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**Report of the OECD Pesticide Risk Reduction Group Seminar on Minor Uses and Pesticide Risk
Reduction**

**4 November, 2003
Canberra, Australia**

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**Report of the OECD Pesticide Risk Reduction Group
Seminar on Minor Uses and Pesticide Risk Reduction**

**Canberra, Australia
4 November, 2003**

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Introduction

This report presents the results of an OECD seminar on ways to achieve risk reduction while addressing issues associated with the use of chemical pesticides or non-chemical means of crop protection on a small scale. Known as “minor use,” small-scale pesticide use most frequently involves pest control in a minor crop or for a small pest problem in a major crop. Minor uses can present registration issues because it is not always economically attractive for a pesticide registrant to maintain a small pesticide use that produces low revenue. It is important, however, for farmers to have access to user-friendly, environmentally sound and economically viable minor use solutions because they may otherwise resort to unauthorised or inappropriate pesticides to protect their crops and yields.

The seminar on minor uses and risk reduction was hosted by the government of Australia, and held at the Hotel Brassey of Canberra on 4 November 2003. It was chaired by Wolfgang Zornbach of the German Federal Ministry of Consumer Protection, Food and Agriculture.

This was the second in a series of seminars planned by the OECD Pesticide Risk Reduction Steering Group, a sub-group of the OECD Working Group on Pesticides. These seminars focus on key issues in pesticide risk reduction of concern to OECD governments. The seminars are intended to provide an opportunity for OECD governments to discuss the issues together with non-governmental stakeholders and to develop recommendations for further OECD activities.

The first seminar in the series addressed compliance by pesticide users, distributors and retailers with the legal requirements and voluntary codes governing pesticide use. (The report for that seminar is available on the OECD public web site: http://www.oecd.org/document/59/0,2340,en_2649_34383_1916347_1_1_1_1,00.html)

Participants

Forty-eight people attended the seminar on minor uses and risk reduction, including representatives of:

- the pesticide regulatory authorities of Australia, Canada, Denmark, Germany, Japan, New Zealand, the UK, the US and the European Commission;
- farmer organisations in Australia and food processors in New Zealand;
- the manufacturers, formulators and distributors of crop-protection products in Australia (AVCARE) and globally (CropLife International); and
- public interest organisations (National Toxics Network, Australia)

A participant list is attached in Annex 1.

Structure and Scope of the Seminar

The seminar aimed to identify:

- opportunities for achieving risk reduction while addressing issues associated with minor uses;
- ways to increase co-operation between governments and stakeholders;
- recommendations or next steps for OECD or others.

The seminar was divided into two parts: a morning session devoted to presentations by governments and stakeholders, and an afternoon round table discussion among all participants.

The results of the seminar will be reported at the February 2004 meeting of the OECD Working Group on Pesticides.

Copies of the presentations and papers developed for the seminar are available in Annex 2. The following provides highlights of the presentations and discussions.

Senator the Honourable Judith Troeth, Parliamentary Secretary to the Australian Minister for Agriculture, Fisheries and Forestry, opened the seminar, welcomed participants and stressed the importance of addressing the issues associated with minor uses domestically, and internationally through OECD.

Dr Gardner Murray, Chief Veterinary Officer and Executive Director of the Product Integrity Animal and Plant Health for the Australian Government Department of Agriculture Fisheries and Forestry, described Australia's approach for protecting food safety. Management of minor uses is an important part of that approach, and they were eager to learn from the discussions during the seminar.

The chair thanked the Australian Government on behalf of the OECD Pesticide Risk Reduction Steering Group for the welcome addresses and for hosting the seminar.

Morning Presentations

How Regulators Address Minor Uses

Australia, Canada, the European Commission, Japan, New Zealand and the United States presented information on how they deal with the problem of registrations of agricultural pesticides for minor uses. An additional paper was available from Germany.

Australia:

- The Australian Pesticides and Veterinary Medicines Authority (APVMA) has legal authority to issue off-label permits, i.e., permits that allow the use of a registered product contrary to the approved label.
- The APVMA can consider applications from users or other third parties for a permit to allow an off-label use to protect minor crops.
- Permit applications seek to use existing registered products on new crops in a manner similar to approved use patterns.
- The need for additional data to make a decision concerning off-label uses depends on circumstances. A principle consideration is whether a suitable MRL can be established for the proposed use based on existing data.

New Zealand:

- The New Zealand Food Safety Authority (NZFSA) does not allow use of pesticides that have not been approved.
- Specific uses of pesticides that are inconsistent with conditions placed on a product registration are also not allowed.
- NZFSA has adopted a system that allows for persons other than the registrant of a pesticide to obtain a registered use for a pesticide and potentially have it added to the product label.
- These “Third Party” registrations of additional uses apply only to pesticides already registered for other purposes, and require the submission of residue trial work on the crops for which extra approvals are sought.
- Growers or other third parties can submit the data generated to the Authority, request formal maximum residue limits to be set if the default level allowed (0.1ppm) is not sufficient, and have the additional use formally registered and included in the conditions of the product registration.

United States:

- The Environmental Protection Agency (EPA), similar to New Zealand, requires registration approval and labelling for all minor use pesticides.
- EPA also allows users and third parties to support registrations for minor uses. EPA has joined in partnership with the Interregional Research Project 4 (IR-4), to increase minor use pesticide registrations.
- The IR-4 is a publicly funded program that conducts research and submits data to EPA to support the registration of pest control tools for growers of minor crops. IR-4 has many field research centres where it conducts projects on food crops, mostly concerning residue studies. It also has a network of analytical laboratories that determine the amount of residues remaining in the crop.
- EPA has taken a number of other steps as well to manage minor crop pesticides, including establishing a full-time minor crop advisor reporting directly to the Director of the Office of Pesticide Programs, designating a public health coordinator to address public minor use issues and creating a minor use team to focus coordination of minor crop issues.
- EPA has set priorities for minor uses including expedited registration for minor uses, and in particular for reduced risk pesticides used on minor crops.

Canada:

- Canada has begun a Minor Use Initiative to make minor use pesticide products, with an emphasis on reduced-risk pesticides, more readily available.
- The new program is modelled after the US IR-4 minor use program and will collaborate with IR-4 on field trials to ensure that more registered minor use pesticides are made available to growers in both countries simultaneously.
- Canada’s Pest Management Regulatory Agency (PMRA) has in place a User Requested Minor Use Label Expansion (URMULE) program that adds minor uses to products currently registered in Canada. Typically, residue data and efficacy/crop tolerance data are required to support the label addition. Funding is shared on a 50/50 cost basis with growers and the government. This program is carried out in close collaboration with the US IR-4.
- PMRA also focuses on minor uses through user requested minor use registrations for new chemicals and conducting minor use joint reviews with the US EPA.

European Commission:

- Under EU legislation, professional agricultural organizations and professional users may request that the field of application of a plant protection product already authorized be “extended” to purposes other than those covered by the authorization.
- Member states may grant such an extension when it is in the public interest to the extent that the intended use is minor in nature.
- There are numerous criteria for such an evaluation, including, among other things, that the owner of the active substances agrees and intends to keep the formulation on the market, the intended application replaces one “essential use”, and the use closes a gap in resistance management in order to prevent an endangering of a sustainable use in IPM.
- In 2002, the European Commission established an Expert Group on Minor Uses, which includes a Minor Use Steering Group and 2 Minor Use Technical Groups (focusing on Northern and Southern zones). Each Group includes Member and Accessing States as well as key stakeholders including industry, producers and environmentalists.
- The Minor Use Steering Group has circulated a detailed questionnaire to Member States asking them to identify five major concerns regarding Minor Uses.
- The Group is also considering a feasibility study on developing a harmonized Minor Uses database.

