

VG97066

**National workshop on the registration of
pesticides for use on vegetables and
other minor crops**

**Peter Merriman, Gordon Berg
Agriculture Victoria, IHD Knoxfield**



Know-how for Horticulture™

VG97066

This report is published by the Horticultural Research and Development Corporation to pass on information concerning horticultural research and development undertaken for the vegetable industries.

The research contained in this report was funded by the Horticultural Research and Development Corporation with the financial support of the vegetable industry and the QFVG.

All expressions of opinion are not to be regarded as expressing the opinion of the Horticultural Research and Development Corporation or any authority of the Australian Government.

The Corporation and the Australian Government accept no responsibility for any of the opinions or the accuracy of the information contained in this report and readers should rely upon their own enquiries in making decisions concerning their own interests.

Cover price: \$20.00
HRDC ISBN 1 86423 903 4

Published and distributed by:
Horticultural Research & Development Corporation
Level 6
7 Merriwa Street
Gordon NSW 2072
Telephone: (02) 9418 2200
Fax: (02) 9418 1352
E-Mail: hrdc@hrdc.gov.au

© Copyright 1999



**HORTICULTURAL
RESEARCH &
DEVELOPMENT
CORPORATION**

**Partnership in
horticulture**



**Natural Resources
and Environment**

AGRICULTURE
RESOURCES
CONSERVATION
LAND MANAGEMENT



National workshop on the registration of pesticides for use on vegetables and other minor crops

**Final Report for the Horticultural Research and
Development Corporation**

**Project VG97066
(January 1999)**

Peter Merriman and Gordon Berg

**Agriculture Victoria, Institute for Horticultural Development,
Knoxfield, 1998.**

**(Agriculture Victoria is a business of the Department of
Natural Resources and Environment, Victoria.)**



AGRICULTURE
VICTORIA

A business of the
Department of
Natural Resources
and Environment

Project VG97066

Principal Investigators

Peter Merriman (Project leader – Agriculture Victoria)

Gordon Berg (Co-project leader – Agriculture Victoria)

Contact Details

Dr Peter Merriman

Institute for Horticultural Development

Private Bag 15

South Eastern Mail Centre VIC 3176

Ph (03) 9210 9222 Fax: (03) 9800 3521

Email: Peter.Merriman@nre.gov.au

Final Report prepared for the Horticultural Research and Development Corporation in completion of the project requirements.

FUNDING ACKNOWLEDGEMENTS

This project was funded by the Australian Vegetable Growers organisation (Ausveg), the Horticultural Research and Development Corporation (HRDC) and the Rural Industries Research and Development Corporation (RIRDC) and the Department of Natural Resources and Environment, Victoria (DNRE).

DISCLAIMERS

The advice provided in this publication is intended as a source of information only. Always read the label before using any of the products mentioned. This publication may be of assistance to you but the State of Victoria and its officers do not guarantee that the publication is without flaw of any kind or is wholly appropriate for your particular purpose and therefore disclaims all liability for any error, loss or other consequence which may arise from you relying on any information in this publication.

This report contains information on chemicals

Any recommendations contained in this publication do not necessarily represent current HRDC policy. No person should act on the basis of the contents of this publication, whether as to matters of fact or opinion or other content, without first obtaining specific, independent professional advice in respect of the matters set out in this publication.

Contents

| | |
|---------------------------------|----|
| 1. INDUSTRY SUMMARY | 4 |
| 2. TECHNICAL SUMMARY | 6 |
| 3. INTRODUCTION | 8 |
| 4. MATERIALS AND METHODS | 9 |
| 5. RESULTS AND DISCUSSION | 11 |
| 6. RECOMMENDATIONS..... | 12 |
| 7. ACKNOWLEDGEMENTS | 12 |
| 8. APPENDICES..... | 12 |

1. INDUSTRY SUMMARY

In January 98 a project was commissioned by Ausveg, HRDC and RIRDC to consider the issue of the issue of approvals for the use of pesticides on so called minor crops. Minor crops is a term which relates to the economics of pesticide registration. In most instances where the use pattern of a pesticide does not generate sales which exceed the cost of registering the product, then the chemical companies choose not to register the product for this purpose. This is referred to as a minor use. For smaller plant industries, particularly horticulture, the lack of suitable pesticides causes significant problems for growers when a pest occurs in the crop for which there is no suitable approved chemical treatment. Secondly if non approved chemicals are used then growers run the risk of failing the audit process under QA and usually cannot trade into that market.

In recognition of these problems this project aimed to develop better ways of approving the use of pesticides on minor crops.

It comprised three phases:

- (1) the commissioning of a limited survey of vegetable growers to demonstrate the extent of the minor use problem;
- (2) the organisation of a national workshop of stakeholders to seek solutions to the minor use problem and,
- (3) the development of recommendations for the establishment of a national minor use program.

Program leaders from minor use projects in California and the United Kingdom were funded to attend the national workshop which was held on 23/24 March 1998 at the Institute for Horticultural Development (IHD), Knoxfield. The workshop primarily addressed the problems of pest, disease and weed control which confronted vegetable industries, but there was also limited representation from other interested plant industry groups.

In attendance were Industry leaders, the Chemical industry and Avcare, Consultants and Resellers, the National Registration Authority, Government scientists and regulators and Funding agencies.

The introductory plenary sessions provided information on the current system and protocols for off-label use; perspectives from the vegetable and agricultural chemical industries and descriptions of minor use programs in the United Kingdom and the United States.

The overseas examples demonstrated the success of programs in geographically small countries like the UK and also in the United States where the wide range of crops and growing conditions are more like Australia. Information provided by the overseas speakers is being used to design an Australian program.

More than 50 delegates endorsed the development of a national program for approving the use of pesticides on minor crops in horticulture which would allow growers improved access to safe, cost effective chemicals.

The meeting requested that a blueprint be developed, incorporating the recommendations of the workshop which specified the infrastructure, processes and protocols required to establish a national program in Australia. The immediate consideration was for the Vegetable industries but there was also recognition that this would provide a model for use by other plant industry groups

The blueprint was completed in July 98 and circulated nationally to stakeholders for comment.

The report from the workshop and the blueprint are attached as a part of this final report

A Consultant's team (TS Agricultural Consultants Pty Ltd) is now further developing the blueprint for HRDC as part of a commissioned project comprising the next phase of the program.

2. TECHNICAL SUMMARY

One of the major problems confronting Horticultural industries nationwide is the availability of pesticides for effective control of pests, diseases and weeds. It arises because of the relatively small size of the businesses in question compared with larger plant industries such as the cereal and other grain industries. The economics of developing and registering pesticides are such that it is uneconomic when the projected returns from sales are less than the costs of registering the product on that particular commodity. For Horticulture this means that many groups are denied use of pesticides which are effectively and safely used in other larger industries. These so-called minor use problems potentially place growers in the invidious situation of the illegal use of pesticides most of which should be readily available. Non-approved use is also increasingly causing serious loss of income for growers. Examples of auditors refusing to sign off on QA protocols where non approved chemicals are used, frequently means that the grower is unable to trade unless data is produced which demonstrates zero residue of the compound in question.

The problem of minor use is not peculiar to Australia, and there are similar difficulties in the European Union and North America. However in these countries special initiatives have been established to resolve the problem and, through a combination of industry and government funded programs, many pesticides are now approved for use on minor crops.

This success was the catalyst for the development of this project which was funded by Ausveg, HRDC and RIRDC, as a one year initiative to evaluate the prospects of creating a National Minor Use Program for Australia.

The project was developed in three components:

- (1) identification of the minor use problem by industry survey;
- (2) convening a national workshop of stakeholders to analyse issues and seek solutions;
- (3) development of a blueprint which described the infrastructure, processes and protocols for the establishment of a minor use program in Australia.

A major feature of the project was the attendance at the workshop by the leaders of established minor use projects overseas. Dr Rick Melnicoe, Western Region Coordinator for the IR 4 Minor Use Program in USA; Dr Peter Chapman Technical Manager for the Pesticides Safety Directorate and Dr Martin McPherson Coordinator Field Program both of whom are involved in the Specific Off Label Approval program in the UK.

Selected surveys in Victoria and reports from other States confirmed that minor use issues were the cause of considerable problems for a range of industries. The workshop was oversubscribed and numbers were restricted to approximately 50 delegates from the Vegetable and Chemical industries, Consultants and Resellers, Government Scientists and Regulators and the National Registration Authority.

The workshop endorsed:

- the development of a National Minor Use Program for the Vegetable Industries and its subsequent extension to other Industries;

- the proposed model/flow chart of processes and protocols for minor use approvals; the establishment of an Office of Minor Use reporting to an Industry Steering Committee; and
- the progression to the next stage through the development of a blueprint which specifies the establishment of the program through an initial pilot stage.

The blueprint was completed by mid July and circulated nationally for comment. The blueprint and the report from the workshop are attached as appendices to this report.

3. INTRODUCTION

"Minor uses" and "off-label uses" of chemicals are significant concerns of the horticultural and other plant industries in Australia. The problem arises because there is little financial incentive for chemical companies to obtain the necessary residue and other data required to incorporate such uses on chemical labels.

Consequently many horticultural industries are denied access to effective pesticides which are registered for use in other plant industries. Application of such pesticides constitutes an illegal use in most States. This frequently causes problems under recently introduced QA systems where audits require that growers use approved chemicals. Where non approved chemicals have been used the grower fails the audit and usually cannot trade into the specified market until data is produced which demonstrates nil residues.

There are a number of initiatives in Australia which are dealing with the problem of minor use of agricultural chemicals in horticultural and other plant industries.

The National Registration Authority administers a Permit scheme which enables individuals or groups to seek approval for Off Label Use of Registered pesticides.

The scheme, although used by some sections of Industry, is generally not well understood, but nevertheless has the potential to provide a basis for the National Minor Use Program.

At the State level a number of industry associations have been active in documenting and seeking resolution of minor use issues. Queensland Fruit and Vegetable Growers (QFVG) has taken a strong leadership role in this area and has a comprehensive understanding of the problem.

The Commonwealth Department of Primary Industries and Energy has committed funds to establish a co-ordination role for minor use issues in the National Registration Authority; and a National Minor Use Steering Committee, which is convened by the NRA.

A third initiative concerns this project which HRDC and Ausveg have supported. It has been led by IHD and aimed to analyse the requirements for establishing a National Minor Use Program in Australia. The momentum for this arose in part from local interaction with growers, the chemical industry, and through discussions with NRA and HRDC, and also with scientists in the UK and California who have responsibility for implementation of successful minor use programs in horticulture.

4. MATERIALS AND METHODS

The project was developed in three components:

- (1) identification of the minor use problem by industry survey;
- (2) convening a national workshop of stakeholders to analyse issues and seek solutions;
- (3) development of a blueprint which described the infrastructure, processes and protocols for the establishment of a minor use program in Australia.

Survey

A survey of celery, lettuce, leek and spinach and parsley growers was conducted in February 1998. The survey was conducted by a confidential questionnaire distributed via Industry group meetings in Victoria and South Australia and personal visits to growers by extension staff.

22 completed questionnaires were received, comprising 6 celery growers, 9 lettuce growers, 6 leek growers and 1 spinach and parsley grower. The results were described and discussed at the National Workshop.

Workshop

The National Workshop on Approval of Pesticides for Minor Uses was held at the Institute for Horticultural Development, Knoxfield from 23 to 24 March 1998. It was attended by representatives from the national vegetable industry, the chemical industry, government agencies, program managers from HRDC and RIRDC and four visiting scientists with first hand experience of minor use programs in the United Kingdom and USA. Workshop facilitation was by Dr Peter Box of Integra, Pty. Ltd.

Planning began in November 1997 and involved preliminary discussions with industry, HRDC and RIRDC. The workshop was organised by a local planning committee comprising

Peter Merriman, Manager Plant Health, IHD
Gordon Berg, Team Leader, IHD
Peter Prammer, Senior Product Manager, NRA
Mark Smith, Program Manager, HRDC
Rob Brown, Program Manager, RIRDC

A National Steering Committee on Minor Use convened by the NRA also provided invaluable comment and advice on planning for the workshop.

In December Peter Merriman visited officers of the USDA minor use program, (known as the IR-4 program) in California, and also met key personnel from the UK off-label program at a conference in York. Protocols and processes used in both of these highly successful programs were used as the basis for developing potential models for a minor use program in Australia.

Arrangements were made for:

Peter Chapman, Head of the Technical Secretariat Branch, Pesticides Safety Directorate,
York, UK
Martin McPherson, Horticulture Research International, Selby, UK

Rick Melnicoe, Regional Coordinator for the IR-4 Program at the University of California, Davis.

to attend the National Workshop and associated meetings with industry in Victoria, Canberra and Queensland. Their visits were supported by funds from HRDC and RIRDC.

Also attending was Steven Crossley from the Pesticides Safety Directorate, Residues Section who was brought to Australia by special initiative funds from the National Registration Authority, Canberra.

The workshop was by invitation only and nominations for attendance were sought from peak industry associations and heads of relevant departments.

Blueprint

The blueprint was developed following the workshop and a draft circulated to all participants for comment. Comments were forwarded to TS Agricultural Consultants for the next phase of the program as required by HRDC.

5. RESULTS AND DISCUSSION

Survey

Table 1 summarises the issues identified in the survey and outlined at the Workshop.

TABLE 1

VEGETABLE SURVEY -
LETTUCE, CELERY, LEEK, PARSLEY

GROWER ISSUES / NEEDS

- chemical wish list - lack of registered chemicals for many pests
 - chemicals from different groups for resistance management
 - uniform legislation across states esp re QA issues (SQF2000)
 - unfair overseas competition where chemicals can be used there and not in Australia, imports and exports
 - chemicals being taken off the market with no information/advice on replacements
 - more effective chemicals
 - safer chemicals (operator safety, environmental safety)
 - inconsistencies with withholding periods
 - cost
 - information
 - on label
 - better definition of commodities/hosts (eg vegetable, leafy vegetable, stalky vegetable uncertainty about what these include)
 - rates expressed on a per ha basis as well as per 100l when required
 - tank mixing information
 - independent advice
 - how to get permits and approvals for new chemicals
 - inconsistency between training in the safe use of chemicals (esp. OH&S) only to have them removed from the market
-

Workshop and draft blueprint

The report of the workshop and the draft blueprint are attached as appendices.

A media release was prepared to raise the awareness of other industries to the proposed development of the national minor use program and is also attached.

As evidenced by the funding of the next stage of development of the program the project has proved to be a significant milestone in identifying the "way ahead" and, most importantly, in securing consensus on the need to establish a minor use program for Australia.

6. RECOMMENDATIONS

The appended blueprint incorporates the recommendations to industry on the development of the program. Comments on this blueprint were sought from all Workshop participants and have been forwarded to TS Agricultural Consultants.

7. ACKNOWLEDGEMENTS

This project was funded by the Australian Vegetable Growers organisation (Ausveg), the Horticultural Research and Development Corporation (HRDC) and the Rural Industries Research and Development Corporation (RIRDC).

We thank Peter Prammer, Senior Product Manager, NRA, Dr Mark Smith, Program Manager, HRDC and Dr Rob Brown, Program Manager, RIRDC for their support during the project and in particular for their assistance as members of the Steering Committee for the Workshop.

We thank all the participants of the Workshop for their active involvement and comments on the draft blueprint.

8. APPENDICES

Report of the National Workshop on approval of pesticides for minor uses.

Blueprint for a national minor use program for approving pesticides for minor uses in Australian horticulture.

