permit renewal activity should not proceed automatically. The default position for lack of feedback should become 'no further action'. Similarly, registrants and the regulator previews of requested crop/pest/solution combinations should be signed-off, to reflect 'approval to pursue'. Those combinations not approved should be removed from further consideration prior to the prioritisation process, and be noted in the HAL database. The distribution of SARPs should be regular and documented.

Communication is 'successful' when the necessary information is in the hands of the right people at the most opportune times. It will facilitate education, engagement, responsiveness and awareness. Communication routes must be extensive, two-way and formalised at various steps in the minor use pathway. Minor use-related communication is expected with:

- Stakeholders
- Agricultural Pesticides and Veterinary Medicines Authority (APVMA)
- HAL project leaders/principle investigators
- Service providers (some are contracted project leaders)
- Registrants and manufacturers
- Other relevant HAL projects
- Other minor use programmes – in other research and development corporations (RDCs) and internationally

Appropriate forms of communication are varied but those relevant to industry stakeholders in the minor use projects include:

- Scheduled meetings
- Databases (some with open access)
- In-person
- Electronic mail
- Formal reports
- Newsletters and magazine articles
- Workshops

Communication on problems in the system and delays should also be documented. Inappropriate or incomplete data that delays submissions or approvals of permit renewals for longer than 6 months, or label extensions longer than 12 months (after package submissions) must be documented and communicated to HAL. 'Drawn out' projects are a cost to the industry and they need to be thoroughly reviewed. Delayed submissions could be identified by APVMA if they

nominated and communicated the scheduled submission period at the time each data generation project was contracted.

Communication that should be formally documented and circulated through the AUSVEG minor use leader (and/or VTAG, IAC) and HAL, include:

- Permit requests - with 'sponsor' (eg. crop groups, consultants) support in writing
- SARPs with strategic input
- Registrant previews and responses to SARPs, proposed crop/pest/solution combinations
- APVMA preview of proposed crop/pest/solution combinations
- Reports of new pests and threats, emerging resistance
- Industry feedback on phytotoxicity, efficacy, human health, compatibility, use pattern
- Prioritisation Workshop negotiations
- Final priority list of researchable crop/pest/solution projects (on open access database)
- Industry approval of priority projects/funds allocation
- Priority lists of other annual crop industries
- Resistance development awareness; stewardship and R&D activity
- APVMA-scheduled data submission periods
- APVMA communication on problems submissions, delayed submissions and approvals

Summary - Key recommendations for increasing process awareness

- Increase education, engagement, communication and industry leadership
- AUSVEG appointment as industry minor use leader
- Operations planned, implemented on an annual schedule
- AUSVEG-driven prioritisation process
- AUSVEG-driven education campaign
- Formalise communication expectations
- Documented communication; easy access feedback loops
- Commitment to strategic reviews (and SARPs)
- Commitment to prioritise low risk, new chemistry
- Commitment to prioritise projects with registrant approval and co-funding
- Meetings with regulators and registrants
- Cross commodity communication
- Circulation of other annual industry priority lists

8 RECOMMENDATIONS – OPTIMAL TIMELINES

8.1 Process and review timelines

Defined timeframes are needed in the minor use system for:

- Industry requests
- SARP annual updates
- Prioritisation
- Registrant consultation
- APVMA previews
- Project approvals
- Tendering
- Data generation
- Permit consolidation and submissions
- APVMA reviews

It is recommended that permits continue to be granted initially for 2-3 years, not four years. Providing an extra year for completion of data generation, is unlikely in my view to result in either earlier, or more complete, data generation. It risks further delays and promotes long-term reliance on permits.

As proposed in the regulatory reforms (from 2014) incomplete submissions should not be accepted. Poor submissions consume scarce resources, and the APVMA and HAL project leaders should consider a maximum time period over which such submissions can be re-worked, before their rejection/withdrawal by either.

The APVMA often reviews 'acceptable' timelines for reviews and responses to enquiries. Response to enquiries, not necessarily answers, within three working days, is recommended. The timeliness of minor use evaluations could be improved by APVMA-allocated submission periods, scheduled at the time of initial permit approval or at the contracting of data generation projects. The scheduling would reduce the log jams. Late submissions would be accommodated but their timely review, not assured. It is expected that there will be both a financial impact on minor crop industries and a time impost on the review/response time for minor use submissions, when proposed regulatory changes are enacted in 2014.

Like investors in the minor use programme, the APVMA as reviewer and regulator, also has reason to consider a priority track for complete, crop group-supported, high priority submissions and those that include 3 or more minor crops on a new label, in addition to emergency requests. In order to continually re-fresh the solutions available to vegetable industries, the criteria for fast-tracked reviews might also consider the nature of the chemistry (low risk, proprietary, IPM compatible) and number of potential beneficiaries.

Suggested timelines within the revised minor use process are shown in Table 14.

Table 14 : Key activity timelines and responsible parties

Activity	Timeframe	Responsible party
Industry needs received, collated.	Annual - 6 months before Prioritisation Workshop (Four months before IAC meeting and funding decisions)	AUSVEG Minor use leader Stakeholders
SARP updates; regulatory, strategic expert input; registrant consultation	1-2x/year for crop groups; completed 3 months before Prioritisation Workshop	HAL strategic input leader; industry reference/expert group
Registrant and APVMA preview of regional request lists	1.5 months before Prioritisation Workshop	AUSVEG minor use leader with registrants and APVMA
Rationalised regional lists Prioritisation Workshop invitation	1 month before Prioritisation Workshop	AUSVEG minor use leader; skilled reference group, crop reps
National prioritisation Signed approval for off-label work	At Prioritisation Workshop (July - same time each year)	AUSVEG minor use leader Registrants
Priority solution requirements - data	1 week after Prioritisation Workshop	AUSVEG minor use leader; APVMA
Industry reviewed priorities Approvals - weighted criteria	1month after Prioritisation Workshop	Representative peak industry committees
DATA GENERATION Registrant consultation Tenders prepared	2 months post-prioritisation	HAL, with PMUC data
Quotes reviewed Service providers contracted	As soon as possible	HAL, PMUC, IAC
a) Trials established Oversight of trials	Regularly in spring/summer On-going over 18 months	HAL contracted service providers PMUC position
b) Desktop permits	On-going over 9 months	HAL-contracted desktop project leader
PERMIT RENEWALS Relevant industries aware of expiry and data expected Registrants advised (5 for generics) Industry feedback requested	Rolling 12 months before permit expiry - quarterly	APVMA Applicant PMUC AUSVEG minor use leader Permit holder
Collated industry feedback (minimum threshold) Documented justification of continued need	Rolling 9 months before expiry	HAL and AUSVEG minor use leader Relevant stakeholders
Data status Submitted to applicant Insufficient/no data No data needed	8 months before expiry	Permit holder - HAL contracted desktop project APVMA advised of data status
Packages submitted	5+ months before expiry	Permit holder; desktop project
APVMA decision on permit extension (when no data prepared) Industry/AUSVEG Minor use leader advised	3 months before expiry	APVMA, HAL
APVMA queries, problems	Addressed within 3 days	All parties

9 RECOMMENDATIONS – REVISED KEY ROLES

9.1 The vegetable industry

In order to increase industry ownership of minor use activity, the vegetable industry would have lead roles and responsibilities in industry education, engagement, communication and prioritisation. Refer also to Sections 5-8.

9.1.1 AUSVEG Minor Use leader

- It is recommended that both the awareness and responsiveness of the vegetable stakeholders be significantly increased.

The appointment of a technically-competent, agronomist or horticulturist to this position would allow the vegetable industry to drive the minor use programme. The AUSVEG minor use leader would have the principle role within the system, to the stage of completed prioritisation, from which the HAL projects would subsequently springboard.

This position would influence both the structure and operation of HAL minor use efforts. Success parameters should include stakeholder awareness and utilisation of the new central contact point for minor use, more informed industry requests, early registrant engagement and input, and industry prioritisation of justified needs with a high chance of success. An early role would be to review with the APVMA and HAL all vegetable permits. There are at present too many under management.

The responsibilities within this key position could include:

- Facilitation of grower education about the minor use programme
- Engagement of growers (by region and nationally) in the requirements of an informed, collective request for permitted off-label uses
- Progression of an annual, on-line system for minor use requests
- Consultation on strategic agrochemical review process (SARPs) with HAL project leader on strategic solutions
- Engagement of specialists, registrants and APVMA on potential solutions
- Rationalisation and collation of requests by pests/crops/proposed solutions for Prioritisation Workshop
- Conducting the annual Prioritisation Workshop with informed participants
- Registration of registrant approval for pursuit of priority solutions
- Consideration of budget for researchable projects including new technologies, proprietary newer and/or low risk chemistry
- Delivery of prioritised list to HAL as basis of HAL projects
- Capture and recording of industry justification for permit renewals as basis of HAL project (quarterly)
- Central facilitation of industry awareness communication on all minor use advice, outputs and issues, including strategic awareness, compliance, trade issues

The AUSVEG minor use leader may benefit from the support of regional resources/experts to ensure national awareness and reach in the prioritisation process. Ideally state department or university crop/pest experts could be engaged on a fee-for-service basis as required, as their networks are often more extensive than those of local consultants and growers.

With the vegetable industry assuming a central, lead role, and other projects being in response to industry prioritised needs, the repositories of important crop/pest/solution knowledge would

correctly be held within the industry, rather than being held largely by a third party individual, as in the current PMUC position.

This industry leadership position for minor use will be the driver of the system up to the completion of the Prioritisation Workshop and delivery of the industry-approved, high priority researchable project list to HAL.

9.1.2 Vegetable growers

- A revised minor use system will be reliant on significantly increased proactive engagement, input and responsiveness of vegetable growers.

Vegetable growers with the assistance of the AUSVEG minor use leader, consultants, researchers, and technical offices should:

- Identify the most important pest problems needing new/revised management and control
- Investigate the problem extent, affected crops, potential solutions
- Submit collective (crop group or multiple sponsors), informed requests with supportive information, to the regional or AUSVEG minor use leader
- Engage expert advice on potential solutions
- Interact closely with the industry AUSVEG minor use leader
- Ensure informed representation at the Prioritisation Workshop
- Ensure commodity group financial support and commitment to the high priority researchable projects
- Respond in timely manner and as required to justify on-going permits
- Comply with all conditions of off-label chemical use.