Japan:

- Japan’s Ministry of Agriculture, Forestry and Fisheries is working with producers, prefecture governments and pesticide manufacturers to facilitate the registration of pesticides for minor crops.
- Japan’s Agricultural Chemicals Regulation Law was amended in 2002 to, among other things, increase the penalty that can be imposed on any person who uses pesticides illegally.

Germany:

- Minor uses are permitted via: (1) an authorisation procedure in which a company submits an application for a product authorisation; or (2) a special minor use approval procedure which extends the uses of an authorised plant protection product; or (3) a special minor use procedure for personal permission to apply a pesticide for very small crops only.
- Approval for minor use is granted only if the plant protection product in question is authorised; the approval must be in the public interest; data must be available providing evidence that there are no negative effects on human health and the environment (including endocrine disruption); and the applicant must confirm the product’s effectiveness and that there are no unacceptable effects on plants.
- Germany and industry work closely together, through a working group on minor uses and its sub-groups, and round-table discussions involving the federal agencies and the agrochemical industry, to address minor use issues.
- A national work group on minor uses conducts efficacy trials and field studies for residue determinations.

Concerns (or Needs) of Stakeholders

Four stakeholders, the agriculture industry from Australia (representing farmers); food processors from New Zealand; Crop Life International (representing the pesticide industry) and the National Toxics Network (representing Public Interest Groups) gave presentations on their interests and concerns regarding Minor Uses.

Farmers (Ag Industry in Australia):

- The Ag industry in Australia reported that they believe the set of guidelines for determining minor uses currently in use in Australia, do not provide sufficient information on the identification or assessment of potential risks and their possible management for pesticides that can be used on minor crops.
- The availability of simplified risk assessment methodologies coupled with generic guidelines or indicative thresholds indicating the level of regulatory control that may be required for a given pesticide and crop use combination, would allow industry groups to more critically assess minor use proposals prior to submission.
- A review of the minor use definition could also be of value. At present the prime determinants are acreage and/or frequency of use. Broadening the scope of the definition to include other factors could be a positive development in risk management.
- Of further benefit would be the classification of pesticides on the basis of risk profile, using such categories as low, medium or high. This would provide industry with an opportunity to better assess and manage potential risks by differentiating between pesticides on the basis of their risk category, with lower risk compounds given preference.
- Finally, progress regarding data protection would also be of value.

Food Processors (Heinz Wattie, New Zealand):

- Heinz Wattie, a major food processor, conducts research and develops workable alternatives for farmers before requiring a change in their practices; for many years, this has included co-funding chemical registrations.
- Processors can be instrumental positive change agents, through their direct links to growers.
- For the very minor use crops in New Zealand, the chemical registration process has been impeding Risk Reduction progress. The process has been very expensive, and slow, and it has become bogged down under new legislation.
- The facilitation of an inexpensive, responsive, chemical registration process is critical to successful risk reduction for minor crops.
- It would be helpful if there was a rapid response (2-3 day) approval process for emergency uses (SUP).

Crop Protection Industry (CropLife International):

- The cost of agrochemical product discovery, development and registration is significant both in terms of time (approximately 9.1 years to launch in major markets) and cost (approximately 184 million dollars).
- Major issues for industry are the costs of efficacy and residue studies, dietary risk concerns (problems if risk assessment is not refined or specific ethnic groups are considered), product liability, and misuse of products on minor crops.
- The decision on what to register is made on a case-by-case basis at a company level and is often driven by return on investment.
- Recommendations to improve minor use crop registrations include:
 - expand crop grouping for efficacy and residue studies;
 - accept residue data from studies with more critical GAP (beyond current practice of extrapolation rules, i.e. 25%);
 - use foreign residue data (especially in the light of the OECD zoning project!);
 - generate consumption figures for minor crops (if not available yet);

- refine the dietary risk assessment regarding "percent crop treated" (will reduce exposure level significantly);
- establish round-table discussions with all stakeholders to identify new opportunities;
- consider ways of cost- or work-sharing, if pesticide industry has financial issues;
- reduce requirements on efficacy and residues as far as possible for minor uses without compromising on safety;
- don't grant authorizations for minor uses, if main data holder/applicant has a liability (efficacy, phytotoxicity) concern;
- establish fast approval procedures where appropriate; and
- create other incentives (e.g. extension of data protection periods).

Public Interest Group (National Toxics Network)

- The National Toxic Network expressed concern that the focus of food production has dwelt for too long on chemical manufacturers, regulators and economists and has not taken seriously societal concerns about pesticide residues in food and environmental degradation.
- The 'minor use' problem should be coupled with pesticide use reduction to reduce the reliance and use of synthetic chemical inputs in farming.
- Off-label use permits are seen as a problem because they do not comprehensively address the health or environmental impacts of pesticides or of sustainable farming livelihoods.
- Administering and monitoring a complicated system of permits and temporary registrations is expensive. An interim system which makes 'minor use' more accountable and transparent, while still allowing the use of 'minor use' chemicals should be required.
- Research and development could be achieved partly through establishing or increasing pesticide levies on industry.
- When establishing Maximum Residue Limits (MRLs) for minor use crops, it is essential to look at the combination of toxicity of certain groups of chemicals (e.g., organophosphates and carbamates or dithiocarbamates) and do a cumulative risk assessment.
- Minor use chemicals should be intensively monitored in order to manage and evaluate the system. Minor use issues should not be left only to government, industry and growers, the whole food supply chain needs to be actively involved, including consumers and public interest groups.

Afternoon Round table Discussions:

Do solutions for minor uses contribute to pesticide risk reduction?

The participants agreed that appropriate solutions for minor uses, if they are provided by a registered chemical agricultural pesticide, a biopesticide or by non-chemical means, can greatly reduce the risks of illegal uses of pesticides, which may lead to risks to human health and the environment. For this reason, it was recommended, that governments should introduce minor use programs to address this worldwide problem.

Key Concerns Regarding Solutions for Minor Uses

A few key concerns regarding solutions for minor uses emerged from the afternoon discussions:

- The main issue governments, growers and registrants must deal with regarding minor uses is the development of sufficient data to support the registration of uses so that products are made available when needed, while ensuring that the uses do not pose unacceptable risks.

- Some countries have developed well-organized regulatory systems for addressing minor use problems, but there is sometimes a lack of information available to growers or grower groups. Sometimes these groups are not well coordinated to work together to take full advantage of minor use programs.
 - In some cases there may also be insufficient information or assistance with the use of IPM to reduce the need for pesticides, especially in minor uses. In some cases, IPM practices could reduce the need for minor use registrations but growers are not always familiar or sufficiently experienced with IPM systems to reduce their reliance on pesticides.
 - On the other hand IPM-programs may be affected by the lack of available agricultural pesticides because of resistance problems or effects to beneficial organisms.
- Several participants noted that they think “off-label” uses can be problematic. They expressed concern that:
 - If a use is not featured on a label, there is no information on Good Agricultural Practice (GAP) or proper use.
 - Liability issues can arise from “off-label” uses.
 - Without full review and addition to the label, there is no assurance that the “off-label” use does not cause environmental effects or worker exposure problems.
 - The source of funding for data generated to support minor uses raised some questions.
 - Some countries (US and Canada) use government funds to help in the generation of data to support minor uses. These countries reported that without government funding, it would be difficult to promote risk reduction facilitated by the generation of data for minor uses, and that data generated through government funding is made publicly available (in the US).
 - Some of the participants said that it would be difficult to get government funding for data generation, as some may question why such funds should be used to support the registration needs of growers and industry. They were also concerned that the funding of such data generation may create unfair advantages for some companies holding the data for registered major uses that could benefit from the extension to minor uses at the expense of other companies with comparable products.