Media release



Natural Resources
and Environment

AGRICULTURE
RESOURCES
CONSERVATION
LAND MANAGEMENT



**REPORT OF
THE NATIONAL WORKSHOP ON
APPROVAL OF PESTICIDES
FOR MINOR USES**

23 & 24 March 1998

**Institute for Horticultural Development
Knoxfield**

Compiled by: Gordon Berg, Bernadette Swanson and Peter Merriman



AGRICULTURE
VICTORIA

A business of the
Department of
Natural Resources
and Environment

CONTENTS

EXECUTIVE SUMMARY AND RECOMMENDATIONS
proposed model for an Australian minor use program
media release

BACKGROUND TO WORKSHOP

PROGRAM

LIST OF DELEGATES

FORMAL PRESENTATIONS

| | |
|--|--|
| Minor use - recent developments: | Greg Hooper, Deputy CEO, NRA |
| Current systems for off-label use: | Peter Prammer, Senior Product Manager, NRA |
| Vegetable industry perspectives: | Gordon Berg, Team Leader, IHD |
| Chemical industry perspectives: | Geoff MacAlpine, Technical Director, AVCARE |
| UK regulatory environment: | Peter Chapman, Head, Technical Secretariat, Pesticides Safety Directorate, UK |
| UK Specific Off-Label Approval Project: | Martin McPherson, Manager SOLA Project, HRI, UK |
| USDA IR 4 - Minor Use Program: | Rick Melnicoe, Regional Coordinator, IR 4 University of California, Davis |
| Proposed Minor Use Model for Australia: | Peter Merriman, Manager Plant Health, IHD |

SYNDICATES

| | |
|---|---|
| Communication | Tony Biggs, Deputy Chair HRDC |
| Identification, Prioritisation and Initiation | Brian Newman, Exec Director AusVeg |
| Data Generation and Analysis | Leon Radunz, Manager Regulatory Affairs, Bayer |
| Liability and Legislation | Geoff MacAlpine, Technical Director, AVCARE |
| Management and Coordination | Vic Edge, Chair Plant Health Committee |

EXECUTIVE SUMMARY AND RECOMMENDATIONS

This document summarises the details and outcomes of a National Workshop on Approval of Pesticides for Minor Uses, which was held at the Institute for Horticultural Development, Knoxfield on 23 & 24 March 1998.

It is part of a one year HRDC project funded by the Australian Vegetable Growers, the Horticultural Research and Development Corporation and the Rural Industry Research and Development Corporation.

The objective of the project is:

to consider the development of a national program for approving minor uses of pesticides for the Vegetable and other plant industries.

It has two components:

- to determine the nature and extent of minor use requirements in Australia using the Vegetable Industry as a model
- to convene a national meeting of growers, chemical industry, government agencies and funding bodies to consider the merits of establishing a national minor use program for Australia

Fifty delegates representing the growers, chemical industry, government agencies and funding bodies attended the two day workshop and unanimously supported the following recommendations

Recommendation 1

to proceed immediately to develop a blue print, by mid 1998, for a national minor use program

Note: the blueprint is based on the preferred model presented overleaf and will be developed as an extension of the current HRDC project at the Institute for Horticultural Development, by Peter Merriman, Gordon Berg and other members of the planning group for the workshop
- the blueprint will be circulated nationally to stakeholders for comment and endorsement as explained in the attached media release

Recommendation 2

to commence the development, by June 1998, of a proposal for the implementation of a pilot national minor use program.

Note: this will be presented for consideration for funding by HRDC, RIRDC and other funding agencies

Additional comments from the workshop recommended that the key initial steps in the development of the program include:

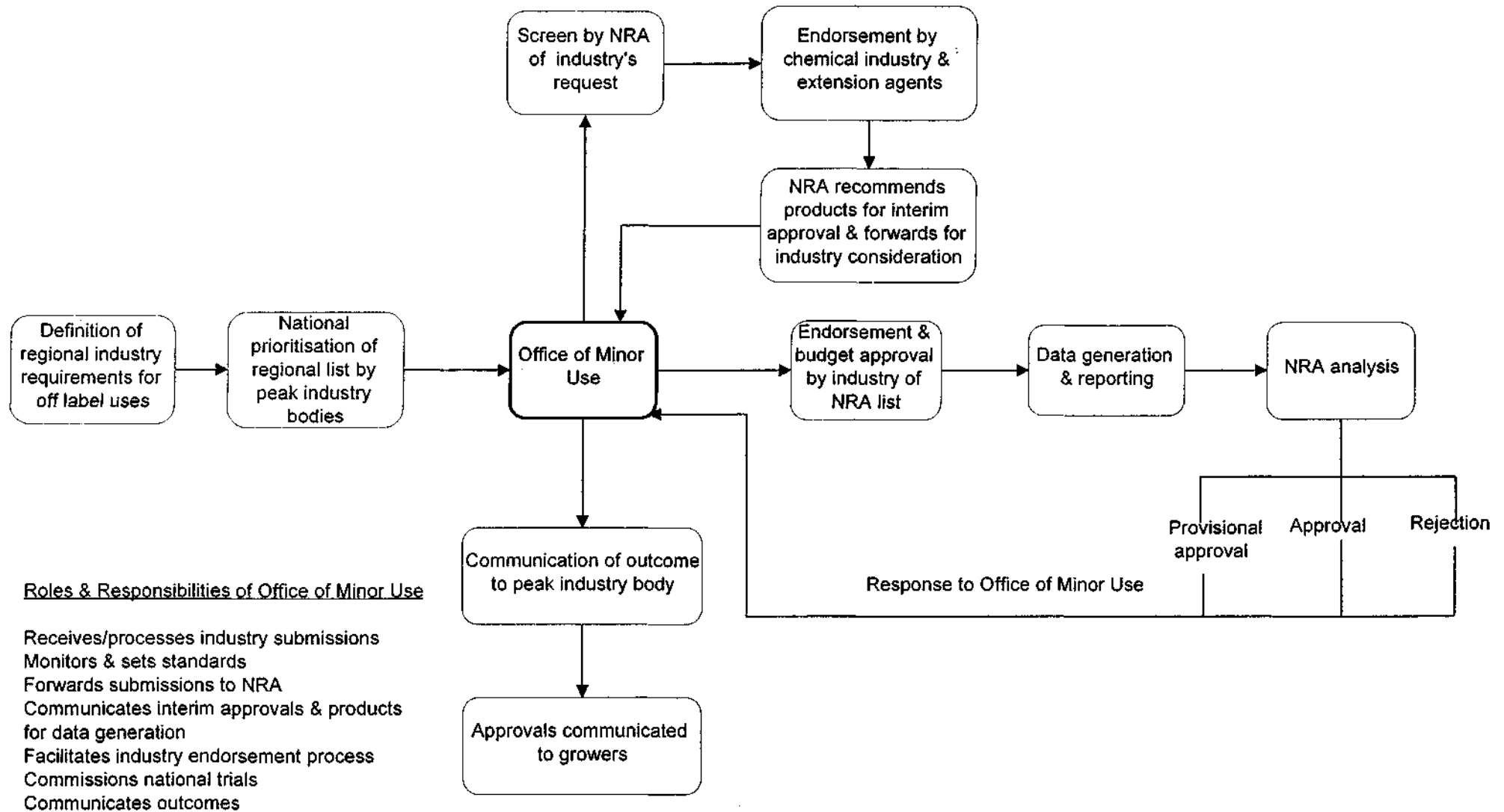
- the establishment of a steering committee including representatives from the Vegetable R&D committee, HRDC and RIRDC to oversee the program
- securing funding for the pilot program
- the appointment of a manager of the pilot program
- fine tuning the blueprint
- defining the resource requirements

NOTE:

- in addition there was consensus that the protocols and processes for a minor use program in Vegetables should be sufficiently flexible for adoption by other plant industries

- the HRDC project terminates in Dec 98, and will present a final report which incorporates the developments arising from recommendations of the workshop

Figure 1. Proposed Model for Australian Minor Use Program





7 Merriwa Street
Gordon, NSW 2072

42 Macquarie Street
Barton ACT 2600



National support for minor use program

"We need a minor use program which is easy for growers to access and allows effective chemicals to be made available," explained John Bishop, a farmer from Queensland's Lockyer Valley and a member of the Queensland Fruit and Vegetable Growers sub-committee for vegetable crops.

This comment reflected the industry view expressed at a national workshop on approval of pesticides for minor use held on 23/24 March at the Institute for Horticultural Development (IHD), Knoxfield in Victoria.

More than 50 delegates representing the vegetable industry in all states, other horticultural industries, agricultural chemical manufacturers, consultants and resellers, various government agencies and research corporations gave overwhelming support to the development of a national program for the approval of minor use chemicals in horticulture.

The workshop was funded by the Australian Vegetable Growers organisation (Ausveg), the Horticultural Research and Development Corporation (HRDC) and the Rural Industries Research and Development Corporation (RIRDC).

Dr Peter Merriman, Manager of Plant Health Programs at IHD and chairman of the organising committee, believes that the workshop outcomes will provide a platform for launching a national minor use chemical program for horticulture.

"The initial drive and support has come from the vegetable industry but all horticultural industries are interested and there could be a real opportunity to widen the program to cover all plant industries," said Dr Merriman.

A meeting of the National Vegetable R&D Committee in early April will consider a recommendation from the workshop to provide interim funds to develop a blueprint for the national scheme.

This document, prepared by the workshop planning group, will be circulated nationally for endorsement by appropriate industry and government agencies. The final copy will be then be used to formulate a mid 1998 submission to HRDC, RIRDC and other organisations for funds to commission a three year pilot program.

The first step in this new initiative will be the appointment of a project manager who will assist in the fine tuning of the planning and development phase and then be responsible for implementation.

An industry convened steering committee comprising representatives from AusVeg,

HRDC, RIRDC and other stakeholders will regularly review progress and future plans to ensure outcomes are delivered on time.

The Knoxfield workshop, facilitated by Dr Peter Box of Integra, included a number of plenary presentations followed by working syndicate groups in which delegates developed issues, strategies and actions for :

- communication,
- initiation and prioritisation of minor use proposals,
- data generation and analysis,
- liability and legislation, and
- national management and co-ordination.

The introductory plenary sessions provided information on the current system and protocols for off-label use; perspectives from the vegetable and agricultural chemical industries and descriptions of minor use programs in the United Kingdom and the United States.

Peter Chapman, of the Pesticides Safety Directorate, and Dr Martin McPherson, of Horticultural Research International, explained the United Kingdom situation and described the operation of their Specific Off-Label Approval (SOLA) scheme. Rick Melnicoe, Western Region Co-ordinator of the IR-4 Program and the Pesticide Impact Assessment Program based at the University of California, Davis, dealt with the United States model.

"The international inputs were invaluable, not only in providing guidance but also, in showing that off-label, minor use programs operate successfully overseas," said Dr Merriman.

"Our overseas visitors demonstrated that programs are possible in geographically small countries like the UK and also in the United States where the wide range of crops and growing conditions are more like Australia," concluded Dr Merriman.

Further information about outcomes from the workshop and progress with the development of the national program for approval of pesticides for minor use may be obtained from:

Brian Newman, Executive Director, Ausveg
Ph. 03.5790 5247; Fax 03.5790 5259

Dr Mark Smith, Program Manager, HRDC
Ph 03.9210 9320; Fax 03.9210 9321

Dr Rob Brown, Program Manager, RIRDC
Ph. 03.9874 7462; Fax 03.9873 1853.

BACKGROUND TO WORKSHOP

The National Workshop on Approval of Pesticides for Minor Uses was held at the Institute for Horticultural Development, Knoxfield from 23 to 24 March 1998. It was attended by representatives from the national vegetable industry, the chemical industry, government agencies, program managers from HRDC and RIRDC and four visiting scientists with first hand experience of minor use programs in the United Kingdom and USA. Workshop facilitation was by Dr Peter Box of Integra, Pty. Ltd.

Planning began in November 1997 and involved preliminary discussions with industry, HRDC and RIRDC. The workshop was organised by a local planning committee comprising

| | |
|--|---------------------------------|
| Peter Merriman, Manager Plant Health) | Institute for Horticultural |
| Gordon Berg, Team Leader) | Development, Knoxfield |
| Peter Prammer, Senior Product Manager, | National Registration Authority |
| Mark Smith, Program Manager, | HRDC |
| Rob Brown, Program Manager, | RIRDC |

A National Steering Committee on Minor Use convened by the NRA also provided invaluable comment and advice on planning for the workshop.

In December Peter Merriman visited officers of the USDA minor use program, (known as the IR-4 program) in California, and also met key personnel from the UK off-label program at a conference in York.

Protocols and processes used in both of these highly successful programs were used as the basis for developing potential models for a minor use program in Australia.

Arrangements were made for

Peter Chapman, Head of the Technical Secretariat Branch, Pesticides Safety Directorate, York, UK
Martin McPherson, Horticulture Research International, Selby, UK

Rick Melnicoe, Regional Coordinator for the IR-4 Program at the University of California, Davis.
to attend the National Workshop and associated meetings with industry in Victoria, Canberra and Queensland. Their visits were supported by funds from HRDC and RIRDC.

Also attending was Steven Crossley from the Pesticides Safety Directorate, Residues Section who was brought to Australia by special initiative funds from the National Registration Authority, Canberra.

The workshop was by invitation only and nominations for attendance were sought from peak industry associations and heads of relevant departments.

A media release has been prepared to raise the awareness of other industries to the proposed development of the national minor use program.

PROGRAM FOR NATIONAL WORKSHOP ON MINOR USE

MONDAY 23 MARCH

9-30 REGISTRATION

10-00 WELCOME and INTRODUCTION

Tony Biggs, Deputy Chairman,
Horticultural Research and Development Corporation

10-30 NATIONAL REGISTRATION AUTHORITY
- MINOR USE STEERING COMMITTEE

Greg Hooper, Deputy CEO, National Registration Authority

10-45 CURRENT SYSTEMS FOR OFF-LABEL USE

Peter Prammer, Leader Minor Use Program, National Registration Authority

11-00 INDUSTRY PERSPECTIVES ON CURRENT SYSTEM
VEGETABLES

Gordon Berg, Team Leader, Institute for Horticultural Development

CHEMICAL INDUSTRY

Geoff McAlpine, Technical Director, AVCARE

11-30 O/S PROGRAMS FOR MINOR USE
UNITED KINGDOM

Peter Chapman, Pesticides Safety Directorate

Martin McPherson, Horticulture Research International

USA

Rick Melnicoe, IR-4 Program

1-00 DISCUSSION

LUNCH

1-45 OUTLINE OF A MODEL FOR AUSTRALIA

Peter Merriman, Manager Plant Health,
Institute for Horticultural Development

- discussion, clarification

2-30 DEVELOPEMENT OF PROTOCOLS AND PROCESS FOR AUSTRALIAN MODEL
SYNDICATES

- define issues, impediments
- identify strategies protocols to improve system
- determine what needs to be done
- action who, what, where

5-00 SYNDICATE PROGRESS

7-00 DINNER (At IHD)

TUESDAY 24 MARCH

8-30 REPORTS FROM SYNDICATES
DATA GENERATION AND ANALYSIS
IDENTIFICATION, PRIORITISATION AND INITIATION OF MINOR USE
PROPOSALS
COMMUNICATION
MANAGEMENT AND COORDINATION
LIABILITY AND LEGISLATION

- detail the protocols and processes

10-15 BREAK

10-45 IDENTIFY RESPONSIBILITIES FOR IMPLEMENTATION

LUNCH

1-30 NATIONAL MANAGEMENT AND COORDINATION

- report from syndicate

2-30 NEXT STEPS

LIST OF DELEGATES

Vegetable growers and industry associations

NSW Mike Wheeler
Vic Tom Schreurs, National Vegetable R&D Committee
Peter Cochrane, National Vegetable R&D Committee
QFVG Shauna Dewhurst, Environmental Policy Officer
Rodney Dunn, Vegetable Sectional Group Committee
and National Vegetable R&D Committee
John Bishop, Board Member and Chair of Heavy Produce Sectional Committee
Alec Harslett, Vegetable Sectional Group Committee
and National Vegetable R&D Committee
SA John Cranwell, National Vegetable R&D Committee
Tas Michael Badcock, Chairman Vegetable Council, Tas. Farmers and Graziers Ass.
and National Vegetable R&D Committee
Tony Fist
WA David Anderson
SAFF Michael Cain, Executive Officer Horticulture (also representing NFF)
NIAA Ian Atkinson, National NIDO NIAA
Ausveg Brian Newman, Executive Director

Chemical industry

Geoff MacAlpine, Technical Director, AVCARE Ltd
Leon Radunz, Regulatory Affairs Manager, Crop Protection Division,
Bayer Aust. Ltd.
Robert Harris, Market Development Manager, Hoechst Schering AgrEvo Pty.Ltd.,
Stephanie Leach, Nufarm Ltd.
Ian Logan, Crop-Care