9.2 Horticulture Australia Limited

- The key roles for HAL in a revised minor use system would exist within several projects. They are recommended to be in: data acquisition and management, submission and permit management, and strategic and tactical development.

HAL itself has a key role and expertise in portfolio management. HAL is an essential minor use process enabler, rather than driver but at times it has had to assume both roles. If the vegetable industry assumes its correct leadership role and drives the programme through the completion of the prioritisation process, HAL could then focus on projects in data management, submissions, and industry development through strategic and tactical awareness and activity. Under a compartmentalised revised minor use system, accountability for tasks and performance will be more easily evaluated as all tasks in industry prioritisation would be led by AUSVEG, and data management, by HAL. The role of the HAL Portfolio Manager in a revised minor use structure could ideally return to coordination and liaison with project leaders, rather than day-to-day business of the system.

Should a national minor use programme be developed at a later date, it is noted that HAL would likely retain roles in resource allocation and coordination, but may have reduced management obligations.

The revised minor use structure as perceived and recommended by this investigator, would continue to require multiple HAL projects, in addition to the appointment of the *AUSVEG minor use leader*:

1. *Data generation coordination project* and on-going review of permit/label change status/database. It would rely on SARP awareness; data consolidation and tender preparation; registrant, regulator and service provider engagement and consultation, and submission consolidation and review.
2. *Strategic pesticide awareness project* – a cross industry project that ensures SARPs are current, on-going (pre- and post-prioritisation) awareness of regulatory changes nationally and internationally; new technologies, products and threats to industries; resistance development; and cross–industry priorities in minor use.
3. *Desktop submission project* – new permits, renewals and consolidation of submissions (and potentially database management depending on terms of project).
4. *Permit holder project* – unless a national holder of permits is agreed; database management.

The existing HAL projects (MT10029, desktop, permit holder, data generation) have numerous tasks that would remain relevant in the revised system, although with different assignment. In the revised compartmentalised system the responsibilities of the PMUC would relate primarily to the data management and submission steps, while the strategic expert would be central to updating SARPs and awareness across industry, and across all related projects. HAL communication will be required between HAL project leaders, the AUSVEG minor use leader, registrants, the APVMA and other authorities.

A structured and well-implemented prioritisation process should see the HAL projects commence with an informed priority list that has registrant, regulator and commodity group/industry sign-off on approval to pursue and data generation requirements. The tender process conceivably would become a straightforward extension of this information, with background data available and protocols approved. Tenders could more reliably be released at the same time each year, as is the current intention. A release time in spring, would ensure more immediate commencement of field work. Training of service providers in research is not a necessary HAL project task, but the training in preparation of tender quotes has been useful.

9.2.1 Strategic pesticide awareness

SARP awareness is a requirement of each proposed HAL project. The HAL strategic project leader should have ‘cross industry’ status and responsibilities to ensure opportunities for shared R&D, resistance threats, regulatory changes and international progress on crop groupings and MRLs are widely known. This role should also include the sharing with other annual industries high priority project lists, and mechanisms by which unrecognised pests and pesticide issues can be reported. An example of increased awareness (via the cotton industry), proactive strategic response and co-investment has been seen recently with the approval by VTAG of investment in a green peach aphid resistance project with the University of Melbourne.

It is recommended that the HAL strategic project leader be in regular communication with New Zealand and Australian regulatory authorities, Food Standards Australia and New Zealand (FSANZ), DAFF’s Biosecurity Services Group, CODEX, and has formal links with the global joint reviews and international chemical expert panels and minor use programmes. Establishing a relationship with NZ authorities, in partnership with APVMA is recommended for early action.

9.3 National regulator

The APVMA role is important in providing smooth passage through the latter steps in the MU programme. It is essential that APVMA has confidence in the communication route to industry stakeholders. The APVMA knowledge of legislative changes, changes in acceptance of crop groupings and representative crops, chemicals under review, compliance issues and delays in the permit system must reach the industry. Correspondence confined to applicants is limiting so

strong relationships with HAL and AUSVEG minor use leaders, as well as registrants, are essential.

It is presumed APVMA will be a beneficiary of the Coalition government's election campaign commitment (September 2013) of $8 million to minor use. The details are unknown but investment to support data generation for proprietary chemistry use on minor crops, and several timeframe and fee waiver incentives, would be valuable.

9.4 Partnerships

Partnerships have the potential to improve cost effectiveness, build capacity regionally and nationally, and increase the number and timeliness of outputs. The existing participants in the minor use programme are industry stakeholders, HAL, AUSVEG, APVMA, the Australian government, registrants, and service providers. However there are few true partnerships in the programme beyond the industry-government one.

Partnerships that share resources and deliver mutual benefits through research, development, communication and education, were once established but have been lost with the decline in respect afforded applied research. Universities and state departments now pursue multi-disciplinary projects that have potential to result in refereed journal publications. The Inter-regional Project 4 (IR-4) programme in comparison relies on land grant university commitment to applied field trials, seen by the institutions as a service to constituents and a teaching tool for students and technicians. The co-contributions of time, resources and expertise by each, delivers broad benefits. The US Dept of Agriculture, State agriculture experiment station and industry direct contributions to the IR-4 program in 2011, were US $18 million. Indirect contributions were of the same magnitude.

The Australian grains industry through Grains Research and Development (GRDC) has formed a partnership with Plant Health Australia (PHA) to coordinate data generation field trials for Category 25 label changes, and there may be potential for this to extend beyond grains.

Partnerships to be built or strengthened in the minor use programme are those between:

- Registrants, the vegetable industry and HAL.

Registrants must be confident there is access to industry support and prioritisation (or 'value') if proprietary chemistry is to be approved earlier for use on minor crops; and resistance management is to be more successful.

- APVMA, DAFF, HAL and industry

It is recommended that these parties work together to review as soon as possible:

  - all minor use vegetable permits
  - the potential to introduce financial and timeframe incentives into the MU programme
  - the likely impact of the proposed regulatory changes on minor crop industries reliant on generic chemistry

- Levied and non-levied vegetable industries

The association between levied and non-levied vegetable industries is not strong, despite each having similar challenges. In the minor use system there are examples of mutually-beneficial data sharing and opportunities to achieve more of this should not be lost. The regulator has reportedly used non-levied industry data to strengthen levied industry applications and consolidated permits have included levied and non-levied crops. While there is some objection to the continuation of this practice on the basis of inequitable investment, it is my recommendation this be reconsidered, with a fee-for-service or voluntary contribution option for payment where levy funds are not available. This opinion is based on recognition that:

  - partnerships need to be built in order to expand the number of beneficiaries of vegetable permits/labels
  - fast-tracked reviews of submissions may rely on whole crop groups or representative crops (some of which may not be in levied industries)
  - future data generation reductions are more likely to be offered to whole crop groups and representative crops
  - representative crops in expanded global crop groupings do not consider which crops are levied in Australia
  - data-sharing across levied and non-levied industries is occurring and mutual benefits have been derived
  - co-investment with non-vegetable industries (eg. grains) may deliver cost efficiencies and maximise the number of beneficiaries
- APVMA, FSANZ and the New Zealand regulator

Although outside this brief it is recommended that these authorities confer on the potential for Australia to recognise more NZ crop protection product registrations, and on the potential to share prioritisation processes and data generation research, as occurs between Canada and the United States.

10 RECOMMENDATIONS – INVESTMENT DECISIONS

10.1 Governance

Proposed within the revised minor use structure, are more visible components of accountability and good governance: industry justification feedback, logical and transparent prioritisation, circulated priority lists, documented consultation, tracked data generation progress etc. An accessible database hosted by APVMA, that provides information on the status of submissions, would also add a valuable level of accountability.

The tender and selection process for data generation and desktop project service providers have been audited and are evidence of current good governance. Proponent merit, cost and trial details are considered in their selection. Project leaders provide milestone and final reports in addition to their confidential GLP reports. It is recommended that project funding decisions follow a formal and transparent process (Section 10.3).

The minor use system has imposed upon it some equity issues that result from 'control of use' variations across jurisdictions.

10.2 Funding needs

It is recommended that the total annual vegetable minor use budget be set in advance of prioritisation. Forth-coming considerations in a revised HAL minor use structure would include funding for:

- **Stakeholder education** - on the minor use process and resistance management
- **AUSVEG-appointed minor use leader**
- **Prioritisation process** - including consultation, communication, Prioritisation Workshop
- **Five HAL-industry projects** – AUSVEG minor use; data generation; strategic; desktop; and permit holder
- **High priority researchable projects**
- **Resistance management** - R&D and cross-industry commitments

The recommended education campaign on the minor use steps has been previously discussed and should be considered for funding as soon as possible. The campaign may be on-going with various areas of understanding initially being the focus:

  - understanding the minor use process
  - grower/industry stakeholder role in the minor use process
  - stewardship and the development of resistance
  - 'control of use' differences and implications

The AUSVEG minor use leader and the prioritisation process are new recommendations that will require funding.

An external review of all active minor use vegetable permits, and of submissions that have stalled longer that a year in APVMA, should be undertaken as soon as possible to determine if the industries or production systems still require the permits, and if the stalled projects warrant or need further investment to achieve an outcome.

It is expected that registrants under the proposed regulatory changes, will be required to submit older chemistry for regular (every 5-7 years) reviews. It is unlikely they will support such reviews if their generic chemistry is not delivering commercial value. The implication is that minor crop industries may as a result lose access to old chemistry. The vegetable Industry Advisory Committee (IAC) will need to evaluate the relative value of the products as they may

be asked to co-fund the reviews, in order to retain access to the products that would otherwise be removed from the marketplace.

The APVMA permit assessment fee if fully costed would be significantly higher than it is at present. The APVMA fee for renewals is $350, and heavily subsidised by the fees paid by registrants for product labels and registrations. Should the APVMA move to a full cost recovery system, the IAC can anticipate higher submission evaluation fees.

10.3 Funding high priority researchable projects

It is appropriate that the vegetable industry invest in the MU programme via levy contributions. It is also appropriate that these funds be matched by the Australian government in recognition of the public good associated with the responsible and legal use of pesticides on food crops. Those consulted in this review agree that investment in the minor use programme should continue at a significant level.