Approaches for Improving Minor Use Programs and Risk-Reduction

- Participants agreed that it is important for countries to establish regulatory programs that require and achieve risk reduction for minor and major uses. Regulatory programs should be strategic and focus resources on opportunities to achieve risk reduction. Minor Use programs should:
 - Set priorities to promote safer products and find incentives to get such products to market quicker,
 - Align stakeholder resources to be as efficient as possible (e.g., consider crop groupings, establish grower priorities),
 - Create incentives including simplified data requirements and expedited registrations without compromising health and safety reviews.
- Programs should also focus on ways to reduce the need for pesticides on minor crops by:

- - Using abatement applications which are more targeted,
 - Developing programs to help farmers find pest management projects to reduce applications to the extent necessary,
 - Eliminating unnecessary uses.
- Growers and others need to work collectively to acquire data for domestic and international requirements. Ways to achieve this could include:
 - Getting national growers associations to work internationally (such an approach worked with hops in the US and Germany),
 - Encouraging growers to work with the food distribution chain including supermarkets. Food distributors want a good reputation and that drives growers to seek a strategy to reduce or eliminate pesticide uses. Also, major importers/retailers (e.g., Sainsbury) know what is happening globally on minor uses, which can be helpful information for growers.
- Governments need to work co-operatively with other governments on minor uses. They could consider:
 - Exchanging information and data where possible and discuss field trials. This is similar to the OECD High Production Volume work where governments share the burden of collecting data and conducting investigations;
 - Developing crop groupings (for MRL's and for efficacy) that every country can recognise, this could simplify data generation and maximise the use of data;
 - Working with international organizations including Codex and JMPR to accept more data and establish Codex MRLs for minor uses;
 - Setting up lists of experts in minor uses within governments to serve as national contact points.

Next Steps

The participants identified several possible activities that could be undertaken to follow up on the minor use seminar:

The potential role for OECD would be to;

- Develop a list of contact points for governments, national or regional grower-groups and associations and other stakeholders to facilitate cooperation on information exchange and data generation for minor uses,
- Consider ways to aid countries to simplify the generation of data (e.g., by developing extrapolations, crop groupings, and/or a guidance document),
- Monitor progress after a few years and consider whether a workshop or other fora of stakeholders might be useful.

Annex 1

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Annex 2

LIST OF SEMINAR PRESENTATIONS AND PAPERS

**(Available on the Pesticide Risk Reduction Steering Group Password Protected Web Page
for the Minor Use Seminar)**

Government Experience and Perspectives

Australia (New South Wales Agriculture)
New Zealand (NZ Food Safety Authority)
Canada (Pest Management Regulatory Authority)
Japan (Agricultural Chemicals Inspection Station and Ministry of Environment)
United States (IR-4)
Germany (Federal Ministry for Consumer Protection, Food and Agriculture)
European Commission (DG Santé et protection des consommateurs)

Stakeholder Experience and Perspectives

Farmer Organisation (AKC Consulting, Australia)
Food Processor (Heinz-Wattie, New Zealand)
Pesticide Industry (CropLife/Bayer Cropscience)
Public Interest (National Toxics Network, Australia)

Minor Use Of Agricultural And Veterinary Chemicals In Australia

INTRODUCTION

The approval of safe and effective agricultural chemical products within all Australian agricultural sectors is a national issue, particularly for those minor users of agricultural chemicals whose use is not sufficiently economically attractive for a manufacturer to seek registration.

Users of agricultural chemical products in Australia must comply with the *control-of-use* legislation that applies in their particular state. This legislation can vary between states, particularly with respect to what constitutes off-label use, but as a general rule only products registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA) can be used. Product registration for novel compounds or new use patterns must be submitted to the APVMA by the registrant, chemical users cannot seek registration for new uses (crops and pests) for existing product labels.

However, the label of a registered product does not always cover all circumstances where that product may be required or prove beneficial. Pest, disease and weed complexes continue to adapt and challenge existing management strategies and outbreaks of exotic pests and diseases need to be controlled or eradicated. The regulatory costs associated with adding new or additional use patterns onto registered product labels can often outweigh the likely economic returns to the manufacturer. These cases are commonly termed ‘minor uses’ and are often neglected by manufacturers in the mainstream registration process. In these situations the APVMA will consider applications from users or other third parties for a Permit to allow an off-label use that would otherwise be illegal.

Industry development programs are identifying opportunities for new agricultural products and new markets, particularly in the horticulture sector. In turn this drives demand for new chemical use patterns that often fall within the minor use category, at least initially. Quality assurance programs and the market access requirements of our trading partners provide strong incentives to regularise these minor uses within the Australian risk management framework for agricultural chemicals.

This paper will consider the market factors that are driving minor uses and how the state and national regulatory framework responds to the demand for new chemical use patterns. The paper will also look at data requirements, assessment procedures and timeframes for both product registration (registrant driven) and off-label Permits (end user driven), with a discussion on some of the actions taken by the APVMA and industry in addressing issues associated with minor uses.

APVMA OVERVIEW

The Australian Pesticides and Veterinary Medicines Authority (APVMA) operates a national system that evaluates and registers agricultural and veterinary chemicals in Australia and regulates products up to the point of sale. Before an agricultural or veterinary chemical product can enter the Australian market, it must go through the APVMA’s rigorous assessment process to ensure that it meets high standards of safety and effectiveness. Any changes to a product that is already on the market (including label changes) must also be referred to the APVMA.

DEFINING MINOR USES

A ‘minor use’ as defined in current legislation is “*a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)*”.

Generally speaking minor uses encompass low acreage crops or situations (minor crops) or the limited or infrequent use of a chemical in a major crop or situation. The APVMA has recently undertaken a review of crops grown within Australia and identified those crops that it considers major crops. These determinations were based upon several factors including, area of production, and value of the industry and dietary consumption of the commodity.

On this basis the APVMA has determined that products for use in major crops must be considered via normal Registration procedures and the use pattern should appear on the label of the registered product. For minor crops, the APVMA has determined that the use patterns can be approved through the issue of a Permit and do not necessarily have to appear on the product label (off-label).