Contract R&D providers & Consultants

Les Mitchell, Agrisearch Services Pty Ltd
Malcolm Roach, IHD Pty Ltd
Ron Meyer, Phytech Development Pty Ltd
Ian McLeod, Serv-Ag Pty Ltd

National Registration Authority

Greg Hooper, Deputy CEO
Peter Prammer, Leader Minor Use Program
Dr Ron Eichner, Manager Residue Evaluation Section

Government Agencies

Dr Vic Edge, Chairman, Plant Health Committee
Stanford Harrison, Policy Officer, Agricultural and Veterinary Chemicals Policy
Section, Department of Primary Industries and Energy, ACT
Cassie Wright, Principal Policy Officer,
Queensland Department of Primary Industries
Roger Toffolon, Program Leader Agricultural and Veterinary Chemicals,
NSW Agriculture
Roger DeKeyser, Senior Policy Officer, NSW EPA
Dr Catherine Hollywell, Manager Chemical Standards Branch,
Department of Natural Resources and Environment, Victoria
John Kassebaum, Farm Chemicals Program Primary PISA
John Mollison, Register of Chemical Products,
Dept. of Primary Industries and Fisheries, Tasmania

Funding bodies

HRDC Paul Ziebarth, Director
Tony Biggs, Deputy Chairman and Editor Good Fruit and Vegetables Magazine
Dr Mark Smith, Program Manager
Jonathan Eccles, Program Manager

RIRDC Dr Rob Brown, Program Manager

International

UK Peter Chapman, Head Technical Secretariat Branch, Pesticides Safety Directorate
Dr Martin McPherson, Plant Pathologist, Horticulture Research International,
Steve Crossley, Pesticide Chemistry Branch, Pesticides Safety Directorate

USA Rick Melnicoe, IR-4 Program Regional Field Research Coordinator

Horticultural Research Institutes

Dennis Richards, Director, Institute for Horticultural Development (IHD)
Dr Peter Merriman, Manager Plant Health, IHD
Gordon Berg, Team Leader IPM, IHD
Dr Wendy Morgan, Industry Manager Vegetables, IHD
Dr Ian Porter, Team Leader IPM, IHD
Bernadette Swanson, Training Officer Farm Chemicals, IHD
John Chapman, Client Services Manager, Queensland Horticulture Institute (QHI)
John Hargreaves, Senior Entomologist, Redlands Research Institute, QHI
Craig Henderson, Senior Horticulturist, Gatton Research Station, QHI

Related projects

Chris Scharpe, AgricultureWA
Dr Prue McMichael, Plant Pathologist/Technical Consultant
Scholefield-Robinson Horticultural Services Pty Ltd

Facilitator

Dr Peter Box, Integra

**NATIONAL REGISTRATION AUTHORITY
- MINOR USE STEERING COMMITTEE**

Greg Hooper, National Registration Authority

MINOR USES



MINOR USE:

A use that is not included on a pesticide label because the cost of research and registration to have that use included is greater than the economic return to the chemical manufacturer.

MINOR CROPS:

- Low value
- High value
- Small area/high value
- Major crops/limited pesticide use
- Contribution to the diet

Presentation to the National Workshop on Minor Use 23-24 March 1998



MINOR USES



NRA's RESPONSE

- Permit System
- Assisted Individual Industries
- Longer Term Strategy
 - Minor Use Program
 - Minor Use Steering Committee

Presentation to the National Workshop on Minor Use 23-24 March 1998



MINOR USES



IMPEDIMENTS TO APPROVAL OF MINOR USES

- Registration Data Requirements
- Absence of Data Protection
- Liability
- Fees and Timeframes

Presentation to the National Workshop on Minor Use 23-24 March 1998



MINOR USES



IMPEDIMENTS TO APPROVAL OF MINOR USES

- No National Coordination
- Absence of Data
- Little Awareness of the System
- Inconsistent State "Control of Use" Legislation
- Communication of Outcomes

Presentation to the National Workshop on Minor Use 23-24 March 1998



MINOR USES



THE ISSUES

FOR GROWERS:

- Availability of approved chemicals for pest and disease control when no registered use exists
- Maintain competitiveness
- No violative residues in domestic or export produce

Presentation to the National Workshop on Minor Use 23-24 March 1994



MINOR USES



THE ISSUES

FOR CHEMICAL INDUSTRY:

- Cost of data generation
- Product liability
- No threat to more significant uses
- Data Protection

Presentation to the National Workshop on Minor Use 23-24 March 1994



MINOR USES



THE ISSUES

FOR NRA/STATES:

- Assist producer industries
- Eliminate illegal use
- "Clean" food
- Adequate data on which to base decisions
- Data useful for international/Codex purpose

Presentation to the National Workshop on Minor Use 23-24 March 1994



MINOR USES



THE PROPOSAL

A cooperative and jointly funded
NRA/State/Industry Minor Use Program

THE OBJECTIVE:

In the short term, to facilitate the approval of minor uses by registration or by off-label permits

In the long term, to facilitate the approval of the majority of minor uses by registration

Presentation to the National Workshop on Minor Use 23-24 March 1994



MINOR USES



THE PROPOSAL

A cooperative and jointly funded
NRA/State/Industry Minor Use Program

KEY INITIATIVES:

- Liaise with grower organisations to prioritise chemical needs
- Review NRA registration requirements and develop policies to support minor use approvals
- Review NRA requirements for establishing MRLs on minor crops or for minor use

Presentation to the National Workshop on Minor Use 23-24 March 1998



MINOR USES



MINOR USE STEERING COMMITTEE

PURPOSE:

- Open up two-way communication between NRA and representatives of various horticultural industries
- Advise on the appropriateness of the program
- Advise on additional initiatives and strategies that may be adopted
- Identify priorities and set in train the necessary data gathering requirements

Presentation to the National Workshop on Minor Use 23-24 March 1998



MINOR USES

MINOR USE STEERING COMMITTEE

MEMBERSHIP:

- Horticulture research and development
- Horticultural production
- Chemical industry
- Government (DPIE)

Presentation to the National Workshop on Minor Use 23-24 March 1998



MINOR USES



THE PROPOSAL

A cooperative and jointly funded
NRA/State/Industry Minor Use Program

KEY INITIATIVES:

- Promote cooperative solutions, including funding arrangements
- Develop and implement procedures that will simplify the approval mechanism for chemicals used in research

Presentation to the National Workshop on Minor Use 23-24 March 1998



NATIONAL REGISTRATION AUTHORITY
- CURRENT SYSTEMS FOR OFF-LABEL USE

Peter Prammer, National Registration Authority



OFF-LABEL PERMITS and MINOR USES

- ◆ OFF-LABEL PERMITS
-
- ◆ BENEFITS TO GROWERS
- ◆
- ◆ LIMITATIONS OF CURRENT SYSTEM
- ◆

• • • • •



OFF-LABEL PERMITS (1)

- ◆ Approvals that allow the use of an agricultural chemical product in a manner that differs from the uses specified on the label, and would otherwise be an offence.
- ◆
- ◆ Issued for minor uses and emergency use situations.
- ◆
- ◆ Very flexible:
 - one or more products
 - one or more persons
 - one or more States
 - single use or a range of uses.
-

• • • • •



OFF-LABEL PERMITS (2)

- ◆ Issued for a defined period or issued indefinitely.
- ◆
- ◆ NRA can issue an off-label permit on its own initiative.
- ◆
- ◆ Issued off-label permits can be:
 - suspended
 - cancelled
 - surrendered

• • • • •



BENEFITS TO GROWERS

- ◆ Legalise the off-label minor use to be undertaken by growers.
- ◆
- ◆ Do not require a fee.
- ◆
- ◆ Proposed use is assessed by the NRA to ensure it will not cause an undue hazard in regards to:
 - human toxicity & occupational health and safety
 - environmental safety
 - residues and trade
 - crop safety.



•
•

• • • • •



OFF-LABEL PERMITS & MINOR USES

- ◆ NRA issued over 650 off-label permits.
- ◆
- ◆ The States issued over 2,500 permits.
- ◆
- ◆ In Australia, the issuing of off-label permits will remain the primary means of approving products for minor uses.
- ◆
- ◆ To meet this challenge:
 - identify limitations inherent in current system
 - removed or reduced limitations.

• • • • •



LIMITATIONS

- ◆ Lack of awareness.
- ◆
- ◆ Lack of industry coordination.
- ◆
- ◆ Lack of data.
- ◆
- ◆ Off-label liability.
- ◆
- ◆ Inconsistent "control of use"
- ◆
- ◆ Lack of communication

• • • • •



Lack of data

- ◆ Registration - applicant supplies complete data requirements.
- ◆ Off-label permits - little or no data to support usepattern.
- ◆
- ◆ Growers do not have resources or a knowledge of requirements to generate data, especially residue data.
- ◆
- ◆ Extrapolation from existing data, Codex, etc..
- ◆
- ◆ Due to lack of residue data, MRLs cannot be set - many minor crop permits are not issued.
- ◆
- ◆

• • • • •



Off-label liability

- ◆ Manufacturers of products are part of the assessment process.
- ◆
- ◆ Agreeing, or acquiescing, to product being included results in having liability for the use of product under the permit.
- ◆
- ◆ Concern over off-label liability results in manufacturers adopting a "no comment" response.
- ◆
- ◆ NRA is unable to indemnify manufacturers against any claims.

• • • • •



Inconsistent 'control of use' (1)

- ◆ NRA - controls "supply" of products.
- ◆
- ◆ States - control "use" via respective 'control of use' legislation.
- ◆
- ◆ Some States legally allow products to be used in an off-label manner, e.g.:
 - ◆ lower rates
 - ◆ less frequently
 - ◆ inclusion of additional constraints, e.g. buffer zones, etc.
- ◆
- ◆ A permit is not required for an off-label uses which is not an offence.

• • • • •



Inconsistent 'control of use' (2)

- ◆ Adoption of inconsistent provisions:
- ◆
 - Vic: Products can be used on different crops and different pests provided MRLs are set and rates and frequency \leq label rates & frequency.
 - Qld: Growers can apply to different pests (same crop and rate) but cannot advise.
 - NSW: Use only according to specific label directions.
- ◆
- ◆ Inconsistent 'control of use' confuses growers and further erodes confidence in the permit system.

• • • • •



Lack of communication

- ◆ Issued off-label permits are circulated to 'interested' persons.
- ◆
- ◆ Many growers are unaware of:
 - ◆ the permit system;
 - ◆ issued permits;
 - ◆ their specific details and conditions.
- ◆
- ◆ Reason for poor communication are:
 - ◆ diverse nature of grower industries;
 - ◆ no direct lines of communication;
 - ◆ lack of one peak representative organisation;
 - ◆
- ◆ The NRA will need to examine alternative communication strategies.

• • • • •

**INDUSTRY PERSPECTIVES ON CURRENT SYSTEM
- VEGETABLES**

Gordon Berg, Institute for Horticultural Development

VEGETABLE SURVEY -
LETTUCE, CELERY, LEEK, PARSLEY

GROWER ISSUES / NEEDS

- chemical wish list - lack of registered chemicals for many pests
 - chemicals from different groups for resistance management
 - uniform legislation across states esp re QA issues (SQF2000)
 - unfair overseas competition where chemicals can be used there and not in Australia, imports and exports
 - chemicals being taken off the market with no information/advice on replacements
 - more effective chemicals
 - safer chemicals (operator safety, environmental safety)
 - inconsistencies with withholding periods
 - cost
 - information
 - on label
 - better definition of commodities/hosts (eg vegetable, leafy vegetable, stalky vegetable uncertainty about what these include)
 - rates expressed on a per ha basis as well as per 100l when required
 - tank mixing information
 - independent advice
 - how to get permits and approvals for new chemicals
 - inconsistency between training in the safe use of chemicals (esp. OH&S) only to have them removed from the market
-

ORNAMENTALS SURVEYS 1993 AND 1997

- 75% of fungicides and 17% insecticides used off-label in Victoria (Vic. wildflowers)
 - lack of information
 - OH&S concerns
 - instances of using inappropriate chemicals with respect to the type of pest being controlled
 - some instances of registered chemicals being in fact available
 - some instances of chemicals unregistered in Australia at all being used
-

INDUSTRY PERSPECTIVES ON CURRENT SYSTEM
- CHEMICAL INDUSTRY

Geoff McAlpine, AVCARE

Crop Protection Industry Perspective

1. The issues for horticulture
2. Government policy and legislation as an impetus for change
 - historical developments
 - impediments to progress
3. Grower and market needs as an impetus for change
 - issue recognition and ability to respond
 - market requirements
4. Getting the 'environment' and 'framework' right

Avcare presentation to the Institute for Horticultural Development, Knoxfield, Victoria 23-24 March 1998

2. Government policy and legislation as an impetus for change

2.1 Historical developments

- Until 1980's state pesticide legislation focussed on efficacy and quality
- NSW Pesticides Act 1978:
 - focus on human health and the environment, including residues in food
 - required 'use' according to product label or permit/pesticide order
 - provided mechanisms to deal with minor-use and off-label use 'before its time' and regarded as draconian
- In some states 'use legislation' still has not caught up with contemporary standards and market needs. There is no uniformity of state laws
- Introduction of the NRA brought national uniformity to the registration process
- Until now no serious national attempt to deal with questions of minor-use or deficiencies in available registered/approved crop protection products for crops

02/27/98

Slide 1

1. The Issues

- 1.1 There are gaps in the current range of registered/approved products for the control of pests/diseases/weeds in horticultural crops
- 1.2 A number of horticultural crops fall into the category of 'minor-use' crops or there are 'uses' (pest/disease/weed instances) which are categorised as 'minor-uses'
- 1.3 There are strong pressures to ensure that only registered/approved crop protection products are used on horticultural crops:
 - valid contemporary standards with regard to residues
 - compliance with legal requirements and QA programs
 - consumer confidence and grower security
- 1.4 There is also need to facilitate access of appropriate products and technologies to secure competitive positions for horticulture

02/24/98

Slide 2

2. Government policy and legislation as an impetus for change

2.2 Impediments to progress

- **Nationally uniform state 'use legislation'**
 - must underpin horticultural industry objectives for local and export markets
- **Supporting NRA processes**
 - criteria for approval of minor-use applications
 - ability to process in a reasonable timeframe
 - processes to communicate outcomes
- **Data protection**
- **Liability under NRA permit/approval for minor use**

02/27/98

Slide 3

Data Protection

A simple example of the practical implications:

If a company invests, say \$0.5M, in the development of an existing crop protection product for use in a new crop or situation in Australia then at the time of registration the label claims become immediately available for all competitors to copy at zero cost.

Result: Not only is there no incentive to invest but the company would be placing itself at a financial competitive disadvantage if it did invest.

- The crop protection and animal health industry has made representations to government on this issue for some 15 years
- In 1997 NFF, Avcare and VMDA developed a joint position on data protection which is currently being considered by the government
- This is the most critical issue facing the future of the crop protection industry in Australia

Consequences of lack of TDP for Agvet Chemicals in Australia

- X Products available overseas are not being developed in Australia;
- X Current products are at risk through not being supported in Australia;
- X Further research and development work for current products has been reduced;
- X Investment in product development cannot be justified in many market segments;
- X Essential research to support certain agricultural objectives, IPM, generation of residue data to support changed agronomic practices and to facilitate trade cannot be financially and commercially justified for an increasing range of uses;
- X Data submitted locally is 'exposed' to commercial exploitation in certain international markets by the acceptance of Australian registration to support local registrations;
- X Australia has a high level regulatory system which does not support the generation or exposure of data. This places companies at significant business risk;
- X The barriers to submission of data are considered unacceptable and unsustainable if a responsible industry presence is to be maintained.

Guidelines for the Registration and Control of Pesticides, FAO Rome 1988

All data submitted by a company in support of its request for registration of its product should be treated as proprietary and should neither be divulged nor used to evaluate a petition submitted by another applicant, unless by agreement with the owner of the data or unless a period of proprietary rights to the data has expired.