Most stakeholders recognise that the budget for gaining minor use approvals is not unlimited, and that investments in generic chemistry permit maintenance may not deliver the returns that investment in delivery of proprietary and lower risk chemistry, can. In recent years, there have been few new permit requests or label extensions for proprietary products, integrated pest management (IPM) compatible products, new technologies or biopesticides.

There are several means by which the focus of investment could be altered. The preferred way is via prioritised funding. In the IR-4 program, budgetary constraints drive competitive negotiations for industry prioritised projects. Some international minor use schemes also consider a maximum number of trials/pest category (weeds, diseases, and insects) or per crop group. Others limit the total number of permits that may be held for the same chemical group. This ensures on-going replacement of chemistry and progression of available solutions that are also useful strategies in resistance management.

In Australia, there has been a tendency to accommodate most industry requests and investment in minor use has therefore fluctuated in response to the length of the wish list, rather than in response to strategic and prioritised needs. A pre-determined budget limit, increased vegetable industry ownership of the scheme, and a competitive prioritisation process, would transparently guide investment into projects that address industry priorities and deliver desired industry development outcomes.

With an understanding that the vegetable industry would benefit from access to more proprietary and low risk chemistry, that industry requests are usually for permits and renewals, and that discretionary funds are usually maintained for emergencies, it is expected that negotiations with registrants and industry groups could be competitive in the prioritisation process, and in funding allocations. Low priority projects should not reach the IAC, nor enter funding consideration.

10.3.1 Structured decision-making

Registrant partnerships in minor use would be increased if it were made known that each year the IAC would allocate some funds for co-funded data generation projects for proprietary chemistry, low risk products, and/or new technologies. When the predicted cost and number of high priority researchable and renewal projects exceed the pre-determined budget, the IAC would be assisted in decision-making by multi-criteria analysis (MCA). It is useful in complex projects and can accommodate a wide range of user needs and sophistication. Professional support in this process would initially be helpful.

In the revised minor use structure, stakeholders would provide input to the prioritisation (of solutions) process, while industry representatives on the IAC, would prioritise their allocation of funds to high priority approved projects, that also meet industry goals, on the industry's behalf.

Of the many possible steps in sophisticated MCA assessments, some that may allow the IAC to transparently rank projects for funding on 'merit' (meeting industry goals), are:

- *Defining the objectives of the decision*
  - the industry goal targeted by the decision making
- *Defining the 'options'*
  - the options are the high priority projects identified in the prioritisation process
- *Defining the 'criteria'*
  - the agreed set of criteria that collectively determine project 'merit'
- *Weighting the criteria*
  - the relative importance of each component of 'merit'
- *Assigning the criteria 'performance values' or ratings*
  - scoring (often 1-5) each criterion for each option (project)
- *Ranking of options*
  - the sum of scores for 'weighting x rating' for all criteria in each project

The IAC may require professional assistance in this process, e.g. to determine the criteria and weightings assigned. For the purpose of furthering discussion of this methodology within the IAC, examples and suggestions are given below and in Table 15.

The selection criteria should be guided by the industry development goals and objectives of the industry's minor use programme. They should be determined by the IAC and will be different for permit renewal projects and projects with potential to deliver new registrations. The weighting of the criteria should reflect the industry goals.

Some over-riding restrictions may also be set prior to decision-making. For example it may be agreed in advance that three co-funded projects for proprietary chemistry data generation will be funded each year. This may be addressed in the criteria weightings or it may be addressed by removing such projects from the total list of options for independent ranking of the top three, with those ranked lower returned to the general MCA for further consideration. It might also be agreed in advance that two regionally-specific projects will be supported each year on the basis of regional comparative merit, and that all emergency requests will be funded. It is also likely that a list may be created for early elimination of projects, from funding consideration, e.g. those for chemicals proposed for review, those with high risk of resistance or ground water contamination etc.

The criteria will need to be determined by the IAC each year, and they may include:

- Product registration potential
- Crop group inclusion – number of crops
- Product life and environmental impact – low risk vs. high risk chemistry
- Permit replacement
- Chemistry ownership – generic, proprietary
- Total cost at net present value
- Project timeframe – e.g. > 3 years and < 3 years
- Registrant co-funding - percentage of cost
- Non-vegetable industry co-funding –as percentage of cost
- Urgency of use – damage/year
- Beneficiary value – number saving $/year

Each criterion for each project is rated (1-5) with 1 being the lowest preference (e.g. high risk chemistry, no chance of registration, few beneficiaries etc.). Some criteria may require measurable sub-criteria for example in project cost it might be helpful to know the cost/year so that the duration of impact on the minor use programme can be considered. Similarly it might be important to know the percentage of project cost contributed by co-funders.

The IAC agrees the weightings and individual members assign ratings for each criterion for each project, delivering therefore individual project rankings for collective IAC discussion.

Table 15 illustrates the MCA outcome of two different projects, by one evaluator. The weightings reflect the industry desire for softer, new chemistry registrations.

Project "A" is an expensive one that registrants have agreed to co-fund 50:50 for a newer chemical that is registered on several major crops, but no vegetables. It would however replace a generic chemistry permit. The product has some reported resistance issues overseas.

Project "B" is a new permit request for a generic product to satisfy three minor crops in one crop group.

The MCA outcome transparently reveals Project A warrants (on the basis of 'merit') funding over Project B, and also the potential impact and importance of the agreed and assigned weightings.

Table 15 : Example - Decision Matrix with MCA analysis

Ranking for purpose (points)	Weighted criteria (W) (1-10)[y]	Project A		Project B	
Rating for project (1[x]-5)		Rating (R)	Wt (W x R)	Rating (R)	Wt (W x R)
Product registration potential	9	5	5x9 = 45	1	1x9 = 9
Crop group inclusion	3	4	4x3 = 12	2	2x3 = 6
Product life and environmental impact	10	2	2x10 = 20	5	5x10= 50
Permit replacement	5	4	4x5 = 20	1	1x5 = 5
Chemistry ownership	4	4	4x4 = 16	1	1x4 = 4
Project total cost	8	2	2x8 = 16	5	5x8 = 40
Co-funding - registrant	6	5	5x6 = 30	1	1x6 = 6
Co-funding - another industry	5	1	1x5 = 5	1	1x5 = 5
Urgent of access	7	3	3x7 = 21	3	3x7 = 21
Beneficiary value	5	3	3x5 = 15	2	2x5 = 10
Project merit ranking (Weight points)			**1 (200)**		**2 (156)**

[x] Individual criteria ratings: 1= least preferred; 5- most preferred

[y] IAC agreed weightings: 10 = most important to industry; 1 least important to industry

10.4 Investment in stewardship

Stewardship is more than resistance management. It incorporates illegal use and occupational health and safety also. Resistance management is not a regulatory consideration and it therefore must be addressed by the vegetable industry, HAL and registrants.

The manufacturers and registrants of crop protection products invest significant funds in R&D, chemistry development and product marketing. The effective life of a registered product is influenced by its use patterns, chemistry, efficacy and alternative chemistry available. Protecting the effective life of products requires management of resistance development. Registrants and re-sellers have a number of strategic 'tools' that limit product availability for minor uses and on minor crops: the label (e.g. specified maximum application number/crop; consecutive applications etc.); packaging (e.g. size, price and volume); manipulated supply (e.g. shelf windows and off-shelf periods); and co-pricing with biological or soft chemistry alternatives.

Normal vegetable growing cycles threaten product stewardship because permitted products may legally be used on multiple, overlapping crops, every season. The vegetable industry should consider industry 'tools' to assist with product stewardship. In the interest of maintaining access to pesticides and sustainably using them, the vegetable industry must assume a higher level of engagement and leadership in resistance management. It is also recommended that HAL continue their support of relevant projects in this area, and consider involvement in cross industry initiatives in stewardship and training. As a minimum, it must be assured that the CropLife references on registered product labels are included also on all permits.

Some vegetable producers are not adequately aware of product stewardship and of the CropLife Australia (CropLife) resistance management strategies. CropLife is the peak industry organisation representing Australia's agricultural chemical and plant biotechnology sector. Its members are developers, manufacturers and formulators of crop protection products and they invest more than $13 million each year on stewardship programmes that include drumMUSTER®, ChemClear® and Agsafe Accreditation and Training. For more details: www.croplifeaustralia.org.au.

It would be sensible for AUSVEG and HAL to continue reinforcing resistance management messages. Communication regarding resistance development, monitoring and management should routinely reach industry stakeholders. Industry members should be provided with regular educational reminders about resistance management and the impact of mis-use of products on the on-going access to permits and effective chemistry; and on the benefits of IPM, surveillance and monitoring, and record keeping. On-farm awareness is essential for early detections of resistance, and also new pest threats.

Awareness of resistance build up in pest populations on other annual crops, and in other regions is essential knowledge that could be collated in the HAL cross-industry strategic expert project or by a select committee formed by the RDC Chairs. The information would be incorporated into SARPs, R&D planning and budgets, and into all industry communiqués.

10.5 Co-investment

It has been difficult for the vegetable industry to realise co-investment opportunities, as the current decision-making is somewhat reactionary and there is no national minor use programme. The vegetable industries to-date have not collectively prioritised and they remain largely unaware of the opportunities for co-investment across industries. Service providers have reported that co-investment opportunities exist between vegetable and non-vegetable crops but often they become apparent after projects have been contracted. It is presumed the HAL cross-industry strategic expert project could address this. The circulation of approved priority lists by

annual crop industries has been recommended and may prove useful in realising these opportunities, before contracting.

Cross industry, shared investment may also become increasingly available as plant industry signatories to the Emergency Plant Pest Response Deed (EPPRD) address their biosecurity obligations. Some industries with similar exotic threats may share the R&D required to develop several shelf permits, as part of their biosecurity preparedness.

The co-funding arrangements with international schemes have not proven fruitful. It is not my view that pursuit of these for co-funding or shared data generation trials is as important as maintaining awareness of the global marketplace, and of the product priorities in the schemes and global joint reviews. Where co-funding benefits are more likely are with New Zealand through engagement with their authorities and with HortResearch funding, much of which is received via HAL.