Notwithstanding the above, the APVMA will consider off-label Permits for major crops where it can be demonstrated that the use is minor. The criteria applied are that the use will not exceed 10% of the total crop area (and remain less than 10,000 hectares) or that the use *would not produce sufficient economic return* in accordance with the definition of a minor use given above. Further details regarding these criteria are explained in the APVMA *Guidelines for Determining Minor Uses* available at <http://www.apvma.gov.au/gazette/gazette0203p39.pdf>

APVMA LEGISLATIVE RISK ASSESSMENT CRITERIA

The APVMA has legislative criteria under which it must assess Registration and Permit applications. The criteria being that the proposed use:

- (i) *would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and*
- (ii) *would not be likely to have an effect that is harmful to human beings; and*
- (iii) *would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment;*
- (iv) *would not unduly prejudice trade or commerce between Australia and places outside Australia; and*
- (v) *would be effective for the intended purpose.*

Situations may arise where it is necessary to use an unregistered product or a registered product in an unapproved manner. These include:

- emergencies – such as outbreaks of exotic pests and diseases for which no registered product exists;
- minor uses – that is use of a product in a situation on a small scale; and
- research – to screen and generate data that supports product registration.

The APVMA can issue Permits that legalise actions that would otherwise be an offence. Permits issued to allow the use of registered products contrary to the approved label are termed **Off-Label Permits**; those issued to allow the use of unregistered products are called **Supply/Use Permits**; and those issued to conduct a trial are termed **Research Permits**. The APVMA may only issue Permits for minor or emergency uses or for the purposes of research. Furthermore, Permits are generally issued in response to an application which is evaluated against the APVMA's risk assessment criteria.

In addition to these legislative requirements, the APVMA has always maintained a policy that a Permit (other than a Permit for research purposes) will not be issued if a suitably registered product is already available for that purpose. An exception to this policy may apply if the applicant can demonstrate that the

products currently registered are ineffective or unsuitable or that use of the proposed product offers advantages with respect to Integrated Pest Management (IPM) or Integrated Resistance Management (IRM) strategies. The APVMA does not consider cost or an applicants desire to use a product considered a lower hazard as justification for the issue of a Permit. These policies are enforced to encourage registrants to include minor uses on the label of registered products.

DATA REQUIREMENTS

The product registrant or permit applicant must provide appropriate information to demonstrate that the proposed chemical product and its use(s) will satisfy the above mentioned legislative criteria. Generally this requires the provision of scientific data on the product and proposed use(s) covering key areas such as;

- Toxicology
- Residues for both local and overseas markets
- Occupational health and safety
- Environment
- Efficacy and crop safety

The APVMA will usually require locally replicated trial data supporting the proposed use in Australia, particularly for registration applications. However, the APVMA will consider overseas or other data provided it can be demonstrated that the data are scientifically relevant to the proposed use in Australia. This is particularly relevant to the consideration of efficacy, crop safety and residue data provided in support of Off-Label Permits. However the relevance of such information is at the discretion of the APVMA and some minor uses may still require locally generated data to ensure the proposed use meets legislative criteria.

Generally Permit applications in support of minor uses seek to use existing registered products on new crops or for pests and diseases in a manner similar to the currently approved use patterns on labels for other crops. Therefore issues such as worker safety and environmental impact remain essentially unchanged and the APVMA can often rely on the existing risk assessments. This is often also the case for efficacy and crop safety requirements where similarities with currently registered use pattern(s) can be demonstrated.

As a result, the APVMA rarely requires detailed data for Permit applications seeking to use currently registered products for related minor uses. A principle consideration for the APVMA is whether a suitable Maximum Residue Limit (MRL) can be established for the proposed use.

Setting Maximum Residue Limits (MRLs)

Maximum Residue Limits (MRLs) must be established in order to allow treated produce to be made available for human (or animal) consumption. The MRL is the highest residue level which is legally permissible in that commodity. It is established based upon residue data that reflects Good Agricultural Practice, and therefore MRLs for a chemical can vary between different commodities and between countries with different use patterns.

Although MRLs and registrations may exist in other countries, the APVMA must still examine residue data to determine whether or not those overseas MRLs and the data available is suitable for the particular crop and proposed use pattern in Australia. In achieving this APVMA considers all available data, including overseas data if it can be determined relevant. The APVMA does not mirror MRLs and use patterns from overseas countries without reviewing available data and ensuring that it satisfies the proposed use pattern.

The APVMA in the consideration of Permits for minor uses regularly extrapolates residue data between like commodities provided the data is sound and a similar use pattern is being proposed. This often allows

the APVMA to establish Temporary MRLs to enable Permits to be issued for interim periods whilst additional local supporting data is generated. The APVMA, in assessing and issuing those permits advises the applicant of any future residue data requirements and importantly the extent of data (samples) required, this can vary from single point trials to more detailed research involving multiple points and residue depletion data. The level of data requested reflects the minimum required for sound decision making, while keeping regulatory costs for minor uses to a minimum.

If minor uses cannot be supported because of deficiencies in the data, the APVMA encourages grower industries to undertake appropriate trials to generate the necessary data. The APVMA has also published guidelines outlining residue data requirements for new uses; a copy of this document is available at <http://www.apvma.gov.au/guidelines/guidln24.shtml>

Guidelines for Minor Uses

The APVMA has identified a need to develop and publish specific guidelines and data requirements for minor uses against all the relevant risk assessment criteria. Specific guidelines have already been developed for residue data requirements for minor uses and those for efficacy and crop safety are under development. In the future, these will be extended to cover guidelines on requirements for environmental impact and occupational health and safety assessment.

APPLICATION AND ASSESSMENT

The APVMA receives and assesses approximately 2,500 product registration submissions and 1,000 permit applications every year. Of the 1,000 permit applications received, approximately 700 are for minor uses (90% agricultural and 10% veterinary).

Applications for registration or Permits are grouped into categories that have legislated assessment timeframes, commonly between 3 and 15 months, depending upon the level of assessment required. For example, a new active ingredient not previously registered in Australia would require detailed assessment against all legislative criteria and fall into a 15 month timeframe, whereas requests for new crop and pest extensions to existing products fall with a 5-8 month assessment timeframe.

In considering Permit applications, the APVMA consults with state departments of agriculture/primary industries and product manufacturers. Their advice is sought in relation to the criteria under assessment; whether or not the proposed use is supported with respect to efficacy and Good Agricultural Practice; or if they are aware of any information that may indicate an undue hazard from the proposed use. Additionally applications may also be circulated for review by other commonwealth agencies on potential adverse affects to human health, occupational safety, the environment and animal welfare. This is particularly so for applications involving new active ingredients or those proposing significant variations from the currently approved label use pattern.

DRIVERS FOR MINOR USE IN AUSTRALIA

There are at least three significant inter-related factors that drive minor uses in Australia. These are the:

- constraints imposed by control-of use legislation at the state level;
- development of new crops and new crop management strategies; and
- requirements of quality assurance and market access programs.

Control of Use Legislation

The extent to which a chemical user is required to follow the directions for use on a product label, and therefore what constitutes off-label use, is defined by the control-of-use legislation in each state. At present, there are still significant differences between states in this area. In those states where the legislation is most prescriptive and users are required to follow all the directions on the label, most variations from the product label will require assessment and approval. Where the required variations fit within the APVMA criteria for a minor, emergency or research use the APVMA will carry out the assessment and, if appropriate, issue a Permit.

It follows then that state control-of use legislation drives differing levels of demand for off-label Permits from the APVMA. There is an obligation on state regulators, therefore, to pursue an agreed level of harmonisation in control-of-use legislation and to ensure that those provisions that drive demand for off-label permits are appropriately risk based. Significant progress has already been made towards these objectives.