The synthesis of new materials and procurement of data on safety and efficacy essential for registration will have taken commercial companies many years and will have been very expensive. The results obtained are as much the property of the company that produced them as is the plant used to manufacture the product.

Therefore, it would be unjust for registration authorities to use, for the benefits of industrial competitors, data submitted to them in good faith.

Each applicant should be required to produce full supporting data, either by doing the work himself or by licence from the owner of the data.

Apart from the injustice of allowing competitors to benefit from the use of data to which they have no right, the consequences of such an action would be to discourage, because it is unrewarding, the research and development required for the production of new pesticides which are needed, for example, for the control of new or difficult pests or to overcome resistance.

Data Protection - Summary

What are the problems being addressed?

- > Firms are unwilling to invest in R&D in, and for, Australian needs
- > Firms are unwilling to expose data in Australia
- > Australia is seen as an undesirable destination for agvet industry investment
- > Damage is being caused to Australia's agricultural and livestock interests which will impact upon the competitiveness of rural industries

Why do the problems exist?

- > Australian legislation for the approval, registration and review of agricultural and veterinary chemical products does not provide meaningful protection of data generated to meet regulatory requirements. The legislation provides strong disincentives to innovation for small and large firms alike
- > Australia is not seen to be adopting standards of international practice
- > Investment decision-makers consider the situation to be unacceptable, increasing their business risks, and are continuing to respond accordingly

Liability under NRA permit/approval for minor use

- Under current *NRA* legislation there is no distinction in the 'areas of consideration' between major or minor use proposals
- To make progress in minor use, the prime consideration needs to be residues. Extrapolation and sound judgement in other areas, such as efficacy, needs to become an accepted part of the evaluation process
- Given that for minor use proposals under permits a significant number of sound judgements need to be made without the luxury of full data packages, the crop protection industry has serious concerns with the liability situation as the manufacturer is liable if:
 - use under permit has been agreed, acquiesced to or supported;
 - manufacturer silent on the matter and fails to respond to *NRA* requests for information, liability may depend on knowledge of any dangers in proposed use

The *NRA* is unable to indemnify manufacturers against claims from third-parties

3. Grower and market needs as an impetus for change

3.1 Issue recognition and ability to respond

- early recognition and response by some sectors, particularly those which are well coordinated and export orientated (eg wine industry)
- in general, the issues are too complex to be able to be resolved without coordinated action and funding

3.2 Market needs

- Market requirements and continuing market access are the driving forces towards achieving solutions to the issues

Due to a range of factors Australia is significantly behind some other countries in developing programs to address the issues. Significant effort is required to secure the future and competitiveness of Australian horticultural industries.

Liability under *NRA* permit/approval for minor use (continued)

Applicants:

The applicant does not have to be the person to whom the permit is to apply and the mere fact of applying does not necessarily give rise to liability.

Persons using under Permit

Person using product in accordance with permit may be liable but would no doubt join the manufacturer in an action

Distributors and Retailers

Liability may be attracted for negligent misstatements as to performance factors or failing to warn of dangers which are known to manufacturers or retailers. Mere act of distribution or sale does not attract liability

(Warning: comments only – do not rely upon as legal advice)

4. Getting the 'environment' and 'framework' right to allow progress

- Barriers and impediments to horticultural industries and to those industries which input to horticulture need to be clearly identified and removed
- Coordinated activity and lobbying is required to ensure a legislative environment which supports horticultural industry objectives
- Programs need to be nationally based and coordinated
- There needs to be strong grower and grower association ownership of the issues and the solutions
- No solutions will be achieved without adequate resources and funding

*“After all is said and done, more is
said than done”*

*Deliberations of this Workshop need to be translated into
coordinated positive action!*

OVERSEAS PROGRAMS FOR MINOR USE
- UNITED KINGDOM

Peter Chapman, Pesticides Safety Directorate



THE MINOR USE REGISTRATION SYSTEM IN THE UK

PETER CHAPMAN

PESTICIDES SAFETY DIRECTORATE



LEGISLATIVE BACKGROUND

- Control of Pesticides Regulations 1986
- Crop becomes statutory condition of use
- Efficacy data to maintain on-label uses
- > 4000 threatened uses identified and submitted
- PSD makes provision for approval of minor uses off-label in 1988/89
- Plant Protection Product Regulations 1995 (implements EU Directive 91/414)



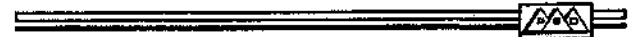
ARRANGEMENTS FOR OFF-LABEL APPROVAL IN THE UK

- Long Term Arrangements for Extension of Use (Exemptions)
- Specific Off-label Scheme
 - Emergency
 - Non-Emergency
- Mutual Recognition for Off-label Uses on Minor Crops
- Current developments in EU and UK



LONG TERM ARRANGEMENTS FOR EXTENSION OF USE (1)

- Grower can extrapolate use from product label without specific approval (permit)
- Excluding:
 - use in or near water
 - use on protected crops
 - use of vertebrate control products
 - use on hard surfaces, moorland, nature reserves etc
 - use of pesticides toxic to bees for crops in flower



LONG TERM ARRANGEMENTS FOR EXTENSION OF USE (2)

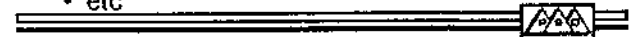
- Non-edible crops and plants, mainly ornamentals
- Farm forestry and rotational coppicing
- Nursery fruit crops
- Hops for propagation/not for harvest
- Extrapolations between specific crops for consumption



LONG TERM ARRANGEMENTS FOR EXTENSION OF USE (3)

Examples of extrapolations for edible crops:

- poppy from sunflower
- linseed from oilseed rape (canola)
- rye from wheat/barley
- blackberry from raspberry
- fodder beet from sugar beet
- pumpkin from melon
- etc





SPECIFIC OFF-LABEL SCHEME (1)

- Application made by growers/growers organisation
- Must include
 - details of problem
 - scale and scope of problem/potential for damage
 - why other methods are unsuitable
 - support to demonstrate need
 - details of urgency of problem



SPECIFIC OFF-LABEL SCHEME (2)

- Application must include data or scientific case to address safety of proposed use including risks to:
 - operators
 - consumers
 - wildlife/environment
- Efficacy data are not required
- PSD evaluates application
- Approval is published and available for all
- Liability rests with grower



MUTUAL RECOGNITION FOR OFF-LABEL USES ON MINOR CROPS (1)

- On-label approval in another MS
- On-label approval for other crops in UK
- Rates, timing and frequency of use no greater than in other MS
- Method of application is same as in other MS
- Harvest interval no shorter than in other MS
- Copy of label and approval doc obtained from other MS + translation into English
- MRL set in other MS or in EU



MUTUAL RECOGNITION FOR OFF-LABEL USES ON MINOR CROPS (2)

- Scope - not applicable to:
 - crops representing > 1% diet
 - grown on >1000ha in UK
 - constitutes >50% domestic animals diet/ >10,000ha grown
 - various other situations eg vertebrate control products



CURRENT DEVELOPMENTS IN EU

- Other MS facing same problem
- Pilot project on exchange of information
- Commission Expert Group on minor uses
- Establishment of an EU database on minor uses?
- Development of flow chart for mutual recognition of authorisations between MS



CURRENT DEVELOPMENTS IN UK - REGISTRATION DATABASE

- Current database on details of approved uses not meeting users needs
- Developing relational database listing:
 - all approval details (including minor uses and off-label approvals)
 - plan to make information available via Internet Website + other providers



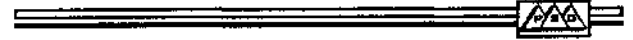


LESSONS



- UK system is effective:
- especially Long Term Arrangements and Specific Off-labels
- Establish appropriate regulatory framework at outset
- Ensure effective communication with all parties
- Establish clear guidelines for operation

Good luck!!



OVERSEAS PROGRAMS FOR MINOR USE
- UNITED KINGDOM

Dr Martin McPherson, Horticulture Research International



The UK SOLA (Specific Off-Label Approvals) Project

Martin McPherson
HRI, Stockbridge House

The UK SOLA Project - It's Conception!

- * Over 50% SOLA's (products) with data requirement
- * Target dates for data submission
- * Immediate revocation if deadline not met
- * Little time for concerted action
- * Requirement for GLP compliance

The UK SOLA Project - Sponsorship?

- Manufacturers unable to support
- Government (MAFF) funds not available
- EU funds not available
- Industry (grower) money allocated via a levy board (HDC)
- as a last resort!

The UK SOLA Project - It's Birth!

- Sponsored Cross-Commodity by HDC
- Initial allocation of £600K in '93
- HRI contracted to undertake the work
- Significant impact on R&D funds

The UK SOLA Project -It's Objectives

- Rationalise existing SOLA's
- Prioritise within tight budgetary constraints
- Initiate & co-ordinate trials
- Meet data submission deadlines
- Ensure all important uses retained!

The UK SOLA Project - In it's Infancy!

- Identify & negotiate trial requirements
 - Major v. Minor crops
 - Protected v. Outdoor crops
 - Trial Details (location, plot size, replication etc)
- Sub-Contract Arrangements
 - Analytical studies
- GLP-Compliant programme

The UK SOLA Project - GLP Compliance

- * Facility Records
 - Personnel (cv's, training records etc)
 - Equipment (maintenance records)
 - Master Schedules (workload)
 - Pesticides (use, shelf-life, C of A)
 - Standard Operating Procedures (SOP's)
- * Quality Assurance Audits
- * Archiving

SOLA Trial Requirements

| | Major Crop | Minor Crop |
|-----------|------------|------------|
| Trial No. | 8 | 4 |
| Protected | 8 * | 4* |
| Outdoor | 4** | 2** |

* over at least one season.

** in each of at least 2 seasons

The UK SOLA Project - Reaching Puberty!

- * Existing SOLA's secured
 - a change in emphasis
- * Long-Term Arrangements revised
- * Opportunity to 'tailor' armoury
 - to fill gaps & replace 'lost' uses
 - to address new problems
 - to introduce new chemistry to minimise resistance risk

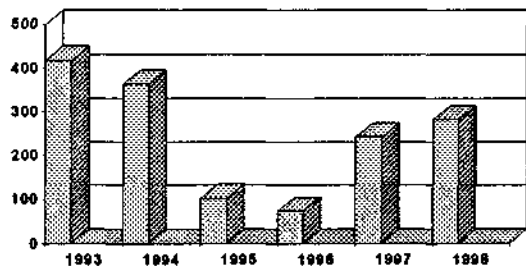
The UK SOLA Project (1993-1996)

| Sector | Crops | Residue Trial No. |
|------------------|-----------|-------------------|
| Field | 40 | 786 |
| Vegetables | | |
| Protected Crops | 7 | 94 |
| Soft/Stone Fruit | 3 | 83 |
| TOTAL | 50 | 963 |

The UK SOLA Project - In It's Prime!

- o Many 'minor' uses secured
- o Excellent network of growers/consultants
- o Numerous gaps in armoury filled
- o Manufacturer support increasing
- o UK 'years ahead' of other EU member states

The UK SOLA Project - Trial No./Year (1993-1998)



CASE STUDIES

Case Study 2 Canker in Beetroot

- o *Phoma betae* - severe storage losses
- o HDC-funded efficacy trials
- o Iprodione (Rovral) effective
- o SOLA application unsuccessful
- o EU MRL (1st priority List) at L.O.D.
- o PSD petitioning Commission in Brussels to raise MRL
- o Effective control measures delayed

Case Study 4 Pythium in Hydroponic Cucumbers

- o Propamocarb-HCl approved On-Label
- 14 day Harvest interval
- o Ineffective use pattern during cropping
- growers harvesting twice/week
- o Data package for shorter HI
- o SOLA granted with 2 day HI
- use permitted during cropping

Case Study 1 Crown Rot in Carrots

- o A Disease of unknown etiology
- o *Itersonilia* spp. suspected
- o Fenpropimorph effective in lab. screen
- o Residues data package generated
- o Emergency SOLA application
- o Widespread use of product in UK
- o Disease not been problematic since

Case Study 3 Disease Control in Celery

- o Leaf-spot & Sclerotinia problematic
- o Previous On-Label uses
- o EU MRL's not supported
-even though companies issued intent originally!
- o Uses to be revoked
- o Rearguard action by PSD in Brussels
- o HDC agreed to support residue trials

The UK SOLA Project - Achievements (1993-1998)

- * Data on 65 crop types
- * Data on 236 products
- * Over 1350 trials conducted
- * Over 1500 SOLA uses secured

Overall - A Great Success!

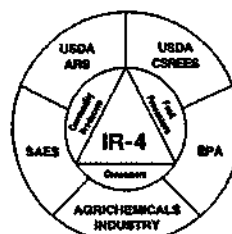
OVERSEAS PROGRAMS FOR MINOR USE
- USA

Rick Melnicoe, IR-4 Program

The Minor Use Registration System in the U.S.

Rick Melnicoe
Western Region IR-4 Coordinator
University of California, Davis

IR-4 Interregional Research Project No. 4



Minor Crop Pest Management

IR-4

Interregional Research Project No. 4

■ Objectives

- ◆ To obtain minor and specialty pesticide tolerances and assist in the maintenance of current registrations, and
- ◆ To further the development and registration of microbial and specific biochemical materials for use in pest management systems

IR-4 Organization

- National Director, Rutgers University
- Headquarter's Staff
- Administrative Advisors
- Technical Committee
- Four Regional Field Coordinators
- Four Regional Laboratory Coordinators
- USDA/ARS Scientists
- State Liaison Representatives
- Cooperating Researchers

Minor Use

- Most fruit, nut and vegetable crops
- Commercially grown flowers
- Ornamental crops
- Infrequent or very limited acreage use on major crops

Major Crops Under FQPA (U.S. Acreage >300,000)

| | | | | |
|--------------|-------------|-------------|------------|-------------|
| Almonds | Apples | Barley | Beans, Dry | Beans, Snap |
| Canela | Corn, Sweet | Corn, Field | Cotton | Grapes |
| Hay, Alfalfa | Hay, Other | Oats | Oranges | Peanuts |
| Peanut | Popcorn | Potatoes | Rice | Rye |
| Sorghum | Soybeans | Sugar Beets | Sugarcane | Sunflower |
| Tobacco | Tomatoes | Turf | Wheat | |

Chemical Industry's Role

- Data Generation
 - ◆ Toxicology, environmental fate, residue methodology, etc.
- Marketing Decisions
 - ◆ Support IR-4 project
 - ◆ Minor Use Volume = Minor Profits
- Resource Management
 - ◆ Assist in conducting field and/or laboratory studies

Financial Decisions

- Cost versus return
- Limited company resources
- New product development

Liability

- Efficacy
- Phytotoxicity
- Environmental
- Corporate

IR-4 Roles

- Obtain tolerances
 - ◆ Individual
 - ◆ Group
- Request additional commodity definitions
- Provide data showing progress toward registration for Section 18 uses
- Facilitate dialog with registrants
- Moral support

Commodity Grouping Basis

- Similar morphology
- In many groups commodities are closely related
- Expected residues within a factor of 5

IR-4 HQ Role

- Establish a project file (assign number)
- Request concurrence with the registrant(s)
- Consult with USEPA
- Discuss at Food Use Workshops
- Assign field and laboratory trials at National Planning meeting

USEPA's Role

- Advises on regulatory status of project
- Reviews and approves petition, sets tolerance or
- Requests additional data, sets tolerance or
- Rejects petition

Identification of Minor Use Needs

- Are losses occurring that warrant control measures?
- Are there available registered pesticides or alternative tactics?
- Are data available to indicate that the pesticide would be suitable for the intended use?
- Is the registrant will to pursue or support a tolerance and registration for the use?