10.6 Marketing investment

There is no evidence, or broadly expressed opinion, that suggests the vegetable industry should actively invest in marketing agricultural products requested or intended for use by vegetable growers. This would presumably require a marketing levy and those paying such a levy generally expect their contributions to be directed to the marketing of produce.

Market research for new chemistry is the domain of crop protection manufacturers. In order to engage registrants in the minor use programme however, the provision of more accurate crop acreage and use pattern data would be useful and some of this may justify some limited 'market research'. There may also be a case for assistance in bringing agricultural products that would not otherwise reach it, to the vegetable marketplace. The supermarket preferred spray programmes however are more influential in this area.

11 RECOMMENDATIONS – SUMMARY

Until a national minor use system is developed, it is recommended that the current vegetable minor use programme (multiple projects and various activities) be revised to address industry ownership, informed participation and responsiveness, goal-focussed decision-making and required consultation.

The segmentation of projects and activity would see:

- the vegetable industry appoint an AUSVEG minor use leader with responsibility for:
  - Industry prioritisation process
  - Industry education and engagement
  - Communication

- HAL manage:
  - Data generation
  - Submission and permit management
  - Strategic and tactical development

More specifically the recommendations include:

- A formal prioritisation process and Prioritisation Workshop
- Five defined levy-funded projects
- Increased industry education and engagement
- Tighter timelines and consequences
- Revised key roles
- Structured decision-making
- Required communication and feedback loops
- Required consultation with registrants and APVMA
- Increased strategic awareness
- Investment in resistance management
- Immediate investment in stakeholder education, appointment of the AUSVEG minor use leader, and a review of existing vegetable permits.

There are also recommendations relevant to the national regulator regarding the:

- Development of an APVMA database for stakeholder access
- Engagement with New Zealand authorities
- Potential submission incentives and scheduling of submissions

12 TECHNOLOGY TRANSFER

The initial opinions and thoughts developed during this review were shared with HAL and AUSVEG at a Melbourne meeting on August 13, 2013. The presentation is attached in Appendix 7.

Through wide consultation in this review there has been on-going sharing of opinions. It is not expected that formal extension of the opinions will occur but stakeholder appreciation of the complexity of the minor use programme would be increased by reading this report.

13 CONCLUSIONS

The minor use system for vegetables is currently effective and serving many stakeholders. The recommendations primarily address industry participation and inefficiencies in the programme. The recommended revised minor use system is underpinned by significantly increased engagement, informed input and responsiveness of vegetable growers, with the formal prioritisation of industry requests being central to subsequent activity and progress through the system.

14 REFERENCES

Documents consulted were HAL and AgAware Pty Ltd internal documents.

Other references are cited within the body of the text as hyperlinks.

Acknowledgements

We express our thanks to HAL and the vegetable industry for their support of this project. We are particularly grateful to Mr Will Gordon and Jodie Pedrana and for the time and expertise they have shared with us and for the guidance they have provided on this project. Consultation has been extensive and we appreciated the time each registrant, service provider, industry committee member gave us. I am particularly indebted to Peter Scholefield and Cheryl Jenkins for their editing and administrative input.

SCHOLEFIELD ROBINSON
HORTICULTURAL SERVICES PTY LTD

PA McMICHAEL
Principal Consultant/Plant Pathologist

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Appendix 1

Review Brief

Extract from:

VG12105 HAL contract with Scholefield Robinson Horticultural Services Pty Ltd
Approved June 5, 2013

Overall purpose of the Review
Objectives:

- To document all current processes, roles and structures associated with pesticide management investment through the vegetable industry R&D program and then recommend improvements including:

  - To review and recommend streamlined, independent processes with appropriate governance with respect to industry consultation on Minor Use Permits or pesticide registration investment, including agreement on optimal timelines (timing is critical as delays lead to additional costs and liability issues)

  - To review and recommend improvements in the commissioning process for minor use and chemical registration projects (including a review of the tender process and also the processes between PMUC and Growcom)

  - Develop parameters/guidelines to assist the industry to determine, with respect to pesticide registrations:
    - Appropriate levels of investment (if any, depending on the nature of the pest, crop, pesticide, market size etc) and

    - What aspects of research (suggest registration process and registration) that are and are not appropriate for the industry to fund (ie. marketing)

  - To review and recommend possible changes to the groupings of crops that are used by APVMA and others with respect to permits

  - To assess and improve our involvement with the IR-4 and other international programs

  - To assess and recommend what role the industry and representative body, manufacturers and HAL, should play in managing chemical resistance issues.

The review will assess achievements to date across each of the objectives and where appropriate, gain an understanding of any successes, difficulties and challenges in meeting each objective.

The review will include evaluations of:

- The process by which investment decisions are agreed
- The process by which the vegetable industry identifies permit priorities
- The timeframes that would optimize the commissioning, development and collation of data adequate to support new, emergency, renewed and revised permits.

Appendix 2

Consultation List

Consultation undertaken as part of this review

Name	Organisation
REGISTRANTS	
Sean Richardson	Syngenta Crop Protection Pty Ltd
Richard Lillingstone	BASF
Nicoletta Childs*	Chemtura
Bronwyn Vorpagel*	CropCare Australasia Pty Ltd
Paul Downard	Dow Agroservices
Luc Streit	Sumitomo
Ben Coombe	Nufarm Australia Limited
Doug Wilson	Nufarm Australia Limited
REGULATORY	
Alan Norden	APVMA
Judy Pattermann	Bayer Crop Science Pty Ltd
Ben Stapley	CropLife Australia
Alison MacGregor	External reviewer - APVMA
HAL PORTFOLIO MANAGEMENT	
Jodie Pedrana	HAL
Will Gordon	HAL
VEGETABLE INDUSTRY	
VTAG members	Vegetable Industry Advisory Group
Kevin Clayton-Greene	VTAG
Jeff McSpedden	VTAG and IAC
Richard Mulcahy	AUSVEG
Tim Shue	AUSVEG
Dean Schrieke	AUSVEG
SERVICE PROVIDERS	
Kevin Bodnaruk	AKC Consulting
Phillip Frost	Peracto Pty Ltd
Les Mitchell	Agri-search Pty Ltd
Kathryn Adams	Agri-search Pty Ltd
Dale Griffin	Crop Protection Research Pty Ltd
Rosemary Henderson	Protech Consulting
Janine Clark	Growcom
Peter dal Santo	AgAware Pty Ltd
OTHER SCHEMES and INDUSTRIES	
Alan Norden	APVMA
Rebecca Sisco, UC Davis	IR-4 Western Region Co-ordinator
Daniel Botts	Minor Crop Farmer Alliance USA – by email
Nicholas Woods	Plant Health Australia
Winegrapes	AWRI
Pistachios	PGAI

*Regulatory role within corporate manufacturer

Appendix 3

Product Generation Costs – Example

Reference : http://ir4.rutgers.edu/StrategicPlanningConference/efficacy.pdf

New Product Selection and Development

Stage 1 - Synthesis And Screening

Herbicide Synthesis | Fungicide Synthesis | Insecticide Synthesis | External Sources

100,000 Candidates/Year : High Throughput Screen

↓

15,000 Candidates/Year : Optimization

↓

Greenhouse Screen : 5-6,000 Candidates

↓

Stage 1F Field Screening
50-100 Candidates/Year

Development of a Crop Protection Product

Year	0	1	2	3	4	5	6	7	8	9	Costs (mUSD)
Chemistry											~ 70
Active Ingredient	Synthesis			Process development							
Formulation		Synthesis optimisation				Pilot production		Production			
		Formulation & Packaging									
Biology											~ 80
Discovery/Profiling		Lab & Greenhouse						Scientific Support			
			Field Validation								
Development & Registration				Global Field Trials					Optimisation		
Toxicology											~ 50
Mammals		Acute, sub-chronic, chronic, mutagenic, carcinogenic, teratogenic, reproduction									
Environment				Algae, *Daphnia*, fish, bird, micro-organisms, bees, beneficials, non-target organisms							
Environment											
Metabolism		Plants, animals, soil, water, air									
Residues				Plants, animals, soil, water, air							
Substances	15'000	500	10	3	2	1	1	1	1	1	~ 200

Appendix 4

International Minor Use Scheme information

Reference 4 (a) http://ir4.rutgers.edu/gmus/presentation%20pdf/day%204%20Kunkel.pdf

Reference 4 (c) Workthemes – Global Minor Use Summit 2
http://www.fao.org/fileadmin/user_upload/agns/news_events/2_final_report_GMUS_12-08-05.pdf

The IR-4 Project

The IR-4 Regulatory Clearance Process

Stakeholder:

- Define Pest Problem
- Identify Pest Management Solution
- Request Assistance from IR-4

The Process Starts with Requests

Submitted from:

- Growers,
- Grower Groups,
- State/Federal Research & Extension Personnel

Request Reviewed by Manufacturer

Requests Prioritized

(Top Priority Researched That Year

Second Priorities Researched as Money Allows)

Field and Lab Research

- Measure Residue levels in Crop/ Crop Group
- Top Priorities completed in 30 months

Data Submitted to EPA

Risk Assessment

Tolerance Established by EPA

Manufacturer Adds Crop to the Product Label

The IR-4 Regulatory Clearance Process

Stage III
Food Crops

- **Priorities are Determined at Annual IR-4 Food Use Workshop**

Stakeholder:

Define Pest Problem

Identify Pest Management Solution

Request Assistance from IR-4

The Process Starts with Requests

Submitted from:

- Growers,
- Grower Groups,
- State/Federal Research & Extension Personnel

Request Reviewed by Manufacturer

Requests Prioritized

Top Priority Researched That Year

Second Priorities Researched as Money Allows

IR-4 Western Region - Priority Setting Tools

PST Instructions

Project Clearance Requests
New Project Requests (41) (August 2012-present)
Make a project request on the IR-4 national website (for next season)
Search national IR-4 database for existing projects and requests

Reports
2013 Projects: Residue, Efficacy, All Studies
Off Table Projects (316)
Efficacy Projects: Fungicides (79), Herbicides (75), Insecticides (38)

IPM-fit
Western Region A & A/B Projects: Report with IPM-fit comments

PST Conference Calls
June 3, 2013 10:00 AM to noon Pacific Time
August 6, 2013 10:00 AM to noon Pacific Time

2014 Potential Projects

All IR-4 potential projects: PST-All (468)

All by Type: Fungicides (163), Herbicides (164), Insecticides (141)

Western Region Priority Projects: PST-WR sorted by Crop (180) or by Priority

WR by Type: Fungicides (53), Herbicides (59), Insecticides (68)

Reports Updated:9/9/2013 6:55:30 AM

Source: Priority setting tools IR-4 Western Region http://wrir4.ucdavis.edu/pst/

Table 1. Work plan: Themes and tasks resulting from the breakout groups and participants.