New Crops and Crop Management

New crops and production techniques continue to drive demand for pest, disease and weed control strategies, including chemical use patterns. This has been particularly apparent in the horticulture sector which has been identified nationally as a major growth area for both domestic and export markets. In 2000-01 Australian horticulture had a gross value of production of \$6.54 billion, ranking third behind the grain and meat industries. The 2000-01 gross value of production (GVP) statistics for the three major product categories were as follows (DAFF 2003):

- Fruit and nuts - \$3,559 million;
- Vegetables - \$2,183 million;
- Nursery Production - \$ 795 million.

Exports of fresh produce have increased significantly in the last decade. In the last five years alone, between 1997-1998 and 2001-2002, exports have increased by 37%. The success of Australia's horticulture export industry relates to the:

- availability of counter-seasonal products to northern hemisphere markets;
- ability to offer a range of quality products because of diverse geographical and climatic conditions;
- Maintenance of a clean and healthy environment, enhanced by HACCP (Hazard Accident Critical Control Point) based quality assurance applications;
- use of advanced infrastructure and post-harvest technology ranging from grading technology, packing equipment, labelling equipment, storage and transport technologies to prolong the life of fresh produce either in storage or during long distance transport. (Horticulture Australia Limited 2003)

The horticulture sector is characterised by small and fragmented industries with limited capacity to fund and coordinate responses to market development or regulatory issues. In some cases, state government based research and extension services provide technical support to these emerging industries. However, the level and scope of the support provided varies depending on the policies of particular state governments and the available resources.

The lack of registered chemical products and approved use patterns is characteristic of new and emerging horticultural crops with most of the use patterns falling into the minor use category. APVMA off-label

Permits for minor use are used to regularise these use patterns and ensure that these industries can access chemical products legally. Almost 60% of the off-label Permits issued for minor uses or emergencies were issued for horticultural crops.

This process consumes considerable resources within the APVMA, state government service providers and industry. The coordination and prioritisation of minor use Permit applications across the vegetable sector by industry funded service providers has introduced important efficiencies into the process and provides a model for other industries. This process is covered later in this paper.

An efficient process for delivering minor use approvals is essential to ensure that access to plant protection products does not become the limiting factor in the development of new agricultural industries. However, industry on its own may find it difficult to generate the investment necessary to fund the development of minor use approvals, including the underpinning data, particularly during the early evolution of new agricultural industries.

Quality Assurance and Market Access

Quality assurance (QA) programs in agriculture provide customers with the assurance or confidence that products meet the appropriate or agreed specifications. They require participants to implement a range of process controls that deliver market based outcomes as well as meeting, and in some cases exceeding, the requirements of relevant legislation. Typically, QA programs in agriculture can require participants to maintain records of chemical use and undergo third party audits, sometimes including residue testing of produce.

One common requirement is that only registered chemicals are used under use patterns approved for the crop or product in question. This provides a strong incentive for growers to regularise any off-label use and ensure that maximum residue limits are in place for all chemicals which may be important in the production of the crop. In some cases, grower organisations will lodge an application with the APVMA for an off-label Permit for a minor use even though the use in question is not illegal under the control-of-use legislation of the state in question. This is particularly the case where the applicant is seeking approval of an MRL for the particular chemical/crop combination. The APVMA will not set an MRL without an approved use pattern.

In effect, the major processors, packers and supermarkets that demand QA from their suppliers have become compliance monitors for control-of-use and food safety legislation. This form of QA driven compliance has generally proven more effective than traditional, regulatory compliance programs.

The implementation of QA programs along the entire food and fibre supply chain is receiving strong support from government. To this end government regulators at both the state and national level need to ensure that requirements for chemical access and use continue to complement industry initiatives in QA. To achieve this, states in particular will need to continue working towards greater uniformity in environmental, worker safety and food safety standards and their application to the agricultural sector.

INCREASING INDUSTRY INVOLVEMENT IN MINOR USE APPROVALS

In March 1998, a National Minor Use Workshop was held with representatives from the horticultural industry, R&D providers, chemical industry, APVMA and other government bodies to progress the development of a National Minor Use Program. The workshop concluded that a national minor use program should be established in Australia and that it could be supported within existing government and industry structures. As a result, an industry funded, National Minor Use Pesticide Program for horticulture was established in 1999.

The program was implemented through the establishment of a dedicated minor use office called Crop Protection Approvals Limited (CPA). The initial priority of CPA was to deliver approved minor uses for the Australian vegetable industry. However, CPA has now extended their commercial services to other industries such as fruits, nuts, olives and aquaculture.

CPA receives, collates and prioritises minor use needs for the vegetable industry with the assistance of Industry Development Officers employed within each state of Australia by Horticulture Australia Limited. Those requests once lodged are prioritised by CPA and industry partners. The APVMA meet formally twice per annum with officers of CPA to discuss and advise on data requirements for projects put to CPA by growers. This process enables CPA to further prioritize projects and determine research work required, particularly residue trials. CPA are today the largest applicant for minor use Permits to the APVMA, accounting for almost 20% of the total number of applications and 35% of those seeking use in horticultural (fruit and vegetable) crops.

Other industry organizations such as the Queensland Fruit and Vegetable Growers Association (QFVG) also provide assistance in meeting the minor use needs of their members, often through collaborative projects with CPA. QFVG and CPA in 2002-2003 collectively accounted for 50% of horticultural (fruit and vegetable) minor use Permit applications lodged with the APVMA.

The APVMA has for a number of years also worked with a Project Team funded by the Grains Research and Development Corporation (GRDC). The project team (Jay4) has conducted an audit of the cereal, grains and pulse industries with respect to chemical needs and current off-label uses. The project team meets annually or as required to discuss regulatory requirements for those uses identified as priorities. A significant number of uses identified by the project team have been identified as minor uses. The project team has also developed a website that allows users and researchers to list chemical needs of interest to the industry (Jay4, 2003).

Australia does not currently have programs such as the United States Department of Agriculture's IR4 program or Agriculture and Agri-Food Canada's, Minor Pesticide Uses program that directly fund the development of minor use approvals. However, state government agriculture agencies do provide support to the development of minor uses as part of specific crop research and development programs or through in-kind contributions to the development of residue and efficacy data.

It is clear, however, that industry organizations need to play an increasing role in identifying and prioritizing the minor use needs of their members. Whether industries choose to take on this role directly or to use the services of existing third party providers such as CPA is a matter of preference and circumstance. What is certain is that this approach provides efficiencies for both chemical users and the APVMA by reducing duplication, particularly where minor uses extend across industries or regions. It also allows industry organizations to screen out those minor use requests that are technically unsound or do not fit with the market objectives of the industry as a whole.

The APVMA has for a number of years worked to better inform users of regulatory requirements for the use of agricultural chemicals with a particular emphasis on minor uses. To this end the APVMA has conducted seminars across Australia, presenting at peak industry conferences and liaising industry bodies that become or may become regular permit applicants. This work has seen the APVMA develop strong links with several peak industry bodies and has greatly assisted those industries in pursuing their minor use needs through the permit system.