Initiating an IR-4 Project

- Contact the State Liaison Representative (SLR)
 - ◆ Discuss the need
- Prepare the request with SLR and submit to Regional Coordinator (RC)
 - ◆ RC reviews and advises SLR of additional information needed, then forwards to IR-4 HQ

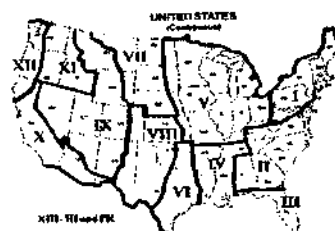
Project Prioritization at Food Use Workshops

- State Liaison Representatives
- Agricultural Scientists
- Commodity Group Representatives
- Individual Growers
- Registrant Representatives

Trial Site Selection Basis

- EPA Residue Chemistry Test Guidelines
 - ◆ OPPTS 860.1500 - Crop Field Trials
- Based on national acreage, production, dietary issues
- U.S. divided into 13 growing regions

U.S. Growing Regions





Number of Field Trials

- Apples
 - ◆ 16 trials nationally
 - ◆ 4 in NE U.S.
 - ◆ 2 in Mid-Atlantic U.S.
 - ◆ 3 in NC U.S.
 - ◆ 1 in a Rocky Mountain State
 - ◆ 1 in California
 - ◆ 5 in Pacific Northwest



Number of Field Trials

- Head Lettuce
 - ◆ 8 Trials nationally
 - ◆ 1 in either NE or mid-Atlantic state
 - ◆ 1 in Florida
 - ◆ 6 in California/Arizona



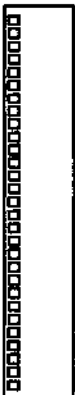
Number of Field Trials

- Artichoke
 - ◆ 3 Trials nationally
 - ◆ All in California



Conducting Research

- National Planning Meeting approves project
- Laboratories accept project
- Regions find researchers
- GLP protocol developed
- Research conducted
- Field report submitted to regional office and sent to HQ
- Laboratory analyses conducted and report sent to HQ
- Tolerance petition developed by HQ, approved by mfg. and submitted to USEPA



IR-4 Successes

- Obtained clearances for over 4,500 food uses
- Clearances for over 5,000 ornamental uses
- Since 1982 data developed to support 20 biopesticide registrations on 107 sites



Limitations

- Funding
- Workload Vs. Manpower
 - ◆ New Use Backlog
 - ◆ FQPA Demands

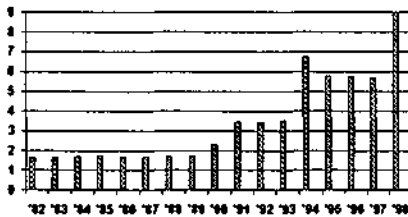
IR-4 Funding Sources

- USDA-CSREES
- USDA-ARS
- Commodity Organizations
- Pesticide Registrants
- Individual Growers

Budget Planning Cycle

- Each Budget has a multi-year Cycle
- 1997 proposals are made from universities for funding. Discussions ensue.
- July 1998 - USDA budget proposal for 2001 to Office of Management Budget.
- September 1998 - OMB returns budget stating how much may be requested. Discussions ensue.
- February 1999 - President's budget to Congress.
- February-September, 1999 - Congressional committee action.
- By October 1, 1999 - Approval by Congress.
- November 15, 1999 - Notice to programs on amount approved.
- April 1, 2000 - IR-4 funds transferred to Regions.

IR-4 Funding History \$ Millions



Pesticides of Concern Under FQPA - Vegetables

| B ₂ | OPs | Carbamates |
|----------------|----------|------------------|
| Bravo | Counter | Cygon |
| Captan | Disyston | Dyfonate |
| Dithane | Guthion | Inidan |
| Maneb | Lorsban | Monitor |
| Vapam | Nemacur | Malathion |
| | | Methyl Parathion |
| | Orthene | MSR |
| | Thimet | |
| | | Berlate |
| | | Paradan |
| | | Lannate |
| | | Sevin |
| | | Vydate |

Pesticides of Concern Under FQPA - Grapes

| Priority Group 1 | OPs | Carbamates |
|------------------|------------|------------|
| Captan | Guthion | Berlate |
| Endosulfan | Lorsban | Paradan |
| Nemacur | Diazinon | Lannate |
| Polpet | Dicofol | |
| Rovral | Dimethoate | |
| Mancozeb | Malathion | |
| Maneb | Dibrom | |
| Madate | Inidan | |
| Orrite | Parathion | |

Australian Opportunities

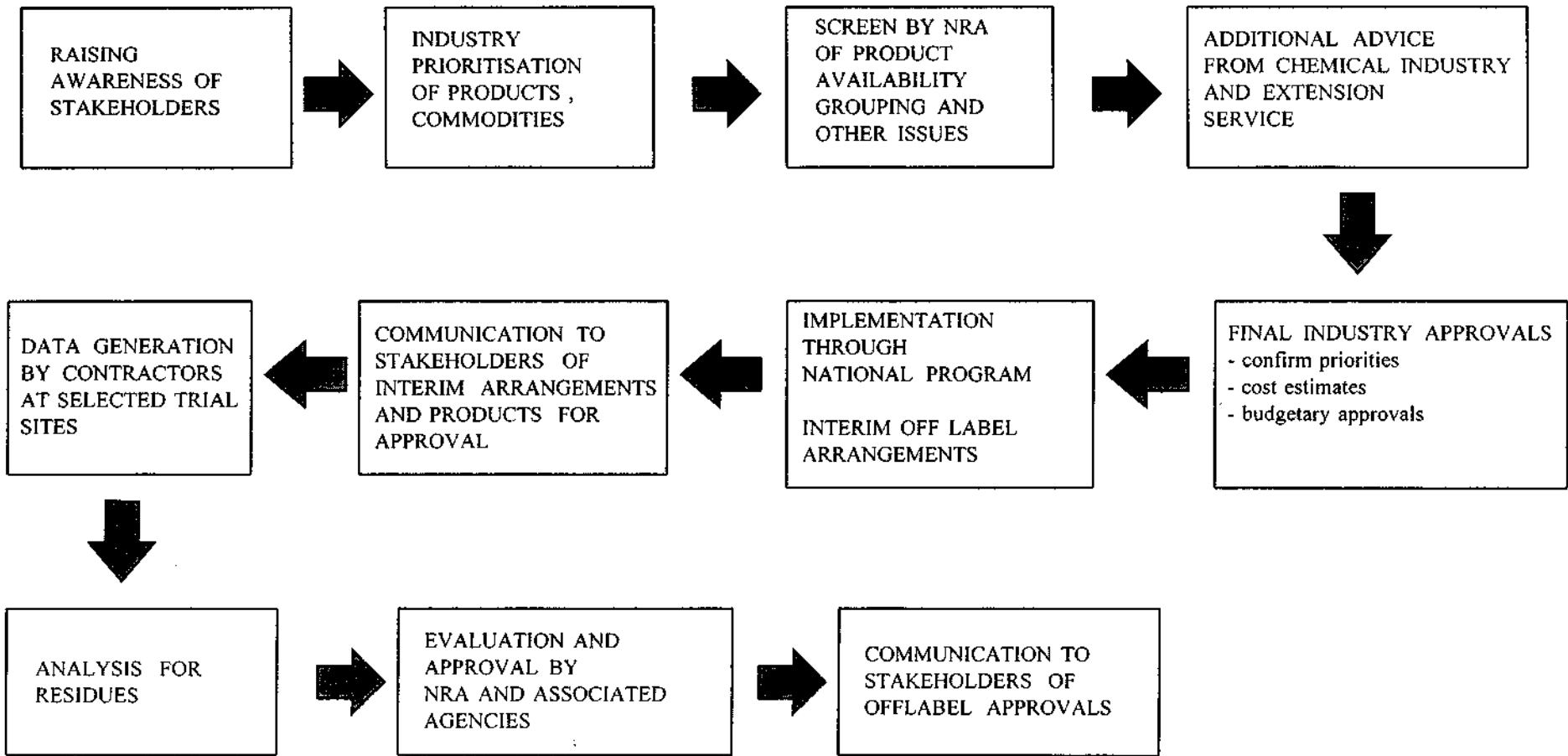
- Establish a rational system for minor use clearances
- Build upon the systems found elsewhere
- Make the program cost effective
- Build a cooperative program which is equitable for all minor uses

OUTLINE OF A MODEL FOR AUSTRALIA

Dr Peter Merriman, Institute for Horticultural Development

Draft process for a national program of approvals for minor use

NATIONAL COORDINATION
agency
roles
planning
budget
reporting



OUTLINE OF A MODEL FOR AUSTRALIA

- the flow diagram presents in general terms how a minor use program may look in Australia
- it is difficult to capture all the elements because it represents a mix of organisation's roles and responsibilities and operational requirements
- it basically concerns steps: (i) identification of industry's priorities for minor use; (ii) screening by the NRA and other specialists to ensure the products are not registered elsewhere, that the product is available, that pesticide resistance is not a risk and that there are no opportunities for product or commodity grouping; (iii) endorsement by industry of the final list and consideration of the budgetary implications of implementation; (iv) interim arrangements from the NRA for products approved for full off label approval; (v) data generation of MRL's and documentation; (vi) final analysis and endorsement (or not) by NRA; (vii) communication of full off label approvals
- the flow diagram does not adequately represent the complexity of the communication process and this may be a responsibility of the group or individual involved in national coordination
- the box on national coordination has been deliberately set on one side and will be considered by the syndicate on management and coordination

SYNDICATE SESSIONS

COMMUNICATION

Leader: Tony Biggs

Membership:

Ian Atkinson IDO, Nursery Industry Association
Michael Cain Executive Officer, Horticulture, SAFF
Tony Fist Tasmanian alkaloids
Wendy Morgan Industry Manager Vegetables IHD
Stephanie Leach NuFarm
Shauna Dewhurst QFVGA
Cassie Wright Principal Policy Officer QDPI
John Chapman Client Services Manager Qld Hort Inst QDPI
Bernadette Swanson Education and Training IHD

- DEFINE AUDIENCE - the project, growers, chemical industry, resellers, govt, consumers,
- DEVELOP A COMMUNICATION STRATEGY - awareness, interim, final approvals
- RESPONSIBILITIES FOR IMPLEMENTATION - who, how, \$

Additional notes:

- ensure the issue of communication between and within organisations is covered
- develop flow diagram if necessary
- consider whether a dedicated small group is required for national communication

Syndicate title: **COMMUNICATION**

Inputs required for your part/s of model:

Issues and suggested strategies or protocols:

| Issues | Strategy or protocol |
|--|---|
| wide communication to stakeholders (prioritises the stakeholders) | identify and prioritise the stakeholders |
| co-ordinated communication (who) | Central committee co-ordinates communication |
| frequent & regular communication | Determine timing , nature & structure of communications |
| internal communication between scheme participants | Central committee co-ordinates internal and external communication |
| appropriatenes and clarity of message | KISS |
| funding | Communication part of core funding |
| responsibility for communication | Communication manager appointed by central committee |
| historical and hysterical baggage (legislation) parochialism complexity of system read and adopt message | Ensure scheme seen as new, improved and accessible Communicate national nature of scheme Simple strategy Evaluate outcomes of communication strategy |

| Recommended actions | By whom | By when | Resources required * |
|--|--------------------|-----------|----------------------|
| prioritise stakeholders | communication Mger | yesterday | |
| Communication Mgr appointed with defined role | | | |
| Survey key stakeholders re communication needs | | | |
| Develop Comm Plan | | | |
| Develop easily assimilated packages | | | |
| Secure funding as part of total package | | | |
| | | | |
| Develop evaluation process of Comm plan | | | |
| ALL NEW ACTIONS | | | |

(* indicate whether new or modifications to existing)

Outputs from your part/s of the model:

Additional points from General Discussion:

1. Communication vitally important to whole process - need stressed for coordination nad manager
2. Need to determine what needs to be communicated, to whom, how, by whom and when
3. Need to consider communication in current permit scheme and what needs to be improved for new scheme. New scheme needs to be proactive.

IDENTIFICATION, PRIORITISATION AND INITIATION OF MINOR USE PROPOSALS

Leader: Brian Newman

Membership:

David Anderson Vegetable Grower, WA
Peter Cochrane Vegetable Grower Vic
Roger de Keyser Senior Policy Officer NSW EPA
Rodney Dunn Vegetable Grower Qld
Ian Logan Crop Care Australia
Peter Prammer Senior Product Manager NRA
Chris Sharpe Research Scientist Ag WA
Ric Melnicoe Western Regional Coordinator IR 4 USDA
Mike Wheeler Vegetable Grower NSW
John Hargreaves Senior Entomologist Redlands Bay QDPI

- IDENTIFICATION OF MINOR USE PROBLEMS WITHIN AND BETWEEN PRODUCTION AREAS: how and where do growers get guidance?
- CRITERIA FOR ESTABLISHING PRIORITY RATING: value of crop, economic damage caused by pest
- DEVELOP A PROCESS FOR IDENTIFYING THOSE USES WHICH ARE REQUIRED BY GROWERS AND ARE CURRENTLY NOT AVAILABLE AS RECOMMENDATIONS ON PRODUCT LABELS - who, how, interim arrangements?
- PROCESS FOR FEEDING INTO NATIONAL SYSTEM AND FURTHER RATIONALISATION SUCH AS COMMODITY AND PRODUCT GROUPING, RESISTANCE MANAGEMENT

Syndicate title: **IDENTIFICATION, PRIORITIZATION AND INITIATION OF MINOR USE PROPOSALS**

| | Issue | Strategy |
|-------------------|---|---|
| 1. | Classifications: Commodity group definition | 19 commodity groups in USA Codex |
| 2. | Define 'minor' | Review |
| 3. Identification | Generating applications | R & D Committees State Grower IDO's R & D Communication Process |
| | Extension officer loss | IDO's Chemical industry agronomists |
| 4. Prioritisation | Setting priorities | Establish priority parameters Use existing R & D commodity groups |
| | Product loss | Response strategy Early notification |
| | Funds | Use existing R & D involuntary levy Voluntary industry contributions Cross commodity funding?? |
| 5. Initiation | Implementation | Fasttrack company Understand cross commodity issues Liaison chemical Co's/NRA/OS Govts Coordinating submissions/HRDC/AHC Administration of work |
| | | |

| Recommended Actions | By Whom | By When | Resources required |
|-----------------------|------------------|--|--------------------|
| 1. | NRA | June 1998 | Crossley funding? |
| 2. | NRA | June 1998 | Existing resources |
| 3. | Growers | Ongoing (HRDC cycle or Out of session) | Nil? |
| 4. | R & D Committees | Ongoing | Nil |
| 5. Proposal structure | AusVeg/HRDC | Soon | Yes!! |
| | | | |
| | | | |

Additional points from General Discussion:

1. Include ability to set priorities outside the statutory groups - bring funds.
2. NRA to check data from overseas.
3. Capture other funding - single committee and good communication.
4. Demands that would be put to the R&D Committee
 - other things may suffer
 - finite resources/time etc.
5. Ability of R&D committee to handle the prioritisation
 - do they have the expertise
 - can they make the necessary judgements
6. Funding and long term viability
7. What has to be done to set up the core group?
8. Role of NRA in the priority setting process

DATA GENERATION AND ANALYSIS

Leader: Leon Radunz

Membership:

Gordon Berg Research Manager IHD
Steven Crossley Section Leader Pesticides Safety Directorate UK
Ron Eichner Manager Residue Evaluation Section NRA
John Kassebaum Manager Farm Chemicals Program PISA
Ron Meyer Phytech Development Pty Ltd Vic
Les Mitchell Manager Agrisearch Services Pty Ltd Shepparton
Martin McPherson Horticulture Research International UK
Prue McMichael Technical Manager Scholefield Robinson SA
Craig Henderson Senior Horticulturalist Gatton QDPI
Ian McLeod Serv Ag Devonport Tasmania

- DEVELOP SPECIFIC FRAMEWORK FOR DATA GENERATION AND ANALYSIS: roles and responsibilities
- GUIDELINES FOR EXTRAPOLATION OF EXISTING DATA - NEED FOR EFFICACY RESIDUE AND PHYTOTOXICITY INFO - use and adaptation of o/s models; lead agency and representation
- ACCEPTABILITY OF O/S DATA
- DEVELOP/CONFIRM GUIDELINES FOR GOOD LAB AND FIELD PRACTICE
- OPPORTUNITIES FOR DATA PROTECTION FOR PRODUCTS
- SITE SELECTION - define geographic locations of commodities; define specialist inputs reqd - entomology, plant pathology weeds to identify number and location of sites

Syndicate title: **DATA GENERATION AND ANALYSIS**

Inputs required for your part/s of model:

- Applications
- Guidelines
- OS data

Issues and suggested strategies or protocols:

| Issues | Strategy or protocol |
|--|---|
| Framework for data generation and analysis | Develop residue guidelines <ul style="list-style-type: none">• exclude efficacy and phytotoxicity• responsibility for efficacy and phytotoxicity to be with the grower Include in residue guidelines |
| Guidelines for extrapolation of data | Useful supporting data and may reduce the extent of local data |
| Acceptability of OS data | Strongly desirable but not essential |
| GLP | Not desirable for national system for off-label/residue data |
| Data protection | Economies of scale by coordination and liaison cover in guidelines |
| Site selection | assistance from AVCARE |
| Turnaround times | as per current permit times |
| Submissions received by NRA | Preferably prioritised by national coordination body |

| Recommended actions | By whom | By when | Resources required * |
|--|---------|---|--|
| Develop residue guidelines <ul style="list-style-type: none"> • major/minor crops • local data residue requirements • role of OS data, major minor crops • include appropriate approval form | NRA | Priority issue for functioning of national coordination group - draft by September | Funding <ul style="list-style-type: none"> • \$\$\$ • priorities |
| | | | |
| | | | |
| | | | |

(* indicate whether new or modifications to existing)

Outputs from your part/s of the model:

- Generation of report to national coordinating committee

Additional points from General Discussion:

1. NRA/DPIE to investigate a change in legislation to absolve the NRA from being required to consider both efficacy and phytotoxicity in assessing an application for approval of a minor use.
2. Overseas residue data. The agreement was reached that overseas data might replace the need for local residue data provided that the data was from comparable conditions of use.
3. Confirmation of proposals.
 - September 1998 deadline for residue guideline was accepted.
 - Efficacy and phytotoxicity data are excluded and the grower takes responsibility for use.
4. Should an approved minor use be considered for inclusion on a label then a full data package and phytotoxicity will be required.