Theme 1 Coordination & Collaboration	**Theme 2** Communication	**Theme 3** Incentives
1.1 Global priority setting process for minor uses • Establish group to explore feasibility of having global priority setting process/meeting 1.2 Databases • Expand existing databases to capture global minor use grower needs/priorities • Expand existing databases to document available minor use data for registration • Investigate the feasibility of having a new single global needs database 1.3 Participation in joint initiatives 1.4 GMU Steering Committee • Establish membership • Identify experts to do feasibility study on database with TOR	2.1 Enhancement of the GMU Portal • Expand GMU portal to include links to various databases currently available from various sources 2.2 Risk communication • Identify and review existing risk communication tools by national authorities, FAO and other organizations • Provide available material on the GMU Portal for dissemination 2.3 Benefit communication • Identify available materials 2.4 Establish list of (and networks of) existing working groups • List will be added to GMU Portal	• Monitor implementation and uptake of regulatory incentives • Promote and implement new incentives as they are developed 3.1 Funding structures and programs • Document existing structures and programs • Develop and release guidance on the establishment of national and regional programs 3.2 Import MRLs • Collect and review existing import tolerance setting procedures • Develop and release guidance on the process for seeking import MRLs 3.3 Authorization procedures and requirements • Document existing authorization procedures and requirements • Monitor new procedures that add value to minor uses 3.4 Economic • Document existing economic incentives 3.5 Liability • Document and assess existing programs addressing liability wavers • Explore possibility of having a meeting of legal experts of government and industry to advise on issues related to liability
Red = short term items (12 months),	Green medium term items	(24-36 months), Blue long term items (5 years)

Table 1. Work plan: Themes and tasks resulting from the breakout groups and participants.

Theme 4 Capacity Development	**Theme 5** Registration of Minor Uses and MRL setting
Tasks: 4.1 National and regional capacity • Disseminate information on existing pesticide and pest management tools (e.g., extrapolation methods, crop grouping, IPM) • Facilitate the strengthening or establishment of new regional expert working groups that support minor use issues • Develop and implementation new tools and guidance • Establish sustainably operating regional expert working groups for minor uses 4.2 Engage policy makers to implement regulatory initiatives • Include decision makers at technical meetings or workshops to demonstrate importance of implementation of technical inputs 4.3 Establish national minor use programs • Provide guidance to national authorities on design and implementation of minor use programs 4.4 Encourage greater participation in data generation • Initiate collaborative projects to better participate in Codex processes (e.g., crop grouping, data submissions, MRL setting process) • Implementation of collaborative projects • Stakeholder engagement in data generation and other areas to support minor uses 4.5 Provide guidance on Codex processes	**Tasks:** 5.1 Harmonized data requirement and submission documents 5.2 Crop Grouping (residue and efficacy) • Explore possibility of establishing a working group to develop a guidance document on efficacy data under CCPR • Hold meeting to explore efficacy crop grouping -Consult existing schemes such as EPPO 5.3 JMPR capacity building • JMPR capacity building as an agenda item at CCPR • Explore possible funding sources for JMPR • Expanding JMPR expert panel to include broader representation 5.4 Transparency in registration decisions 5.5 Working towards common MRLs • Side meeting at April 2012 CCPR to discuss barriers to harmonization • Support and involvement for Crop grouping at CCPR and representative crops • Develop questionnaire through the electronic Working Group on Minor Uses/CCPR on import MRL setting by national authorities • Urge regulatory bodies to utilize Codex standards
Red = short term items (12 months), **Green** medium term items (24-36 months), Blue long term items (5 years) CCPR = Codex Committee on Pesticide Residues JMPR=Joint WHO/FAO Meeting on Pesticide Residues	

Appendix 5

Crop Grouping Information

Extract from

INDEX OF CROPS/CROP GROUPS/CROP SUBGROUPS, AND CROP DEFINITIONS
August 23, 2012

Crop Groups and Subgroups - Number and Name	Representative Commodities	Commodities
1. ROOT AND TUBER VEGETABLES	Carrot, potato, radish, and sugar beet	Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; beet, garden; beet, sugar; burdock, edible; canna, edible; carrot; cassava, bitter and sweet; celeriac; chayote (root); chervil, turnip-rooted; chicory; chufa; dasheen (taro); ginger; ginseng; horseradish; leren; parsley, turnip-rooted; parsnip; potato; radish; radish, oriental; rutabaga; salsify; salsify, black; salsify, Spanish; skirret; sweet potato; tanier; turmeric; turnip; yam bean; yam, true.
1A. Root vegetables subgroup	Carrot, radish, and sugar beet	Beet, garden; beet, sugar, burdock, edible; carrot; celeriac; chervil, turnip-rooted; chicory; ginseng; horseradish; parsley, turnip-rooted; parsnip; radish; radish, oriental; rutabaga; salsify; salsify, black; salsify, Spanish; skirret; turnip
1B. Root vegetables (except sugar beet) subgroup	Carrot and radish	Beet, garden; burdock, edible; carrot; celeriac; chervil, turnip-rooted; chicory; ginseng; horseradish; parsley, turnip-rooted; parsnip; radish; radish, oriental; rutabaga; salsify; salsify, black; salsify, Spanish; skirret; turnip.
1C. Tuberous and corm vegetables subgroup	Potato	Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chufa; dasheen (taro); ginger; leren; potato; sweet potato; tanier; turmeric; yam bean; yam, true
1D. Tuberous and corm vegetables (except potato) subgroup	Sweet potato	Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chufa; dasheen (taro); ginger; leren; sweet potato; tanier; turmeric; yam bean; yam, true
Crop Group 1 Crop Definitions	A	B
	Radish, oriental,	*Raphanus sativus* var. *longipinnatus* (root and tops), including Chinese

	roots	or Japanese radish (both white and red), winter radish, daikon, lobok, lo pak, and other cultivars and/or hybrids of these
	Radish, oriental, tops	*Raphanus sativus* var. *longipinnatus* (root and tops), including Chinese or Japanese radish (both white and red), winter radish, daikon, lobok, lo pak, and other cultivars and/or hybrids of these
	Sweet potato	Sweet potato, yam
2. LEAVES OF ROOT AND TUBER VEGETABLES (HUMAN FOOD OR ANIMAL FEED)	Turnip and garden beet or sugar beet	Beet, garden; beet, sugar; burdock, edible; carrot; cassava, bitter and sweet; celeriac; chervil, turnip-rooted; chicory; dasheen (taro); parsnip; radish; radish, oriental (daikon); rutabaga; salsify, black; sweet potato; tanier; turnip; yam, true
3-07. BULB VEGETABLE GROUP	onion, bulb; onion, green	Chive, fresh leaves; chive, Chinese, fresh leaves; daylily, bulb; elegans hosta; fritillaria, bulb; fritillaria, leaves; garlic, bulb; garlic, great-headed, bulb; garlic, serpent, bulb; kurrat; lady's leek; leek; leek, wild; lily, bulb; onion, Beltsville bunching; onion, bulb; onion, Chinese, bulb; onion, fresh; onion, green; onion, macrostem; onion, pearl; onion, potato, bulb; onion, tree, tops; onion, Welsh, tops; shallot, bulb; shallot, fresh leaves; cultivars, varieties, and/or hybrids of these
3-07A. Onion, bulb, subgroup	onion, bulb	Daylily, bulb; fritillaria, bulb; garlic, bulb; garlic, great-headed, bulb; garlic, serpent, bulb; lily, bulb; onion, bulb; onion, Chinese, bulb; onion, pearl; onion, potato, bulb; shallot, bulb; cultivars, varieties, and/or hybrids of these
3-07 B. Onion, green, subgroup	onion, green	chive, fresh leaves; chive, Chinese, fresh leaves; elegans hosta; fritillaria, leaves; kurrat; lady's leek; leek; leek, wild; onion, Beltsville bunching; onion, fresh; onion, green; onion, macrostem; onion, tree, tops; onion, Welsh, tops; shallot, fresh leaves; cultivars, varieties, and/or hybrids of these
Crop Group 3-07 Crop Definitions	A	B
	Onion	Bulb onion; green onion; and garlic
	Onion, bulb	Bulb onion; garlic; great headed garlic; serpent garlic; Chinese onion; pearl onion; potato onion; and shallot, bulb

	Onion, green	Green onion; lady's leek; leek; wild leek; Beltsville bunching onion; fresh onion; tree onion, tops; Welsh onion; and shallot, fresh leaves
	Garlic	Garlic, great headed; garlic, and serpent garlic
3. BULB VEGETABLES	Onion, green; and onion, dry bulb	Garlic; garlic, great-headed; leek; onion, dry bulb and green; onion, Welsh; shallot
4. LEAFY VEGETABLES (EXCEPT BRASSICA VEGETABLES)	Celery, head lettuce, leaf lettuce, and spinach	Amaranth (Chinese spinach); arugula (roquette); cardoon; celery; celery, Chinese; celtuce; chervil; chrysanthemum, edible-leaved; chrysanthemum, garland; corn salad; cress, garden; cress, upland; dandelion; dock (sorrel); endive (escarole); fennel, Florence; lettuce, head and leaf; orach; parsley; purslane, garden; purslane, winter; radicchio (red chicory); rhubarb; spinach; spinach, New Zealand; spinach, vine; Swiss chard
4A. Leafy greens subgroup	Head lettuce and leaf lettuce, and spinach	Amaranth; arugula; chervil; chrysanthemum, edible-leaved; chrysanthemum, garland; corn salad; cress, garden; cress, upland; dandelion; dock; endive; lettuce; orach; parsley; purslane, garden; purslane, winter; radicchio; spinach; spinach, New Zealand; spinach, vine
4B. Leaf petioles subgroup	Celery	Cardoon; celery; celery, Chinese; celtuce; fennel, Florence; rhubarb; Swiss chard
Crop Group 4 Crop Definitions	A	B
	Lettuce	Lettuce, head; and lettuce, leaf
	Lettuce, head	Lettuce, head; crisphead varieties only
	Lettuce, leaf	Lettuce, leaf; cos (romaine), butterhead varieties
	Endive	Endive, escarole
	Celery	Celery, Florence fennel (sweet anise, sweet fennel, finochio) (fresh leaves and stalks only)