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October 2003

Overview of Minor Use of Regulation in Australia

**Overview of Minor Use Regulation
in Australia**

OECD Pesticide Risk
Reduction Steering Group

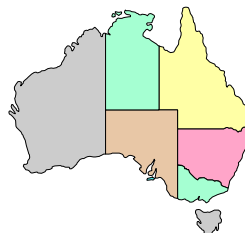
Seminar on Minor Uses
and Risk Reduction



Canberra, Australia
4 November 2003

**The Australian Regulatory System for
Agricultural and Veterinary Chemicals**

- All chemical products on the market must be registered
- Australian Pesticides and Veterinary Chemicals Authority (APVMA)
- National risk assessments include toxicology, occupational health and safety, environment protection, livestock and crop production
- Complemented by State control of use legislation



Accommodating Off-Label Uses

- an off-label use can be a minor use where there is little economic incentive to include use on a product label
- minor use on a minor crop or species
- limited use on a major crop or species
- approved through off-label Permits issued by APVMA
- 1000 applications for Permits of which 80% are for minor uses

Data Requirements for Minor Use Permits

- applications are mostly for additional uses to existing products
- need for additional data will depend on circumstances
- need to set maximum residue levels for food crops and products
- often requires local residue data

What drives demand for minor uses?

- control of use legislation drives demand for off label Permits for minor uses
- need to focus on high risk off label uses that need approval
- quality assurance programs provide strong incentives to comply with approved uses
- supply chain QA programs effectively monitor compliance with chemical and food safety legislation

New Crops and Crop Management

- new crops, new pests, diseases and weeds
- 60% of off label permits are for minor use in horticulture
- meeting demand through industry based programs that collate, prioritise and generate data for minor use approvals
- industry coordination model strongly supported by government

Future Directions for Minor Use

- guidelines on specific minor use data requirements
- increased awareness of minor use regulatory requirements and compliance
- encourage greater industry coordination of minor use approvals
- continued support of QA programs as a risk reduction strategy for food and fibre products
- pursue increased harmonisation of control of use legislation based on risk reduction criteria

Regulatory Control of Minor Uses of Pesticides on Food Crops in New Zealand
John Reeve, New Zealand Food Safety Authority

**REGULATORY CONTROL OF MINOR
USES OF PESTICIDES ON FOOD
CROPS IN NEW ZEALAND**

**John E Reeve, Programme Manager
(Toxicology and Residues)**

**Agricultural Compounds and Veterinary Medicines Group,
New Zealand Food Safety Authority, P O Box 2835,
Wellington New Zealand**

Minor uses:

- ❖ Usually too expensive for registrants to formally register (Costs versus size of market).
- ❖ Lack of approvals could lead to trade problems for exporters.

Regulators:

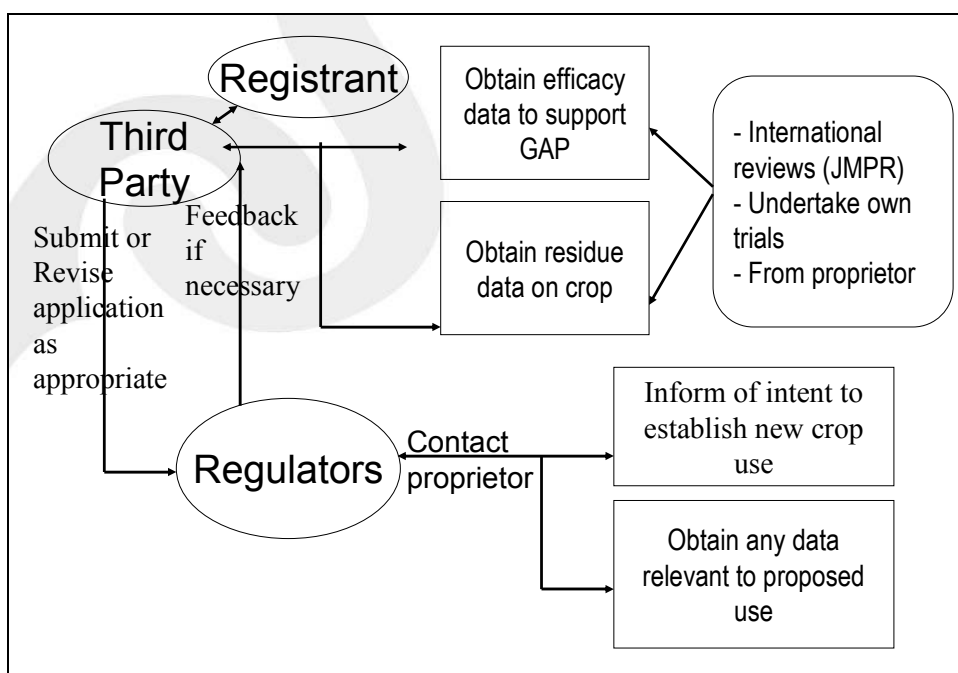
- ❖ Have no information on residues.
- ❖ Have no information on efficacy.
- ❖ Have no maximum residue limits set (potential for food to have illegal residues in it).
- ❖ Have done no assessment of acceptability of residues.
- ❖ Have done no risk analysis of the use.

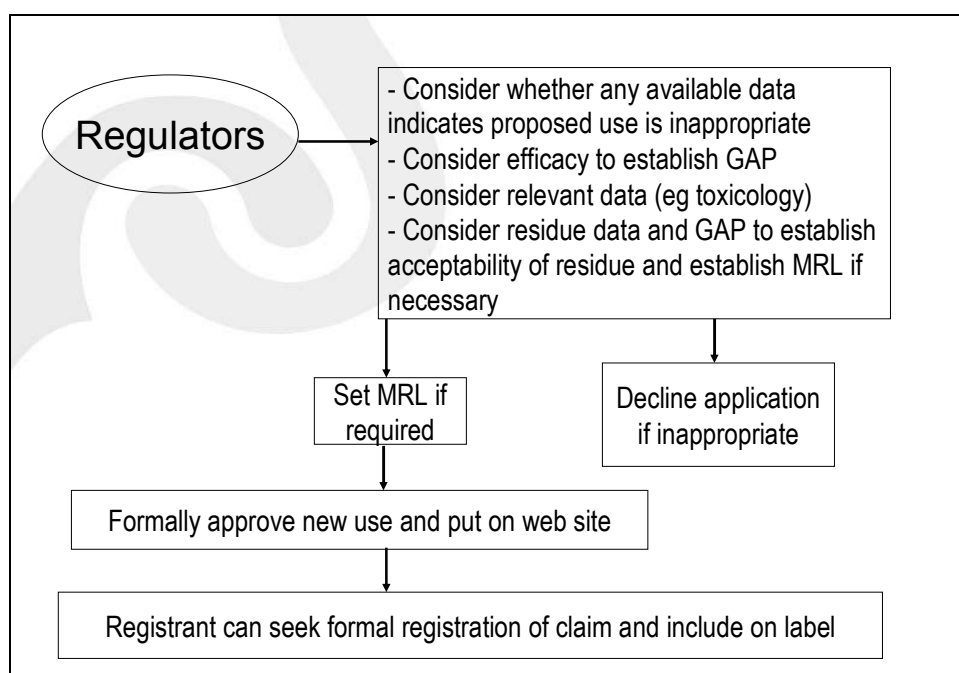
In New Zealand:

- ❖ We have a default MRL of 0.1 ppm unless elsewhere specified.
- ❖ New legislation does not allow unapproved uses of pesticides unless specific conditions have been set to allow for such use.
- ❖ Market basket surveys and Total Diet Surveys have been used to keep watch on the situation.