LIABILITY AND LEGISLATION
Leader: Geoff MacAlpine

Membership:

Wayne Cornish Chair NFF Farm Chemical Committee
Alec Harslett Vegetable Grower Qld
Catherine Hollywell Manager Chemical Standards DNRE Vic
Malcolm Roach Director Independent Horticultural Distributors Dandenong Vic
Rob Brown Program Manager RIRDC
Roger Toffolon Program Leader Agriculture and Veterinary Chemicals NSW
Jonathan Eccles Program Manager HRDC

- WHO IS LIABLE AND FOR WHAT
- DO NRA PERMITS HAVE JURISDICTION IN ALL STAES AND TERRITORIES
- WHAT IS THE IMPACTOF THE LACK OF UNIFORMITY OF STATE USE LEGISLATION
- EVALUATE WHETHER MINOR USE PROGRAM CAN BE IMPLEMENTED UNDER CURRENT ARRANGEMENTS
- IDENTIFICATION OF ALTERNATIVES AND MECHANISMS FOR CHANGE
- IDENTIFY APPROPRIATE LEAD AGENCY, ASSOCIATED GROUPS AND RESOURCES

Syndicate title: LIABILITY AND LEGISLATION - LIABILITY

Inputs required for your part/s of model:

Who is liable and for what?

Issues and suggested strategies or protocols:

| Issues | Strategy or protocol |
|--|--|
| <p>There are many parties to the registration and approval process that will carry some liability.</p> <p>NRA advice outlines specific issues of liability with respect to manufacturers and their involvement in the permit process.</p> <p>Liability</p> | <p>Identify protocols which reduce liability for all parties, and for the manufacturers in particular.</p> |

| Recommended actions | By whom | By when | Resources required * |
|--|---------|---------|----------------------|
| DPIE to provide legal advice on how the liability of all parties can be minimised. | DPIE | ASAP | |
| | | | |

(* indicate whether new or modifications to existing)

Outputs from your part/s of the model:

Additional points from General Discussion:

1. Need to push DPIE to provide quick response/consideration on liability.
2. Liability of advisors needs to be considered.

Syndicate title: **LIABILITY AND LEGISLATION - LEGISLATION**

Inputs required for your part/s of model:

1. **Do NRA Permits have jurisdiction in all states and territories?**
2. **What is the impact of lack of uniformity of state use legislation?**

Issues and suggested strategies or protocols:

| Issues | Strategy or protocol |
|--|---|
| <p>1. Yes. NRA permits have jurisdiction in all states.</p> <p>NRA permits can only apply to use patterns which would otherwise be illegal in the state/territory. There are currently differences in what it is legal to do with a registered product in each state/territory.</p> <p>2. Growers may have less incentive to apply for minor use in those states where approval of the use pattern is not required by state use legislation.</p> | <p>Improve understanding of state control of use legislation and how it relates to NRA legislation.</p> <p>Promote a national approach to minor use applications to eliminate any local disincentive.</p> |

| Recommended actions | By whom | By when | Resources required * |
|--|---|---------|----------------------|
| Prepare document on major principles of control of use in the state/territories utilising previous national WP work. | Minor use steering C'ttee together with DPIE AgVet Chem | | |
| | | | |

(* indicate whether new or modifications to existing)

Outputs from your part/s of the model:

Additional points from General Discussion:

1. Alignment of state legislation desirable.

MANAGEMENT AND COORDINATION

Leader: Vic Edge

Membership:

Michael Badcock Chair Vegetable Council TFGA
Greg Hooper Deputy CEO NRA
Mark Smith Program Manager HRDC
Peter Chapman Head Technical Secretariat Branch Pesticides Safety Directorate UK
John Cranwell Vegetable Grower SA
John Bishop Vegetable Grower and Board Member QFVG
Stanford Harrison Senior Policy Officer DPIE Canberra
Robert Harris Market Development Manager Hoechst Schering AgrEvo
Peter Merriman Manager Plant Health IHD
Paul Ziebarth Vegetable Grower and Board Member HRDC

- EVALUATE O/S MANAGEMENT SYSTEMS AND DEVELOP PREFERRED MODEL WITH ALTERNATIVES IF NECESSARY
- IDENTIFY AGENCY, ROLES, FUNCTIONS AND RESPONSIBILITIES
- DEVELOP PLANNING AND BUDGET CYCLE
- IDENTIFY RESOURCES REQUIRED FOR MANAGING PROJECT
- DEVELOP REPORTING RELATIONSHIPS - hrdc, growers, scarm, the project personnel

Syndicate title: **MANAGEMENT AND COORDINATION**

Issues - Impediments

- lack of coordination of examining and treating problems (eg. between states)
- repeat emergencies (ad hoc submissions)
- inadequate communication
- no easy mechanism to generate data - funding deficiency
- no prioritisation process in place
- funding process

What needs to be done

1. Minor use subcommittee - take on brief to establish management committee
2. Set up Office of Minor Use
 - within or near HRDC
 - set up with minor use subcommittee + HRDC + ?
3. Define roles and responsibilities for office of minor use
4. Determine costings - consult
 - Funding - HRDC, Govt. (Commonwealth and States), Chemical Industry
 - Who runs Office?
 - Industry (HRDC)
 - Agchem (AVCARE)
 - NRA (Staffer)

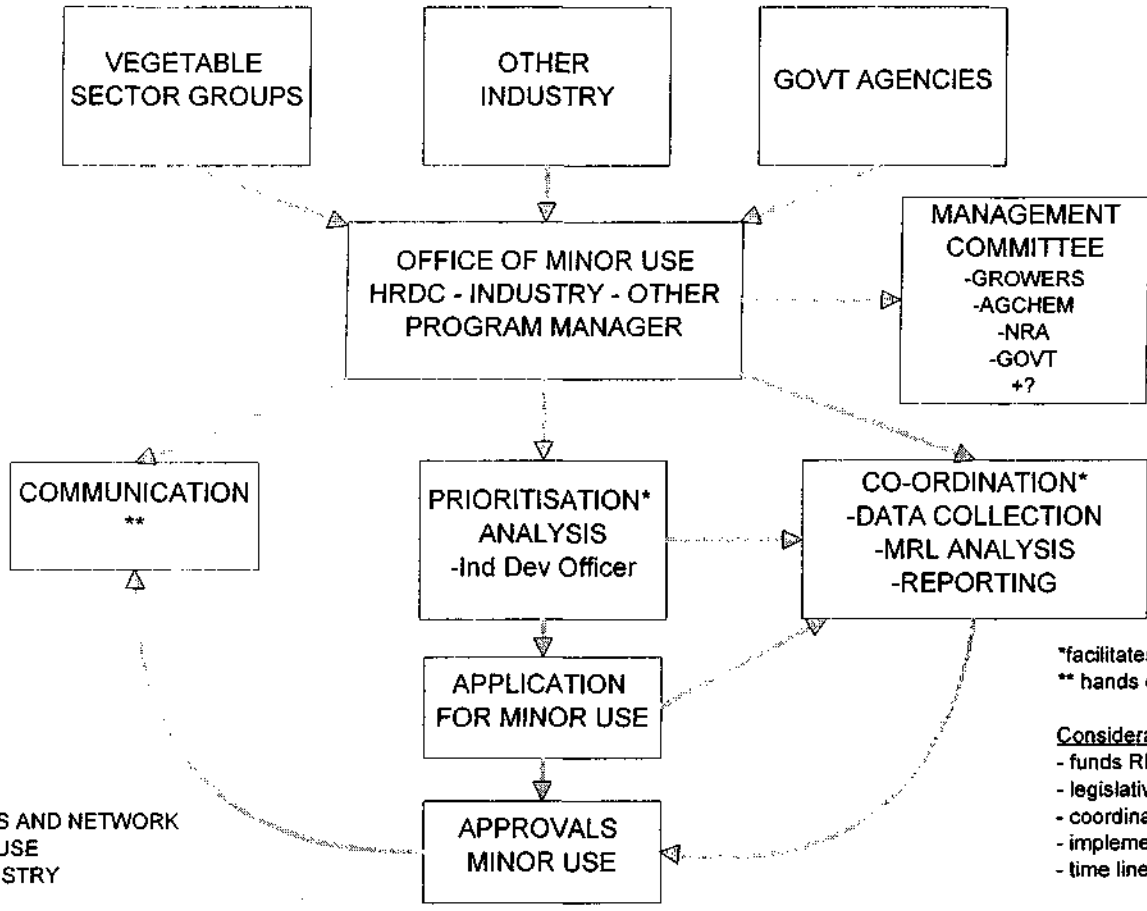
See attached flow chart for possible process

Additional points from General Discussion:

1. Need to consider location of Office of Minor use
2. Three important functions of process:
 - industry determining its requests
 - entity which will take request and translate it into a submission
 - submission passed to NRA to assess
3. Consider job specifications of Manager:
 - seek out and receive grower proposals
 - establish priorities for projects
 - liaise with NRA, Chemical companies
 - control residue trials and data generation
 - prepare submission to NRA
 - promulgate approvals

Action

1. Develop a blue-print for the development of a National Minor Use Program and its communication to horticulture by December 1998 (Merriman and staff - extension to existing project).
2. Establish a steering group asap (Vegetable R&D committee, HRDC, RIRDC) to oversee the process, generate a proposal for funding a 3 year pilot program beginning July 1998, and which includes the appointment of a manager and fine tuning of the blue-print.



*facilitates prioritisation & coordination
 ** hands on responsibility

- Consideration:
- funds RIRC/Industry/?
 - legislative changes
 - coordination HRDC
 - implementation phase
 - time lines

- USE HRDC/RIRDC MECHANISMS AND NETWORK
- ESTABLISH OFFICE OF MINOR USE
- NATIONAL FOCUS/CROSS INDUSTRY
- APPOINT PROGRAM MANAGER AND DEDICATED IDO LOCATED AT NRA

DRAFT FOR COMMENT

BLUEPRINT FOR A NATIONAL MINOR USE PROGRAM FOR APPROVING PESTICIDES FOR MINOR USES IN AUSTRALIAN HORTICULTURE

JUNE 1998

Prepared as part of a project funded by the Australian Vegetable Industry, HRDC and RIRDC.

Prepared under the direction of the National Registration Authority Minor Use Steering Committee by:

**Peter Merriman and Gordon Berg, Institute for Horticultural Development, Knoxfield
Peter Prammer, NRA, Canberra**

CONTENTS

| | PAGE |
|---|-------------|
| 1. INTRODUCTION | 4 |
| 2. DEVELOPMENT OF A NATIONAL PILOT PROGRAM | 6 |
| 2.1 TIMELINES | 6 |
| 2.2 IMPLEMENTATION | 7 |
| 2.2.1 SUBMISSION FOR FUNDING | 7 |
| 2.2.2 APPOINTMENT OF STAFF, DEVELOPMENT OF NETWORKS, ESTABLISHMENT OF PROCESSES AND PROTOCOLS | 8 |
| 2.2.3 IMPLEMENTATION OF THE PILOT PROGRAM | 8 |
| 2.2.4 IMPLEMENTATION OF FULL MINOR USE PROGRAM | 9 |
| 2.3 PROPOSED RESPONSIBILITIES OF AGENCIES, INFRASTRUCTURE, PROCESSES AND PROTOCOLS | 10 |
| 2.3.1 ESTABLISHMENT OF THE OFFICE OF MINOR USE | 10 |
| 2.3.2 APPOINTMENT OF PREFERRED CONTRACTORS GENERATION OF RESIDUE DATA AND FOR ANALYSING PLANT SAMPLES FOR RESIDUES | 10 |
| 2.3.3 ESTABLISHMENT OF INDUSTRY INFRASTRUCTURE FOR INITIATING AND PRIORITISING MINOR USE PROPOSALS | 11 |
| 2.3.4 ANALYSIS OF SUBMISSIONS FOR MINOR USE APPROVALS BY THE NRA | 11 |
| 2.3.5 RESPONSIBILITIES OF ADDITIONAL EXPERT PANELS | 11 |
| 2.3.6 ESTABLISHMENT OF A CONSULTATION PROCESS FOR ENDORSEMENT OF MINOR USE PROPOSALS BY THE AGRO-CHEMICAL INDUSTRY | 12 |
| 2.3.7 PROTOCOLS FOR FINAL INDUSTRY ENDORSEMENT, INCLUDING BUDGET APPROVALS, OF PRODUCTS FOR INCLUSION THE MINOR USE PROGRAM | 12 |
| 2.3.8 ESTABLISHMENT OF TEMPORARY AND FULL MINOR USE APPROVALS BY THE NRA | 12 |

| | | |
|-----------|--|-----------|
| 2.3.9 | COMMUNICATION OF THE COMPONENTS OF THE MINOR USE PROGRAM TO STAKEHOLDERS | 12 |
| 3. | APPENDICES | 13 |
| 3.1 | OBJECTIVES, ACTIVITIES, INFRASTRUCTURE AND STAFF REQUIREMENTS OF THE OFFICE OF MINOR USE | 13 |
| 3.2 | GUIDELINES FOR RESIDUE TRIALS | 15 |
| 3.3 | PROCESS FOR IDENTIFYING AND INITIATING BIDS FOR MINOR USE APPLICATIONS | 16 |
| 3.4 | COMMODITY AND CHEMICAL GROUPINGS | 17 |
| 3.5 | GLOSSARY | 18 |

1. INTRODUCTION

A National Workshop on Approval of Pesticides for Minor Uses was held in March 1998. The workshop was funded by the Vegetable Industry, HRDC and RIRDC. It has been reported in a separate document available from the authors of this blueprint.

The workshop recommended:

- to proceed immediately to develop a blue print, by mid 1998, for a national minor use program
- to commence the development, by June 1998, of a proposal for the implementation of a national minor use program

A model for the program was developed at the workshop and is illustrated in **Figure 1**. There was consensus at the workshop that the protocols and processes for a minor use program in vegetables should be sufficiently flexible for adoption by other plant industries.

The program would complement the existing NRA Off-Label Permit scheme and provide industry driven mechanisms to identify and fund minor use proposals and associated residue and other studies. The data from these studies would provide the basis of submissions to the NRA for full Minor Use Approvals. The proposed program would establish an "Office of Minor Use" to manage and coordinate this industry driven process. It would incorporate features of successful overseas programs in the USA and UK which were outlined at the workshop.