5. BRASSICA (COLE) LEAFY VEGETABLES	Broccoli or cauliflower; cabbage; and mustard greens	Broccoli; broccoli, Chinese (gai lon); broccoli raab (rapini); Brussels sprouts; cabbage; cabbage, Chinese (bok choy); cabbage, Chinese (napa); cabbage, Chinese mustard(gai choy); cauliflower; cavalo broccolo; collards; kale; kohlrabi; mizuna; mustard greens; mustard spinach; rape greens
5A. Head & Stem Brassica subgroup	Broccoli or cauliflower and cabbage	Broccoli; broccoli, Chinese; brussels sprouts; cabbage; cabbage, Chinese (napa); cabbage, Chinese mustard; cauliflower; cavalo broccolo; kohlrabi
5B. Leafy Brassica greens subgroup	Mustard greens	Broccoli raab; cabbage, Chinese (bok choy); collards; kale; mizuna; mustard greens; mustard spinach; rape greens
Crop Group 5 Crop Definitions	A	B
	Brocoli	Broccoli, Chinese broccoli (gia lon, white flowering broccoli)
	Cabbage	Cabbage, Chinese cabbage (tight-heading varieties only)

	Turnip tops or turnip greens	Broccoli raab (raab, raab salad), hanover salad, turnip tops (turnip greens)
6. LEGUME VEGETABLES (SUCCULENT OR DRIED)	Bean (*Phaseolus*) (succulent & dried), pea (*Pisum*) (succulent & dried) and soybean	Bean (*Lupinus*) (includes grain lupin, sweet lupin, white lupin, and white sweet lupin); bean (*Phaseolus*) (includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean); bean (*Vigna*) (includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean); broad bean (fava); chickpea (garbanzo); guar; jackbean; lablab bean; lentil; pea (Pisum) (includes dwarf pea, edible-podded pea, English pea, field pea, garden pea, green pea, snowpea, sugar snap pea); pigeon pea; soybean; soybean (immature seed); sword bean
6A. Edible-podded legume vegetables subgroup	Any one succulent cultivar of edible-podded bean (*Phaseolus*) & any one succulent cultivar of edible-podded pea (*Pisum*)	Bean (*Phaseolus*) (includes runner bean, snap bean, wax bean); bean (*Vigna*) (includes asparagus bean, Chinese longbean, moth bean, yardlong bean); jackbean; pea (*Pisum*) (includes dwarf pea, edible-podded pea, snow pea, sugar snap pea); pigeon pea; soybean (immature seed); sword bean
6B. Succulent shelled pea and bean subgroup	Any succulent shelled bean cultivar (*Phaseolus*) and garden pea (*Pisum*)	Bean (*Phaseolus*) (includes lima bean, green; broad bean, succulent); bean (*Vigna*) (includes blackeyed pea, cowpea, southern pea); pea (*Pisum*) (includes English pea, garden pea, green pea); pigeon pea
6C. Dried shelled pea and bean (except soybean) subgroup	Any one dried cultivar of bean (*Phaseolus*) and any one dried cultivar of pea (*Pisum*)	Dried cultivars of bean (*Lupinus)* ; bean (*Phaseolus*) (includes field bean, kidney bean, lima bean (dry), navy bean, pinto bean, tepary bean); bean (*Vigna*) (includes adzuki bean, blackeyed pea, catjang, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean); broad bean (dry); chickpea; guar; lablab bean; lentil; pea (*Pisum*) (includes field pea); pigeon pea
Crop Group 6 Crop Definitions	A	B
	Bean	*Cicer arietinum* (chickpea, garbanzo bean); *Lupinus* spp. (including sweet lupine, white sweet lupine, white lupine, and grain lupine).

		Phaseolus spp. (including kidney bean, lima bean, mung bean, navy bean, pinto bean, snap bean, and waxbean); *Vicia faba* (broad bean, fava bean); *Vigna* spp. (including asparagus bean, blackeyed pea and cowpea)
	Bean, dry	All beans above in dry form only
	Bean, succulent	All beans above in succulent form only
	Pea	*Cajanus cajan* (includes pigeon pea); *Cicer* spp. (includes chickpea and garbanzo bean); *Lens culinaris* (lentil); *Pisum* spp. (includes dwarf pea, garden pea, green pea, English pea, field pea, and edible pod pea). [Note: A variety of pesticide tolerances have been previously established for pea and/or bean. Chickpea/garbanzo bean is now classified in both the bean and the pea categories. For garbanzo bean/chickpea only, the highest established pea or bean tolerance will apply to pesticide residues found in this commodity.]
	Pea, dry	All peas in dry form only
	Pea, succulent	All peas in succulent form only
7. FOLIAGE OF LEGUME VEGETABLES	Any cultivar of bean (*Phaseolus*), field pea (*Pisum*) and soybean	Plant parts of any legume vegetable included in the legume vegetables that will be used as animal feed.
7A. Foliage of legume vegetables (except soybean) subgroup	Any cultivar of bean (*Phaseolus*) and field pea (*Pisum*)	Plant parts of any legume vegetable (except soybeans) included in the legume vegetables group that will be used as animal feed.
8-10. FRUITING VEGETABLE GROUP	Tomato, standard size, and one cultivar of small tomato; bell pepper and one cultivar of small nonbell pepper	African eggplant; bush tomato; bell pepper; cocona; currant tomato; eggplant; garden huckleberry; goji berry; groundcherry; martynia; naranjilla; okra; pea eggplant; pepino; nonbell pepper; roselle; scarlet eggplant; sunberry; tomatillo; tomato; tree tomato; cultivars, varieties, and/or hybrids of these
8-10A. Tomato subgroup	Tomato (standard size and one cultivar	Bush tomato; cocona; currant tomato; garden huckleberry; goji berry; groundcherry; naranjilla; sunberry; tomatillo; tomato; tree tomato;

	of small tomato)	cultivars, varieties, and/or hybrids of these
8-10B. Pepper/Eggplant subgroup	Bell pepper and one cultivar of small nonbell pepper	African eggplant; bell pepper; eggplant; martynia; nonbell pepper; okra; pea eggplant; pepino; roselle; scarlet eggplant; cultivars, varieties, and/or hybrids of these
8-10C. Nonbell pepper/Eggplant subgroup	One cultivar of small nonbell pepper or one cultivar of small eggplant	African eggplant; eggplant; martynia; nonbell pepper; okra; pea eggplant; pepino; roselle; scarlet eggplant ; cultivars, varieties, and/or hybrids of these
8. FRUITING VEGETABLES (EXCEPT CUCURBITS)	Tomato, bell pepper, and one cultivar of nonbell pepper	Eggplant; groundcherry (*Physalis* spp); pepino; pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); tomatillo; tomato
Crop Group 8 Crop Definitions	A	B
	Tomato	Tomato, tomatillo
	Pepper	All varieties of pepper including pimento and bell, hot, and sweet pepper
9. CUCURBIT VEGETABLES	Cucumber, muskmelon, and summer squash	Chayote (fruit); Chinese waxgourd (Chinese preserving melon); citron melon; cucumber; gherkin; gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra); *Momordica* spp (includes balsam apple, balsam pear, bittermelon, Chinese cucumber); muskmelon (includes cantaloupe); pumpkin; squash, summer; squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); watermelon
9A. Melon subgroup	Cantaloupe	Citron melon; muskmelon; watermelon
9B. Squash/Cucumber subgroup	One cultivar of summer squash and cucumber	Chayote (fruit); Chinese waxgourd; cucumber; gherkin; gourd, edible; Momordica spp; pumpkin; squash, summer;squash, winter
Crop Group 9 Crop Definitions	A	B

	Melon	Muskmelon, including hybrids and/or varieties of *Cucumis melo* (including true cantaloupe, cantaloupe, casaba, Santa Claus melon, crenshaw melon, honeydew melon, honey balls, Persian melon, golden pershaw melon, mango melon, pineapple melon, snake melon); and watermelon, including hybrids and/or varieties of (*Citrullus* spp.)
	Muskmelon	*Cucumis melo* (includes true cantaloupe, cantaloupe, casaba, Santa Claus melon, crenshaw melon, honeydew melon, honey balls, Persian melon, golden pershaw melon, mango melon, pineapple melon, snake melon, and other varieties and/or hybrids of these.)
	Squash	Pumpkin, summer squash, and winter squash
	Squash, summer	Fruits of the gourd (*Cucurbitaceae*) family that are consumed when immature, 100% of the fruit is edible either cooked or raw, once picked it cannot be stored, has a soft rind which is easily penetrated, and if seeds were harvested they would not germinate; e.g., *Cucurbita pepo* (i.e., crookneck squash, straightneck squash, scallop squash, and vegetable marrow); *Lagenaria* spp. (i.e., spaghetti squash, hyotan, cucuzza); *Luffa* spp. (i.e., hechima, Chinese okra); *Momordica* spp. (i.e., bitter melon, balsam pear, balsam apple, Chinese cucumber); *Sechium edule* (chayote); and other cultivars and/or hybrids of these

Source: **http://ir4.rutgers.edu/other/CropGroup.htm**

With Crop Grouping

Tolerances for many crops can be established with fewer residue studies, resulting in a more efficient registration process.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-NIFA, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

United States Department of Agriculture
National Institute of Food and Agriculture

Agricultural Research Service

6/12

International Crop Grouping Consulting Committee

Chairperson:
B. Barney (IR-4)
Advisors:
J. Baron (IR-4) - Technical
B. Schneider & B. Madden (EPA) - Regulatory
L. Rossi, S. Funk (EPA) & Erica Muller (the Netherlands), - CODEX
D. Kunkel (IR-4) & S. Wong (PMRA) - NAFTA
M. Doherty & W. Donovan (EPA) - ChemSAC
J. Wiersema (USDA/ARS) - Commodity Taxonomy
S. O'Toole (USDA/APHIS) - Commodity Importation
J. Herndon (EPA) - Government & Public Liaison
P. Schwartz (USDA/ARS) - Technical

Crop Group Workgroup Chairpersons:
M. Arsenovic, W. Barney, J. Baron, M. Braverman, K. Dorschner, D. Kunkel, C. Palmer, K. Samoil, V. Starner, D. Thompson

IR-4/EPA Crop Grouping Working Group

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For more information on the Crop Grouping Project and its participants visit the IR-4 website at:
www.ir4.rutgers.edu

The IR-4 Project

The IR-4/EPA Crop Grouping Project

An International Effort

Crop Grouping Project

Crop grouping in the U.S. is a well accepted and cost effective approach that facilitates the efficient establishment of pesticide tolerances for both major and minor crops. The purpose of Crop Grouping/Classification is to facilitate the establishment of Maximum Residue Limits (MRL) on crop groups and to provide maximum crop protection with minimum effort. The US crop grouping regulation has brought great benefit to growers, researchers, agri-chemical companies as well as regulatory agencies since 1983.