To attempt to resolve the situation:


- ❖ We have instituted a system of “Third Party” approvals.
- ❖ The New Zealand law allows for persons other than the registrant of a pesticide to obtain a registered label claim for a product without causing liability for the registrant unless they choose to adopt the claim.
- ❖ The pesticide must be already registered for the system to be used.
- ❖ Approvals are Trade Name product specific.





Outcomes to date:

- ❖ Experience to date has been that excellent cooperation has been achieved between third parties and pesticide registrants to the mutual benefit of both.
- ❖ Growers (the third party) paid for the residue and efficacy data and the registrants have then formally registered the new claim.
- ❖ Registrants have been able to obtain formal registration of the new claim without further data or evaluation being required.
- ❖ MRLs have been set.
- ❖ Labels updated.



❖ Regulators have proper risk assessment of residues in the minor crops and pesticides that have gone through this process

A real win/win for all

Regulatory Control Of Minor Uses Of Pesticides On Food Crops In New Zealand

**John E Reeve, Programme Manager (Toxicology and Residues),
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The minor use of pesticides is usually not formally approved by Regulatory Authorities, and is “off-label” use. The control of residues in the treated crops has posed difficulties for regulators because there is usually little information available on what those residues are, and hence there are problems in carrying out robust risk analysis of this minor use. For some years, New Zealand has adopted a default maximum residue limit of 0.1 ppm residues in foods for pesticides for which formal residue limits have not been set, and this has allowed for some regulatory control. This mechanism does not alleviate the problem of not having good residue data, and in addition, the commencement of new legislation in New Zealand has made it illegal to use pesticides other than as formally approved.

Recently, the New Zealand Food Safety Authority (NZFSA) has adopted a more robust way of dealing with this issue. Before use, all plant compounds (pesticides) must be registered under the Agricultural Compounds and Veterinary Medicines Act 1997, and used in accordance with conditions placed on their registrations at the time of their formal approval. To deal with the minor use problem, the NZFSA has adopted a system of “Third Party” registration. Users of an existing pesticide are now able to commission residue trial work on their crops. They can then submit the data generated to the Authority, request formal maximum residue limits to be set if the default is not sufficient, and have the additional use formally registered and included in the conditions on the product registration. It is not necessary to have the registrant formally register the additional use (and having to cope with the costs involved) and include the extra use on the label of their product.

The NZFSA contacts the registrant of the pesticide regarding the proposed minor use and requires them to submit any data that may preclude acceptance of the proposed minor use. To date, the involvement of the registrant has led to them agreeing to assist the applicant in the process and they have formally gone through the process of applying for a new use and change to their label.

The new type of registration allows New Zealand regulators to properly assess potential risk from the use of pesticides on minor crops and ensure proper protection of consumers.

Canadian Minor Use Registration Program
Richard Aucoin, Pest Management Regulatory Agency

Canadian Minor Use Registration Program
Improved access to reduced risk products

Canberra, 2003

Dr. Richard Aucoin
A/Chief Registrar
Pest Management Regulatory Agency
Health Canada



Minor Use Definition

Minor use products are those used in such small quantities that manufacturers find the sales potential is not sufficient to seek a registration in Canada.

- Typically low acreage, high value crops
- Typically horticultural crops:
 - fruits, vegetables, berries, herbs and spices, floriculture and ornamentals



The PMRA has four programs that lead to registration of products for minor uses:

- URMULE: User Requested Minor Use Label Expansion
- URMUR: User Requested Minor Use Registration
- Minor Use Joint reviews with the US EPA
- Regular new active substances submissions and end use products (including joint reviews)



URMULE

- Grower initiated request (with registrant support)
- Adds minor uses to products currently registered in Canada
- Typically need residue data and efficacy/crop tolerance
- Under the Canadian Pest Control Products Act no off label uses are legal
- MRLs are established for all new minor uses



URMULE

- 1989/1990 funding established, \$250,000 / yr on a 50/50 cost shared basis with growers
- 1996: began close collaboration with US IR-4 program conducting joint minor use field residue trials to facilitate simultaneous registration in both countries
- 1998:
 - Residue Chemistry Guidelines (a joint US EPA, PMRA NAFTA effort)
 - Developed common North American residue field trial zones
 - Facilitated generation of mutually acceptable residue data
 - Residue field studies and residue laboratory studies must be conducted in compliance with GLP principles (OECD)



The Minor Use Initiative

- 2002: the Ministers of Agriculture and Agri-Food Canada (AAFC) and Health Canada announced a Minor Use Initiative
- objectives are:
 - making minor use pesticide products, with emphasis on reduced-risk products, more readily available;
 - providing Canadian producers with access to new pest management technologies to improve their competitiveness domestically and internationally;
- conduct field trials and lab analyses;
- integrate data generated in Canada with the US IR-4 pesticide program;
- prepare registration submissions to PMRA.
- AAFC has modelled this new program after the US IR-4 minor use program and will collaborate with IR-4 on field trials to ensure more registered minor use pesticides are available to growers in both countries simultaneously
- PMRA will increase resources available



The Minor Use Initiative

- \$54.5 million made available over six years to give Canadian producers better access to minor use and reduced risks pesticides
- AAFC will improve access to minor use pesticides and conduct field trials of minor use pesticides by:
 - conducting field trials and lab analyses;
 - integrating data generated in Canada with the US IR-4 pesticide program;
 - preparing registration submissions to PMRA.



Factors for Success

- Use of IR-4 data and coordination with US IR-4 and US EPA
- Crop and pest groupings
- Smart use of representative crops (e.g., Pyraclostrobin, Spinosad)
 - Pyraclostrobin - 1 submission = X minor uses
 - Spinosad - 8 submissions = 68 minor uses
- Front-end Loading (crops and pest) in registrant submissions
- Resources

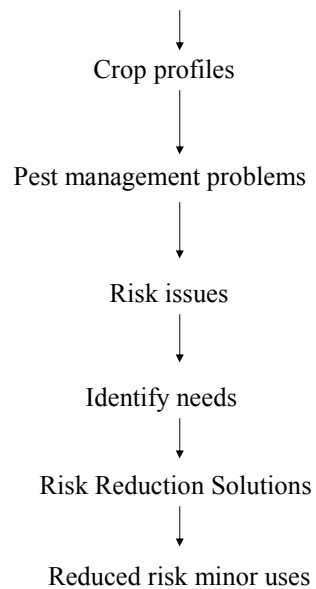


Linkages to Risk Reduction

- Joint reviews with US EPA: Reduced timelines for Reduced Risk products
- Canada only: Reduced timelines for Reduced Risk



Commodity Based Risk Reduction Strategies



The Measure to Risk Reduction in Japan
Katsuya Sato, Agricultural Chemicals Inspection Station & Yoichi Kamiya, Agricultural Chemicals Control Office

The measure to risk reduction in JAPAN

1: The revision of the Agricultural Chemicals Regulation Law (for agricultural pesticide)

2: Developments in Aquatic Risk Assessment in Japan

Katsuya Sato

Agricultural Chemicals
 Inspection Station
 Independent Administrative
 Institution

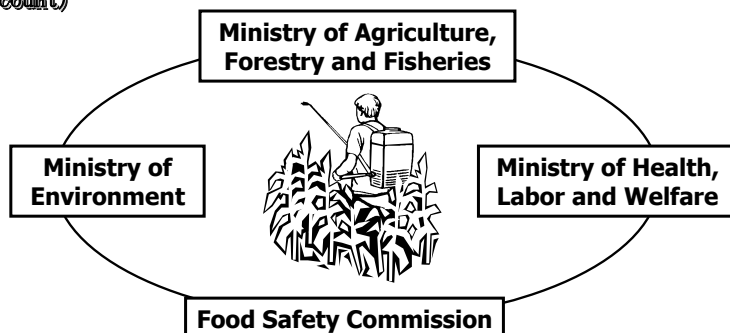
Yoichi Kamiya

Agricultural Chemicals Control
 Office,
 Water Environment Department,
 Ministry of the Environment

The pesticide regulation system in Japan

Japanese pesticide registration system has been operated under the Agricultural Chemicals Regulation Law since 1948.