This draft blueprint document is now presented for comment and endorsement by workshop attendees. Subject to its endorsement, the blueprint will then be further developed as a project submission to fund the pilot program which is proposed to be conducted under the guidance of a Steering Committee.

The blueprint comprises three components:

1. Timelines for development of the program
2. Implementation
3. Identification of responsibilities of agencies, infrastructure, processes and protocols

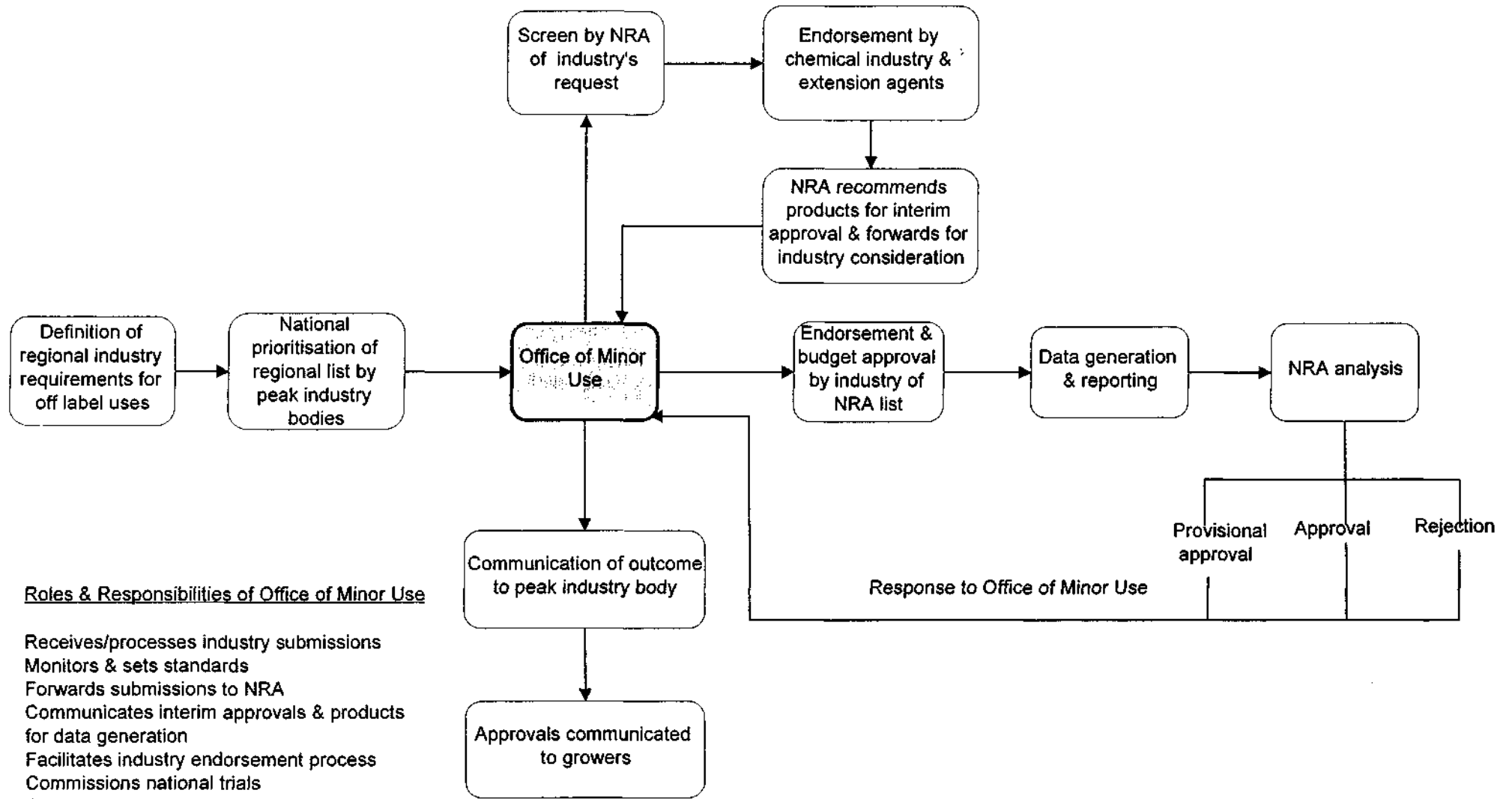
Two stages are proposed:

- **an establishment phase** where the necessary infrastructure, networks and protocols are procured and developed for the nominated start up date;
- **an implementation phase** involving efficient transition to implementation of a pilot program, where the system will be tested using selected products and commodities as a prelude to full implementation.

Funding for the development of the blueprint has been obtained through an additional allocation of \$11000 to the existing project which supported the national workshop.

Additional funds for establishment and implementation will be sought through the separate submission to HRDC, RIRDC and the Agrochemical Industry and possibly other funding agencies.

Figure 1. Proposed Model for Australian Minor Use Program



2. DEVELOPMENT OF A NATIONAL PILOT PROGRAM

2.1 TIMELINES

The timelines for the overall program from development of the blueprint to implementation of a national minor use pilot program are:

- | | |
|----------------|--|
| MAY/JUNE 98 | <ul style="list-style-type: none">• preparation of the first draft of the blueprint including identification of infrastructure, development of process and protocols;• feedback on first draft from National Minor Use Steering Committee |
| JUNE/JULY 98 | <ul style="list-style-type: none">• consideration of blueprint by national stakeholders including: State Industry Associations, Agro-Chemical Industry, National Registration Authority, Department of Primary Industries and Energy, State Government Regulatory agencies |
| AUGUST/SEPT 98 | <ul style="list-style-type: none">• final endorsed blueprint used to prepare submission for funding the establishment and implementation of the national program |
| SEPTEMBER 98 | <ul style="list-style-type: none">• consideration of submission by respective funding agencies and, subject to necessary approvals, commencement of national program:• (i) establishment of infrastructure, including Office of Minor Use and Steering Committee• (ii) implementation of pilot program |

2.2 IMPLEMENTATION

Implementation of the national minor use program is foreshadowed in four stages:

- preparation of the full submission for funding to appropriate agencies
- appointment of staff, assignment of responsibilities, establishment of networks, development of processes and protocols
- implementation of pilot program for defined number of products
- implementation of full minor use program

2.2.1 Submission for funding

The blueprint document which has been endorsed by stakeholders is the basis for the preparation of the funding submission, which is the responsibility of the Vegetable R&D Committee with Dr Mark Smith Program Manager HRDC and Dr Rob Brown Program Manager RIRDC.

The key components will be defining the objectives, milestones and outcomes; estimating the budget and the recommended source of funds.

Objective

- to establish a national pilot program for approving minor uses of pesticides in the vegetable industry

Milestones

- the establishment of the Office of Minor Use (including the appointment of a Program Manager), a Steering Committee and other associated infrastructure,
- the development of processes and protocols,
- the development of a communication strategy,
- the implementation of the pilot program,
- the implementation of a review of performance and how other industry groups might be involved
- the preparation of a final report

Outcomes

- infrastructure established for the National Minor Use Program,
- selected products evaluated for Full Minor Use Approval,
- recommendations for implementing a full minor use program.

Budget – the budget will require partition into two components

- (i) costs of establishing and maintaining infrastructure and
- (ii) costs of “processing” products through the minor use program.

The stakeholders, and therefore potential fund sources, include AusVeg, DPIE, HRDC, RIRDC, State Government and the AgroChemical Industry.

Note: the budget for the current minor use initiatives is derived from the Department of Primary Industries and Energy, AusVeg, HRDC, RIRDC and Agriculture Victoria. DPIE contributes to the establishment and maintenance of the minor use program within the NRA, and the remaining funds have been used to primarily for the national workshop and minor surveys of the Vegetable Industry

Issues for consideration in developing the submission

- the duration of the project – 2 or 3 years
- assigning budget items from the various funding agencies eg the DPIE component might be used for infrastructure within the NRA to ensure efficient processing of products for minor use approvals; the RIRDC component could be used to part fund the establishment the Office of Minor Use; HRDC and Vegetable Industry funds could be used to complement RIRDC in establishing the Office of Minor Use but also for supporting the cost of data generation and analysis of specific products.
- rationalising the role of the NRA Minor Use Steering Committee in relation to the Steering Committee proposed for the project

2.2.2 Appointment of staff, development of networks, establishment of processes and protocols

Subject to the submission for funding being approved, the first activity of the project will be to establish the resources required to process products (fungicides, herbicides, insecticides, nematocides) nominated by Industry for evaluation by the program.

It is proposed that an interim management group work on the establishment of the various aspects of infrastructure while staff appointments are being made, especially to the Office of Minor Use. This will avoid unnecessary impediments to project development because of the need to wait for the appointment of Program Manager.

However, once appointed, the Program Manager would then assume responsibility for further implementation under direction from the Steering Committee. Within three to six months of the commencement of the project it is expected that all the infrastructure, as previously described, will have been established and participants will be ready to move to an implementation phase.

2.2.3 Implementation of the pilot program

The pilot program will be used to develop and test the system for prioritising, processing and analysing products for minor use.

The selection process for products will require careful consideration, to ensure it covers the important groups of pesticides used by vegetable growers. It is anticipated that the time required for processing an initial group of products through the system will be 18 months.

In this initial process it is proposed that State industry groups, such as the QFVG that have already identified minor use issues and requirements, in collaboration with the national vegetable industry group Ausveg, prioritise a list of chemical/commodity/pest cases. The list should include representative examples of pests, diseases and weeds. It should also aim to include specific crops that are grown in a number of regions within Australia.

The Office of Minor Use, the NRA and Avcare will then screen the list to determine if there are any impediments that would prevent specific cases being progressed for the pilot studies. This screening process would consider issues such as:

- current registration status of the chemical
- is the chemical likely to be available in the market for the foreseeable future?
- IPM and resistance management considerations
- are currently registered products available for the required use or other alternatives?

The list would be finalised with reference to the industry groups and the required desk-top and field studies initiated to provide the data for the proposals.

An important and final element of the pilot program will be to review the performance of the system and recommend modifications which could be adopted in a "full" National Program. This should be a part of the Pilot Program and it is proposed that the Steering Committee for the project would have responsibility for progressing this.

In particular it will be important that the review considers the development of strategies to ensure communication across other industries, so that these groups understand clearly how they might also participate in the National Program, especially in relation to co-funding the Office of Minor Use.

2.2.4 Implementation of full minor use program

The implementation of the full minor use program will depend on recommendations from the pilot program and whether the various industries, in addition to vegetables, decide to support the initiative. Clearly the Vegetable Industry will need to consider whether it wishes to proceed to full implementation and then establish the mechanism of achieving this.

In addition there have already been high levels of interest expressed from the ornamental, fruit, herb, forestry and grains industries and it would appear that there will be opportunities for significant levels of cross industry funding which could be used to offset the investment from the Vegetable Industry.

Decisions will be required on how best to ensure coordination of the issue of minor use across industries, and how to invest these funds in a single national program which will avoid unnecessary duplication of resources.

2.3 PROPOSED RESPONSIBILITIES OF AGENCIES, INFRASTRUCTURE, PROCESSES AND PROTOCOLS

Infrastructure, processes and protocols which were proposed for incorporation into the framework of a national project and endorsed by the national workshop are illustrated in **Figure 1**.

The main steps in this process are:

- establishment of an Office of Minor Use and Steering Committee
- appointment of a list of preferred and accredited contractors to generate field data and analyse plant samples for residues
- initiating an industry driven process of identifying and prioritising requests, and of approving the budget for products which have been endorsed for inclusion in the minor use program
- establishment of expert panels to analyse industry requests
- development of a consultation process with the Agro-Chemical Industry and State Chemical Standards groups concerning inclusion of products in the Minor Use program
- establishment by the NRA of the process of Temporary Minor Use Approval of products endorsed for evaluation in the Minor Use program; and for Full Minor Use Approval based on residue data from field trials
- establishment of a communication strategy, by the Office of Minor Use, for products undergoing evaluation in the Minor Use Program

2.3.1 Establishment of the Office of Minor Use

The infrastructure requirements of the Office of Minor Use, together with the responsibilities of the Office and key selection criteria for appointment of staff are presented in **Appendix 3.1**.

The recommended process will comprise two steps:

- (i) the identification of a preferred location and
- (ii) the appointment of a Manager and associated support staff to run the national project.

It is proposed that HRDC call for expressions of interest from organisations to host the Office of Minor Use and concurrently advertise for the appointment of a Program Manager.

The Steering Committee will have the responsibility for selection of preferred sites and the Program Manager. It is proposed that the Steering Committee continues to have the responsibility for overseeing the Office of Minor Use. The membership of the Committee will need to be reviewed to ensure that it includes representation from all key stakeholders, such as relevant industry and funding groups. Line management of the appointed Program Manager of the Office of Minor Use will be the responsibility of the Organisation hosting the Office.

Issues for consideration in establishment of the Steering Committee

- The NRA Minor Use Program Steering Committee has taken on the interim responsibility for overseeing the development of this blueprint with additional input from HRDC
- The membership and roles of the Steering Committee which will oversee the pilot program needs to be determined.
- Options include the modification of the existing NRA Minor use Program Steering Committee or the establishment of a new Steering Committee.

2.3.2 Appointment of preferred contractors for generation of residue data and for analysing plant samples for residues

The Office of Minor Use in collaboration with the NRA and Avcare will develop terms of reference and guidelines for contractors. An issue for consideration will be the requirement to operate under internationally accepted principles of "Good Field and Laboratory Practice". **Appendix 3.2** gives examples of guidelines for Good Laboratory and Field Practice used in the USA IR-4 and UK minor use programs, and protocols prescribed for residue trials by the NRA and overseas programs. Protocols to be developed for an Australian program will include protocols for trials, and possibly GLP and accreditation and auditing requirements for contractors and analytical laboratories.

The proposed process will call for expressions of interest, based on specific Terms of Reference, from which a preferred list of contractors will be appointed to undertake field and analytical services. The list may require review and this would be a responsibility of the Program Manager in collaboration with the Steering Committee.

2.3.3 Establishment of industry infrastructure for initiating and prioritising minor use proposals

The network of State and National R&D panels which has been established by the Vegetable Industry to select applications for Industry and HRDC funding could also assume responsibility for initiating and prioritising applications for the pilot program. These grower panels would prioritise applications at the State level and forward them for further rationalisation and coordination at a National level. Similar panels could be used for other plant industries.

The recommended process for identifying and initiating bids will be based on a set of criteria similar to those used by the USA IR-4 minor use program a component of which is presented in **Appendix 3.3**.

2.3.4 Analysis of submissions for minor use approvals by the NRA

Applications for approvals for minor use will be checked to ensure that the work does not duplicate other applications involving similar products on related commodities. To assist this the National Registration Authority, in collaboration with the Office of Minor Use, will develop guidelines which deal with the proposed process for:

- grouping commodities (eg bunching vegetables, leafy vegetables, root vegetables) where residue data derived for one species can safely be extrapolated to a related species without the requirement for additional field trials
- extrapolation of available residue data between chemical products with similar technical specifications

The NRA currently adopts the Codex Alimentarius Classifications of Food and Feeds and it is proposed that these also be used for the Minor Use Program (**Appendix 3.4**).

2.3.5 Responsibilities of additional expert panels

The need to ensure that products proposed for minor uses are evaluated in representative growing regions in Australia, and do not adversely affect resistance management or IPM is the responsibility of additional expert panels.

Expertise for these aspects is likely to be dispersed between various groups and agencies. The Office of Minor Use, in collaboration the NRA, will need to convene panels of experts to consider these issues as they arise.

The proposed process for identifying potential problems of resistance management, and numbers of trial sites will be based on a set of principles which will be applied on a case by case basis. For resistance management a key issue will be to ensure that the product for minor use approval will not increase the selection pressure for resistance in the target species and, in addition, will not have adverse effects on biological or other treatments.

In relation to the number of trial sites required for the generation of residue data, a key issue will be to select the minimum number of sites for the Australia environment where for example decline curves for pesticides are expected to be substantially different. This analysis would include factors such as variations in UV radiation, frequency and intensity of rainfall and other abiotic and biotic factors.