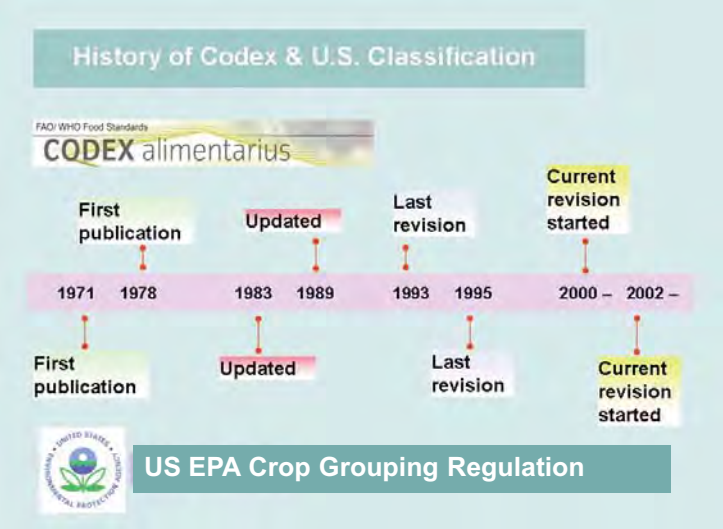
IR-4 has been a major contributor of data and research resources for crop grouping since the concept began in 1971. The current crop grouping scheme includes about 500 crops and was published in the Federal Register in 1995. In 1998, IR-4's G.M. Markle and J.J. Baron, together with EPA's B.A. Schneider, published the second edition of *Food & Feed Crops of the United States* (MeisterPro Reference Guides, 1998), which provides crop monographs and instructions on the use of crop grouping for residue studies.

With the rapid development of global food crop markets and import/export activities, an expansion of the crop grouping scheme is warranted. In 2002, the USDA/IR-4 International Crop Grouping Symposium proposed to expand the current scheme through adding significant numbers of "new crops" and "crop groups". In 2003, the IR-4/EPA Crop Grouping Working Group was established to bring these proposals to federal regulation. To assist this effort, an International Crop Grouping Consulting Committee (ICGCC) was established in 2004, which included crop, regulatory and agri-chemical experts representing about 40 countries.

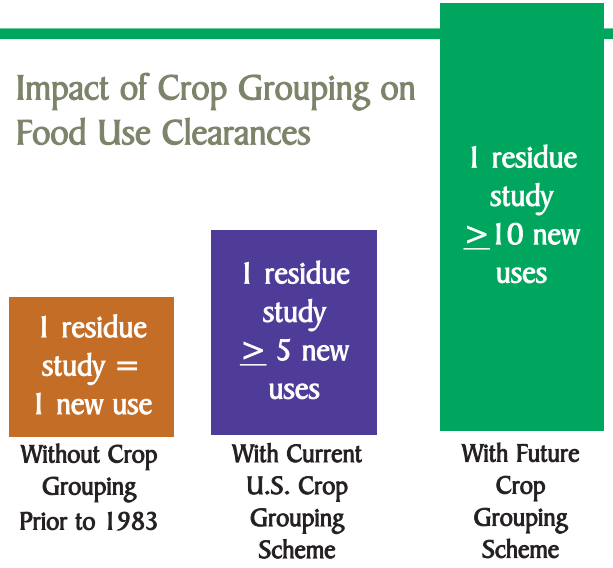
This effort has significantly promoted the harmonization of US and Codex crop classification systems. Since 2005, the Chairperson of the ICGCC and a representative of the Codex crop classification revision have worked closely in creating a joint proposal for an extended revision of the Codex Classification of Foods and Animal Feeds. The acceptance and use of representative commodities by Codex is particularly important for growers of specialty crops because of the considerably more efficient use of scarce resources to develop regulatory data on these crops. After six years of effort a huge milestone was achieved this year. The CCPR agreed to forward the first set of completed commodities to the Codex Commission for implementation, which will revise the Classification of all fruit commodity groups. This group includes peaches, plums, cherries and other stone fruit, apples, pears and other pome fruit, blueberry, cranberry raspberry and other berries/small fruit, and assorted tropical and subtropical fruits. The CCPR also decided to fully implement the use of crop groups and representative commodities for all fruit commodity groups.

ICGCC Participants

Argentina
Australia
Bangladesh
Belgium
Brazil
Burkina Faso
Canada
Chile
China
Columbia
El Salvador
France
Germany
Guatemala
Honduras
Hungary
India
Israel
Japan
Kenya
Lebanon
Mali
Mexico
Morocco
New Zealand
Nicaragua
Nigeria
Republic of Korea
Senegal
South Africa
St. Kitts
Taiwan
Thailand
Trinidad
United Kingdom
United States



Impact of Crop Grouping on Food Use Clearances



Benefits of a Harmonized Crop Classification System

- Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and Countries - save time on data review and standardize MRL determination
- CCPR/CAC - facilitate commodity trade by setting MRLs on harmonized crop groups
- Growers - have more access to pest control products and increased capacity to export commodities
- Consumers - have better access to safer specialty crop produce
- Manufacturers - save time and cost on supervised trials based on crop groups & subgroups
- A harmonized effort today will prevent a duplication of efforts in the future

Appendix 6

New Permit Request Form

Request for new pesticide access in vegetable crops

Complete 3 pages and submitted on-line to:

AUSVEG Minor Use leader at:---------- or

Regional coordinator at: ----------

Date submitted: ----------

By: ----------

This request has been prepared by: _____

In conjunction with: _____

Your position in the industry is: ----------

This request has in principle support (sponsorship) from:

☐ Crop group ☐ Focus group ☐ Crop expert ☐ Registrant of product ☐ Other

Provide contact details for each 'sponsor'.

_____

_____

_____

Has a similar request been filed by you or your sponsors before?

Please not your request will be prioritised amongst others at the **Prioritisation Workshop** on _____.

It is important you document the scientific and industry support for this request and that your industry has informed representatives to advocate for the best solutions to crop problems, at the National Prioritisation Workshop.

For more details please contact _____.

REQUEST FOR PEST, DISEASE, WEED off-label SOLUTIONS

QUESTION	RESPONSE
Crop problem Correct name of pest, disease, weed Identified by	
Acreage affected	
Frequency of problem	eg. Not known, new to region, new on crop
Other crops affected Locally Region State	
Possible solutions identified Solutions currently in use? Registered solutions? effective? Other solutions?	☐ Attached data
Solution preferred? Chemical Biological Is it registered for use on other crops?	
Nature of request (describe output) Permit Registration Emergency response	
Scope of request Crop group Representative crop Individual crop	
Trade awareness MRL established?	
Crop exported?	
Permit holder	
Treated crop bi-products? Reach animals?	
Supermarket approved use likely?	
Any other comments?	

SPECIFIC DETAILS			
CHEMICAL REQUESTS			
Class of chemical			
Registered on any vegetable crops?	Yes	No	
Registered for use in NZ?			
Chemical use , efficacy awareness Personally trialled on crop?	eg. How, when? results?		
Research trials? Attach data, source	Yes	No	
	eg. Who? Where? Crop? IPM compatible?		
Proposed use pattern?	eg. Rates, frequency, stage of growth, pre-harvest interval		
Other chemicals used in production of your crop?			
Chemicals in same chemical group as requested solution?			
Potential area over which requested solution might be applied?	Year 1	Year 2	
Pest/disease resistance been seen? Reported?			
REGISTRANT COMMENTS Name		Signed	
AUSVEG MU leader comments			
BIOLOGICAL/BIOCIDE REQUESTS			
Chemical use, efficacy awareness Personally trialled on crop? Data/details	eg. How, when? results?		
Research trials? Data/details	eg. who? where? crop? IPM compatible?		
Would the biocide fit your production program?	Explain		
REGISTRANT COMMENTS Name:		Signed	
AUSVEG MU leader comments			

Appendix 7

Milestone Presentation to AUSVEG

VG12105 - Review of pesticide investment in the vegetable industry

PRUE McMICHAEL
Scholefield Robinson Horticultural Services

This project has been funded by HAL using the vegetable industry levy and matched funds from the Australian Government.

AUSVEG and HAL
Melbourne August 13, 2013

Horticulture Australia

Terms of Reference

REVIEW: Current processes, roles, structures

RECOMMEND streamlined processes:
Industry Consultation – on permits, investment, timelines
Improvements - commissioning of projects; PMUC and Growcom

DEVELOP guidelines – investment decisions

REVIEW – crop groupings

ASSESS – involvement with IR4 and others

Horticulture Australia

Current situation - Complexity in the Minor Use programme

- CROP NUMBER and ACREAGE
- REGIONAL DIFFERENCES

- UNDERSTANDING of PROGRAMME
- ENGAGEMENT and CONSULTATION

- COST OF REGISTRATION
- RETURNS on INVESTMENT
- LIABILITY
- RISK – RESISTANCE, NON-COMPLIANCE

- LEGISLATION

Current situation – Pros and Cons

Pros	Cons
Aims are sound	Slow, expensive, complex – on-going
Legal use of products	Engagement limited
Government support	End users not drivers
Beneficiaries are growers	Disincentives for registrants
Decisions include growers (through VTAG, IAC)	No clear prioritisation
	Renewals> new labels
	Applied R&D and resources
	Co-operation, co-investment
	Legislative complications

Horticulture Australia

General Steps in the Current Process

CROP PROTECTION PRODUCT NEEDED?