Eventually it should be possible to prescribe the number of regional trials for specific crops as is the case in the UK and USA. A regional program similar to that of the USA IR-4 program is most appropriate.

2.3.6 Establishment of a consultation process for endorsement of minor use proposals by the agro-chemical industry

Recommendations from the NRA on pesticides for evaluation in the minor use program will be referred to the respective manufacturing Company or Agency and Avcare for comment and endorsement prior to conducting residue data trials to gain information on issues that might prevent a proposal being successful.

The process will be coordinated by the Office of Minor Use and be based on a set of simple criteria including issues such as whether the product, as formulated, will remain on the market for the foreseeable future and that the company has no substantial objection to the minor use proposal because of concerns over OHS, environmental fate or other factors.

2.3.7 Protocols for final industry endorsement, including budget approvals, of products for inclusion the minor use program

The final step before trialing products, to generate residue data packages, requires that the appropriate panel of the national Vegetable R&D Committee, or other industry panel, commits funds for the field trial and analytical program which, then, can be matched by HRDC or other RIRF agency.

The budget planning cycle process will need consideration by industry and funding agencies, particularly to determine whether the core minor use program is block budgeted on an annual basis but still retains the flexibility to handle ad hoc emergency requests.

2.3.8 Establishment of Temporary and Full Minor Use Approvals by the NRA **Temporary Minor Use Approval**

Temporary Minor Use Approval arrangements are proposed for individual products which have been endorsed by industry, NRA and the Office of Minor Use and funded for evaluation under the minor use program.

The requirements of the Permit System currently in use by the NRA is outlined in the NRA publication "Permits for Agricultural and Veterinary Chemical Products" and could be utilised for such temporary approvals. Such approvals would be time bound to allow the generation of residue data for full approvals.

Full Minor Use Approval will be considered by the NRA following detailed analysis of the submission prepared by the Office of Minor Use which will include the reports of residue data trials from contractors and the analytical laboratories residue results.

The NRA will recommend either Full Minor Use Approval, Provisional Minor Use Approval or failed Minor Use Approval, and in this latter case the Temporary Minor Use Approval would be revoked.

2.3.9 Communication of the components of the minor use program to stakeholders

The Office of Minor Use will have responsibility for communication to industry, government and other clients and stakeholders.

A communication strategy will be developed for each of the components of the program where stakeholders require information. These include:

- calling for bids from growers,
- advising of successful bids and arrangements for interim off-label approval,
- seeking information and endorsement from Chemical Companies and State Chemical Standards groups
- communicating full off-label approval and revocation of interim off-label approvals.

The committee which organised the National Workshop will prepare the outline of the communication strategy for endorsement by the Steering Committee and refinement by the Office of Minor Use.

3. APPENDICES

APPENDIX 3.1 OBJECTIVES, ACTIVITIES, INFRASTRUCTURE AND STAFF REQUIREMENTS OF THE OFFICE OF MINOR USE

Office of Minor Use

Objectives:

1. To obtain minor use approvals for plant industries (vegetable industry in pilot program).
2. To ensure plant industries have access to safe, cost effective chemicals for pest, disease and weed control.

Specific activities:

1. Manage the National Minor Use Program and its reporting to stakeholders.
2. Coordinate bids for minor use applications from growers and industry groups.
3. Coordinate prioritisation of bids on a national basis.
4. Prepare and manage budget estimates and data generation plans for funding approval.
5. Consult with the NRA and the Agrochemical industry on proposed applications.
6. Appoint contractors to conduct and report data acquisition studies, and audit and review their performance.
7. Analyse data and prepare applications for submission to the NRA.
8. Communicate approvals to industry and growers.

Infrastructure requirements:

- physical requirements - office/meeting rooms etc.
- desirable technical infrastructure and capabilities:
 - library resources
 - electronic medium capabilities/ communication networks/ technology transfer capability
 - access to plant health expertise (pests, disease and weeds)
 - access to analytical chemical expertise
- strong links and existing networks to key stakeholders
 - growers
 - grower organisations
 - retail organisations
 - NRA
 - Agrochemical industry
 - state chemical standards groups
 - research providers
 - funding bodies

Staff requirements:

Program Manager, support staff and possible access to Visiting Scientists

Manager Office of Minor Use

Duties:

1. Manage and coordinate the activities of the Office of Minor Use under the direction of the Steering Committee (& Line Manager) of the National Minor Use Program.
2. Communicate the activities of the Office of Minor Use to growers, grower organisations, plant industries, the agrochemical industry, government agencies and statutory authorities, funding bodies and the public.
3. Develop processes and protocols for obtaining minor use approvals (establishment phase).
4. Coordinate applications for minor use approvals (implementation phase).
5. Develop long term plans for the National Minor Use Program (other plant industries).
6. Secure funding and stakeholder support for the Program.

Desirable attributes:

Knowledge, training, experience in areas of:

- Agricultural Science/ Science/ Environmental Science
- Plant health, IPM
- Agrochemicals including use and control of use (from registration processes to technology transfer to growers)
- Residues in plant products, toxicology

Demonstrated ability to:

- Plan and coordinate programs
- Lead and manage staff
- assemble, assess and report scientific data
- Prepare submissions/proposals/reports
- Communicate to all groups of stakeholders
- Procure funding and develop scientific programs

Key selection Criteria:

1. A degree in Agricultural Science or an equivalent field, preferably with post graduate qualifications.
2. Knowledge, substantial experience and demonstrated achievements in Plant Health (pests, diseases or weeds).
3. Knowledge, substantial experience and demonstrated achievements in, the use and control of use of agrochemicals, Australian registration requirements, and management of chemical residues in plants.
4. Demonstrated ability to conceive, procure funding for, conduct, statistically analyse and report pest management or agrochemical projects.
5. A sound knowledge and appreciation of current issues and challenges facing Plant Industries with respect to agrochemical use.
6. Demonstrated leadership skills and ability to lead, manage and coordinate work, personnel and resources.
7. High level of oral and written skills to liaise effectively with stakeholders including growers, grower organisations, plant industries, the agrochemical industry, government agencies and statutory authorities, funding bodies and the public.

APPENDIX 3.2 GUIDELINES FOR RESIDUE TRIALS

Guidelines for residue trials

General guidelines for residue trials are described in the NRA publication "Guidelines for registering agricultural chemicals (Part 5a Residues)." In addition the Office of Minor Use, the NRA and Avcare will develop additional guidelines (initially for vegetable trials) which include further detail such as:

- number of trials
- location of trials (representing appropriate Australian growing regions for specific crops)
- site selection
- trial design (statistically sound design, number of replicates, plot size)
- growing condition requirements (eg. irrigation management) which reflect the range of normal agricultural practices for specific crops
- sampling requirements, method of storage and dispatch of samples
- analytical methods for residue analysis

Useful examples of overseas guidelines include:

- IR-4 program
 - "EPA Residue Chemistry Test Guidelines - Crop Field Trials"

Good Laboratory Practice (GLP) and Accreditation

To ensure the quality and integrity of data and that field trials and analytical tests are carried out to internationally acceptable standards the development of guidelines for GLP by the Office of Minor Use and the NRA in consultation with research providers should be considered. Appropriate auditing processes may also be developed and implemented.

Useful examples of such guidelines include:

- IR-4 program
 - "Operational handbook of IR-4 to fulfil the requirements of EPA for GLP"
 - "GLP Standards - The IR-4 Project"
- UK Minor Use Program
 - "Data Requirements Book"
 - "PSD Registration Handbook"

For analytical testing it is proposed that only laboratories that are NATA accredited for specific analytical tests be used.

APPENDIX 3.3 PROCESS FOR IDENTIFYING AND INITIATING BIDS FOR MINOR USE APPLICATIONS

Identification and prioritisation of bids will require consideration of:

- impact of the pest, disease or weed
- impact of the use of non-approved chemicals on quality assurance systems
- resistance management
- new pest incursions
- continuous harvesting withholding period interactions

The following issues are addressed in identifying Minor Use needs in the USA IR-4 program:

- A. Are losses occurring that warrant control measures?
- B. Could the need be met through use of available registered pesticides or alternative tactics?
- C. Is information available to indicate that the proposed pesticide would be suitable for the use, i.e., availability of preliminary test data, or the pesticide is registered for use on similar crops and pests?
- D. Is the manufacturer/registrant of the pesticide willing to pursue a tolerance and registration for the minor use? If not, is he willing to cooperate with IR-4 to obtain the necessary clearance?
- E. can the requestor, or others in the state, conduct the necessary field tests under GLP to provide efficacy data, phytotoxicity data and samples for residue analysis?
- F. Other relevant factors.

APPENDIX 3.4 COMMODITY AND CHEMICAL GROUPINGS

A. Commodity groupings

Codex Alimentarius commodity groupings are currently adopted by the NRA. It is proposed that these groupings also be adopted as a basis for the National Minor Use program. Any specific differences to other requirements for specific export markets such as the US should be considered where appropriate.

For example The US EPA/IR-4 Program has well documented regulations which define categories of commodity and crop groups for purposes of determining residue tolerances. The groupings allow extrapolation of estimates of residues from specific crops to related crops in certain circumstances.

EPA regulations governing commodity groups used in IR-4 program

Examples of relevant sections include:

- **Definitions of 39 commodity descriptions such as "beans" or "cabbage".**

For example:

Beans: includes *Cicer arietinum* (chick peas, garbanzo beans); *Lupinus* spp. (including sweet lupine, white sweet lupine, white lupine, and grain lupine). *Phaseolus* spp. (including kidney beans, lima beans, mung beans, navy beans, pinto beans, snap beans and wax beans); *Vicia faba* (broad beans, fava beans); *Vigna* spp. (including asparagus beans, blackeyed peas and cowpeas).

Beans (dry): includes all beans above in dry form only.

Beans (succulent): includes all beans above in succulent form only.

- **Definition of 27 Commodity Groups where crops are considered to be related for the purposes of establishing residue tolerances (for non-systemic chemicals only).**

For example, group numbers:

1. Apples, crab apples, pears and quinces.

9. Beans, peas, soybeans (each in dry form)

11. Group including broccoli, brussel sprouts, cauliflower, kohlrabi.

- **Definition of 19 Crop Groups and associated Subgroups for the purposes of establishing residue tolerances.**

For example:

Crop Group 1: "Root and tuber vegetables Group"

Crop Group 4: "Leafy vegetables (except Brassica vegetables) Group"

The USA regulations state that there is a maximum of a five-fold variation allowed for commodities within a crop group for any given chemical otherwise individual tolerances are required and this may need to be considered in the Australian program.

B. Chemical groupings

Similarly it is proposed that some extrapolation between chemical products be permitted for the purposes of determining residue tolerances. Products with similar chemistries, formulations and concentrations may be grouped. Checks would include:

- active ingredient
- concentration and rate
- formulation
- withholding period

APPENDIX 3.5 GLOSSARY

National Registration Authority (NRA) is responsible for registering all agricultural and veterinary chemical products before they can be supplied and used within Australia.

NRA's Minor Use Steering Committee (MUSC) was established by the NRA to oversee the direction and development of the NRA's Minor Use Program.

NRA Minor Use Program a program initiated by the NRA to examine longer term strategies in which the registration requirements and processes could be modified to address the shortage of pesticide products available for minor uses in Australia.

National Minor Use Program is the Program proposed to be established in this blueprint. It will be guided by a Steering Committee. It has yet to be decided if this Steering Committee will be based on the NRA Minor Use Steering Committee or if it will be a new Steering Committee.

Office of Minor Use is proposed to be set up under the National Minor Use Program.

Pilot program is a project conducted under the National Minor Use Program proposed in this blueprint which will develop and test the system for generating submissions for approving pesticides for minor uses. It will consider pesticides used in the vegetable industry.

Full implementation of the National Minor Use Program refers to the development of the pilot program to the stage where it supports proposals from other Horticultural Industries and potentially other non-horticultural Plant Industries.

Maximum Residue Limit (MRL) is the maximum concentration of a residue, resulting from the officially authorised safe use of a pesticide or veterinary chemical, that is recommended to be legally permitted or recognised as acceptable in or on food, agricultural commodity, or animal feed.

Off-label permit is an approval issued by the NRA that allows an agricultural chemical product (pesticide) to be used in a manner that would otherwise be an offence against control of use legislation.

Minor Use Request (MUR) an application to the NRA for a minor use off-label permit.

Minor Use Approval (MUA) an approval (off-label permit) issued by the NRA in response to a Minor Use Request.

Temporary Minor Use Approval (TMUA) an interim approval issued under the Minor Use Program based on temporary MRL's or when further data is required against any of the assessed criteria.



National support for minor use program

7 Merriwa Street
Gordon, NSW 2072



Level 1 AMA House
42 Macquarie Street,
Barton ACT 2600

"We need a minor use program which is easy for growers to access and allows effective chemicals to be made available," explained John Bishop, a farmer from Queensland's Lockyer Valley and a member of the Queensland Fruit and Vegetable Growers sub-committee for vegetable crops.

This comment reflected the industry view expressed at a national workshop on approval of pesticides for minor use held on 23/24 March at the Institute for Horticultural Development (IHD), Knoxfield in Victoria.

More than 50 delegates representing the vegetable industry in all states, other horticultural industries, agricultural chemical manufacturers, consultants and resellers, various government agencies and research corporations gave overwhelming support to the development of a national program for the approval of minor use chemicals in horticulture.

The workshop was funded by the Australian Vegetable Growers organisation (Ausveg), the Horticultural Research and Development Corporation (HRDC) and the Rural Industries Research and Development Corporation (RIRDC).

Dr Peter Merriman, Manager of Plant Health Programs at IHD and chairman of the organising committee, believes that the workshop outcomes will provide a platform for launching a national minor use chemical program for horticulture.

"The initial drive and support has come from the vegetable industry but all horticultural industries are interested and there could be a real opportunity to widen the program to cover all plant industries," said Dr Merriman.

A meeting of the National Vegetable R&D Committee in early April will consider a recommendation from the workshop to provide interim funds to develop a blueprint for the national scheme.

This document, prepared by the workshop planning group, will be circulated nationally for endorsement by appropriate industry and government agencies. The final copy will be then be used to formulate a mid 1998 submission to HRDC, RIRDC and other organisations for funds to commission a three year pilot program.

The first step in this new initiative will be the appointment of a project manager who will assist in the fine tuning of the planning and development phase and then be responsible for implementation.

An industry convened steering committee comprising representatives from AusVeg,

HRDC, RIRDC and other stakeholders will regularly review progress and future plans to ensure outcomes are delivered on time.

The Knoxfield workshop, facilitated by Dr Peter Box of Integra, included a number of plenary presentations followed by working syndicate groups in which delegates developed issues, strategies and actions for :

- communication,
- initiation and prioritisation of minor use proposals,
- data generation and analysis,
- liability and legislation, and
- national management and co-ordination.

The introductory plenary sessions provided information on the current system and protocols for off-label use: perspectives from the vegetable and agricultural chemical industries and descriptions of minor use programs in the United Kingdom and the United States.

Peter Chapman, of the Pesticides Safety Directorate, and Dr Martin McPherson, of Horticultural Research International, explained the United Kingdom situation and described the operation of their Specific Off-Label Approval (SOLA) scheme. Rick Melnicoe, Western Region Co-ordinator of the IR-4 Program and the Pesticide Impact Assessment Program based at the University of California, Davis, dealt with the United States model.

"The international inputs were invaluable, not only in providing guidance but also, in showing that off-label, minor use programs operate successfully overseas," said Dr Merriman.

"Our overseas visitors demonstrated that programs are possible in geographically small countries like the UK and also in the United States where the wide range of crops and growing conditions are more like Australia." concluded Dr Merriman.

Further information about outcomes from the workshop and progress with the development of the national program for approval of pesticides for minor use may be obtained from:

Brian Newman, Executive Director, Ausveg
Ph. 03.5790 5247; Fax 03.5790 5259

Dr Mark Smith, Program Manager, HRDC
Ph 03.9210 9320; Fax 03.9210 9321

Dr Rob Brown, Program Manager, RIRDC
Ph. 03.9874 7462; Fax 03.9873 1853.