POTENTIAL SOLUTIONS - permit? Who decides?

DATA in SUPPORT? Who finds/collates? Assesses validity?

a) Data acceptable; extrapolation
SUBMISSION FOR NEW PERMIT
SUBMISION FOR EMERGENCY PERMIT
APVMA REVIEW ⇨ PERMIT *

b) More data needed and provided –
Crop safety? efficacy? residues?
SUBMISSION FOR NEW CROP ON LABEL
SUBMISSION FOR NEW LABEL
*SUBMISISON FOR RENEWAL
APVMA REVIEW ⇨ PERMIT

Steps in the Process

EACH STEP HAS:

- Components reliant on input from others
- Critical, but different timeframes
- More than one invested and interested party
- Different costs and contributors
- Decision-making constraints

Examples of components of process

CROP NEEDS?

- Consideration of:
  - Crops affected, acreage, frequency
  - Potential solutions – Proprietary, generic? efficacy?
    Reliance on pesticides changed
    SARPs? legal? unknown?
  - Permit? - timeframe, justification
  - Support? – other crops? registrants? international?
- Limitations
  - General understanding of the process
  - Timely engagement
  - Industry prioritisation

Examples of components of the Minor Use process

DATA BACKGROUND – Who contributes? Who drives this?

- Existing? Universities, state departments, manufacturers, APVMA, overseas
- Suitable? APVMA preview, industry use patterns, rates
- Available? Non-levied crop? Manufacturers – protected data?
- Strategic? Replaces old chemistry? IPM compatible?

Limitations
- **Clear roles - Consultation**
  Vegetable industry - who? how?
  Registrants – how many for a generic?
  APVMA; other data holders
- **Disincentive to share data**
- **Decision making** with/without full knowledge?

Examples – components of the Minor Use process

MORE DATA NEEDED and GENERATED

Generating data:
- Early collation by crop group?
- Protocols? confirmed by registrants? Cross-checked industry?
- Tenders offered; competitive? awarded on merit? evidence,Yes
- Expensive with/without registrant support
- Equitable? if prioritised by industry
- Timeframes agreed? enforced?

- Advance to submission – two projects: Growcom; AgAware
- Limitations – Few service providers, no university engagement
  Communication – cross industry; within/between projects
  Data and review delays
  APVMA scheduling?

Registrant support?

- In principle support usually
- Financial support not often provided because:

Disincentives of Minor Use participation >> incentives

Commercial imperative – local, global
Limited data protection
Generic products – multiple suppliers, buying groups,
no guarantee of returns
Budgeted investment for new chemistry
Awareness of opportunities
Crop group more appealing than individual crops
Overseas data acceptance
Stewardship principles
Liability incurred with any use

Why do few permits advance to labels ?

- Permits are cheaper
- Permits have finite life, but renewal 'can be anticipated'
- Renewal data less than label extension requirement
- APVMA cannot force label/registration
- APVMA does not offer financial incentives
- Relationships not built between industry, DAFF, APVMA
- Need a simpler path to a label

Implications: Now - permit 'maintenance' project
Limited refreshing of permits/crop
Late entry of new chemistry, technology, to minor crops
Production constraints, esp. QA industries

Terms of Reference

REVIEW: Current processes, roles, structures

RECOMMEND streamlined processes:
Industry Consultation – on permits, investment, timelines
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DEVELOP guidelines – investment decisions
REVIEW – crop groupings

ASSESS – involvement with IR4 and others

Considerations: Process improvements

EDUCATION – Showcase and workshop the system to growers
ENGAGEMENT – Industry within; with APVMA; across industry

Introduce a PRIORITISATION PROCESS

- *Stakeholder input essential – on-line requests with evidence of support, collation by crop group
- *Driven by the vegetable industry
- *Registrant input to prioritisation essential
- *Appoint Minor Use co-ordinator within industry
- Minor Use Projects - starting point post-prioritisation

Aim for: Industry ownership through collective prioritisation - technical consultants, registrants, key growers, researchers

Consideration of process improvements

ROLES

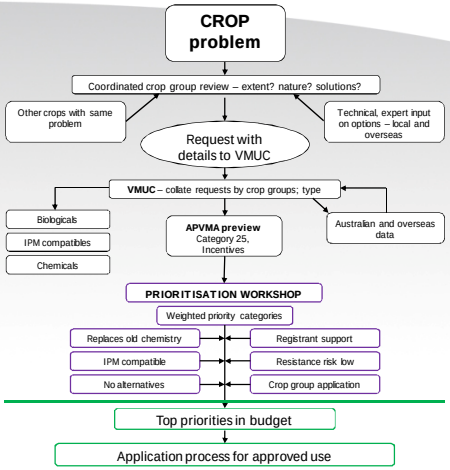
Vegetable industry – Drive engagement, Prioritisation
Vegetable industry - Renewals justification
Vegetable industry - Communication leader

Priority process communication - industry members, APVMA, other industries, data sources, researchers, IAC, VTAG, Registrants
Accessible database
Industry justification - renewals

Roles - continued

HAL – Liaison but not driver
*Cross industry technical leadership
Minor Use project – Data management, strategic
Tender and submission collation
Data generation oversight
*Scheduling with APVMA
*Data repository maintenance
*Strategic awareness development
Renewals project – Vegetable industry permit holder
Starting point – post-justification, 12 mths before expiry
Submission preparation
*Accessible database

Regulators – States, APVMA, DAFF (MRLs, CODEX, trade, IP)



Investment decisions on behalf of industry

NOW: **Review of all permits in vegetables**
Industry engagement with DAFF and APVMA
– incentives, scheduling, Category 25, efficacy data (NZ)

IN FUTURE:

- *Formal request system via Veg MU coordinator
- *Collective, weighted prioritisation – VTAG
- Science and risk underpinning – and strategic
- *Pre-determined budget; trials/year
- *Agreed Go/No Go points

Relies on - Clear priority setting guidelines
- Communication; industry awareness, engagement, input
- Assurances for high priorities – fast tracked? label incentives?

Incentives? Fast-track through process?

Reward – high priorities, timely complete, strategic submissions

Initiatives - for APVMA consideration:

- * Registrants conducting own residue studies (on generics)
- * Reducing efficacy data (as per NZ)
- * Scheduling APVMA submission time
- * Elevated priority/faster review by APVMA for:
  - Crop group submissions
  - IPM compatible, soft chemistry, low resistance potential
  - Cross–industry packages
- Registrant data protection
- Fee waiver for permits of 5+ years with full data – force label
- Reduction of renewal period
- Transparency

Reduce commitment? - Late, incomplete packages; individual submissions

Industry prioritisation criteria?

Weight the factors:

- Crop group support, relevance
- Regional need – damage potential
- Solutions – prior performance, safety, regulatory
- Strategic merit
- Compatibility – IPM, stewardship?
- Budget and resources – within limit?
- Scientific support – data sources, validity
- Cross-industry relevance? support?
- Registrant support
-

TIMELINES – suggested improvement

Critical – delays cost money and increase liability

* **Pre-determined timelines** are needed for:

- All consultation steps - documented
- Indicative industry budget decision
- Permit requests entered on-line
- Data review by crop group, technical committee
- Prioritisation – by veg industry
- Tender collation and preparation by the Minor Use project
- Data generation contracts (and APVMA scheduled)
- Renewal justification – by veg industry 12 months before expiry
- Renewal project submissions – 5 months before expiry
- APVMA advice on approval, deficiencies etc.

Terms of reference

- **REVIEW:** Current processes, roles, structures
- **RECOMMEND** streamlined processes:
- Industry Consultation – on permits, investment, timelines
- Improvements - commissioning of projects; PMUC and Growcom
- **DEVELOP** guidelines – investment decisions
- **REVIEW** – crop groupings
- **ASSESS** – involvement with IR4 and others

Related R&D and Investment

RESISTANCE MANAGEMENT

Registrant investment – CropLife, windows, pricing, volume tools

Industry investment – MU projects, projects in IPM program, cross-industry (aphids), monitoring (state departments)

To be continued?

YES, essential
- Embed in education, monitoring, strategic screening, reporting requirements
- Biosecurity – strategic review with prioritisation, shelf permits?
- Advice on permits as per labels (CropLife)?

MARKETING – no justification at present

Crop groupings

- **CODEX guidance** on these
- Crop grouping – components not as important as cohesion and collective prioritisation by crop group
- Canada – different groups with fruit and veg outdoors; fruit and veg indoors
- USA – priorities encompass crop group, eg. high priority need in leeks drives regulatory assessment and R&D for *Allium* spp. Label for crop group.

Related R&D

INTERNATIONAL MINOR USE SCHEMES

IR4 – USA

Key features – Regional, collective prioritisation; budget/resource limits 50-70 trials/yr; University role; 98% ⟹ label

Canada – Prioritisation to budget - trials/crop group/year; engaged with USA system

New Zealand – more products available in NZ. Efficacy difference

Engagement with international schemes? legislation, funding cycles, MRLs, value for money? time?

On-going consideration

- Decision matrix within a budget
- Communication – role, nature and route
- APVMA and DAFF partnership building
- Practical prioritisation – on-line, regional, national
- Education
- Practical incentives added into system
- International schemes – realistic engagement
- New roles – Vegetable industry MU coordinator?
- Impact of proposed legislative reforms – outside ToR

Consultation to-date

Final report due end of August 2013

Registrants

Syngenta – Sean Richardson
BASF – Richard Lillingstone
Chemtura - Nicoeltta Childs
CropCare –Bronwyn Vorpagel
DOW – Paul Downard
Sumitomo – Luc Streit
Nufarm –Ben Coombe, Doug Wilson

Service providers

Kevin Bodnaruk
Phillip Frost
Les Mitchell
Kathryn Adams
Andrew Keats
Rosemary Henderson
Dale Griffin

Other

AgAware
Growcom
HAL
Pistachio Growers (PGAI)
Alison MacGregor-reviewer