(The law has been revised taking the needs of society into account)



Recent problem on pesticide

- The increase of distribution, manufacture and personal import of non-registered pesticide
- The increase of illegal use



The increase of pesticide risk on human health and environment

Public concern regarding pesticide use

The major points of revision

- No one shall manufacture, process and/or import pesticide without the registration by the minister of AFF.
- Reinforcement of the prohibition of the use of pesticide
 - No one may use those pesticides of which label isn't true or proper.
 - The standard, to be complied with by the pesticide users for ensuring a safe and proper use.
 - Keep the record of the pesticide's use
- Obligation of the labeling that any herbicide for non-agricultural use shall not be used for agricultural purpose
- Increase of penalty fee, etc.
 - For natural person : One million Yen (\$10,000, 8,000euro)
 - For juristic person : One hundred million Yen (\$1,000,000 800,000euro)

The expected result

- Ensuring food safety (exclusion of illegal use)

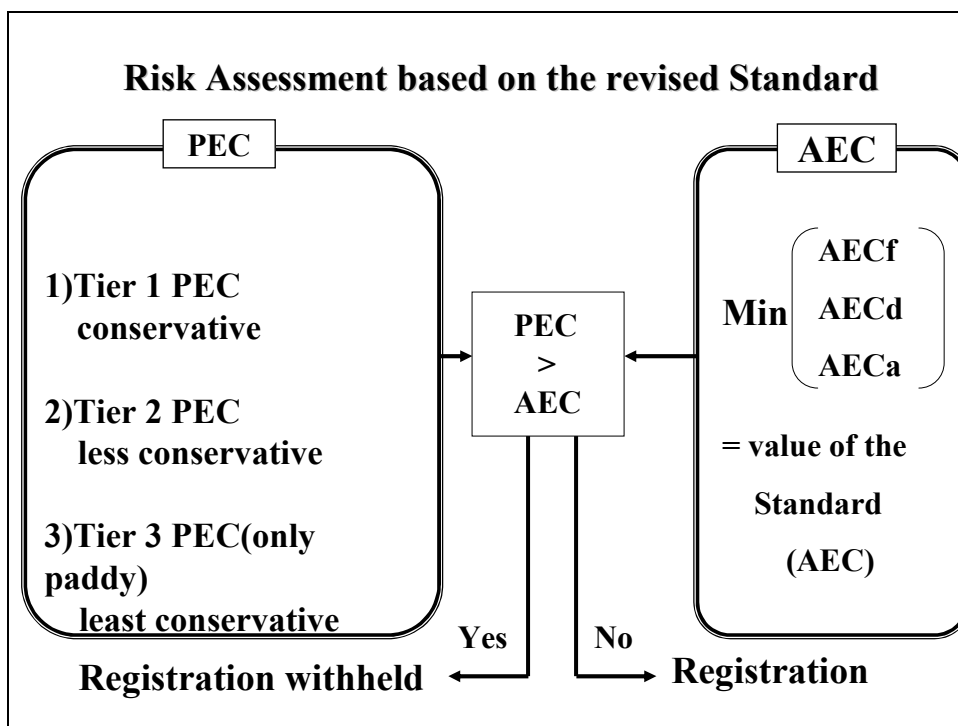
Penalty will be imposed, when the pesticide user illegally uses.

The number of registered pesticides for minor crops is small, so, now, to cope with the problem, MAFF has been working on the facilitation of the registration of the pesticide for minor crops etc. together with producer, prefecture governments and pesticide companies.

(Because of a small number of registered pesticides for those crops)

Outline of Japanese Regulatory System of Pesticides

Stage of control	Ministry of Agriculture, Forestry and Fisheries	Ministry of the Environment
【Pre-marketing】	Application for registration	
Registration	<p style="text-align: center;">↓</p> <p style="text-align: center;">Examination based on cut-off criteria (i.e. “the Standards to withhold registration”)</p> <p>1)false description in application 2)damage to crops 3)damage to users 4)-7) ← 8)designation misunderstanding efficacy 9)inferior efficacy 10)inconformity with official standards</p>	<p style="text-align: center;">Establishment of the Standards on</p> <p>(4)persistence in crops 5)persistence in soil (6)damage to aquatic animals and plants 7)water pollution</p>
【 Post-marketing】	<ul style="list-style-type: none"> •cancellation of registration • prohibition of sale 	<ul style="list-style-type: none"> • restriction of use of pesticide of water pollution



Derivation of the value of the Standard (AEC)

Test species	<ul style="list-style-type: none"> ✧ Fish : Killifish(<i>Oryzias latipes</i>) or Carp(<i>Cyprius carpio</i>) ✧ Crustacean: <i>Daphnia magna</i> ✧ Algae : <i>Pseudokirchneriella subcapitata</i>
Endpoint	<ul style="list-style-type: none"> ✧ Fish: 96 hr-LC₅₀ ✧ <i>Daphnia magna</i>: 48 hr-EC₅₀ ✧ Algae: 72 hr-EC₅₀
Uncertainty factor	<ul style="list-style-type: none"> ✧ Fish: 10 ✧ Crustacean: 10 ✧ Algae: 1 <p style="margin-left: 40px;">Less than 10 would be applicable according to sensitivity analysis for fish and crustacean.</p>
Value of the Standard	Minimum AEC(AECf= 96 hr-LC ₅₀ x1/10, AECd =48 hr-EC ₅₀ x1/10, AECa =72 hr-EC ₅₀ x1)

Developments in Aquatic Risk Assessment in Japan
Yoichi Kamiya. Agricultural Chemicals Control Office,
Water Environment Department, Ministry of the Environment

Since 1963, Japan had set aquatic regulatory standards for the protection of aquatic organisms that the median lethal concentration for carp was less than 0.1ppm. This served as the “Standard to Withhold Registration”, a cut-off criterion, of agricultural chemicals, to prevent hazard to aquatic organisms. Considering the current social needs of preservation of the ecosystem and circumstances around the ecological effect to be caused by agricultural chemicals, the Ministry of the Environment revised the Standard in March, 2003. The new Standard is based on the risk assessment procedures of comparing the predicted environmental concentration of an agricultural chemical in a river according to the proposed usage, to the value of the Standard derived from its acutely effective concentration to aquatic organisms. With the introduction of this new system, it is expected that the Japanese risk management of agricultural chemicals will be improved for preserving the aquatic ecosystem.

1. Introduction

In the Japanese regulatory system for agricultural chemicals, the risk to non-target aquatic organisms was based on the acute toxicity to carp. This hazard-based approach had been used for about 40 years, and played a certain role to prevent serious damage to fish caused by agricultural chemicals. However, it has been of importance to avoid hazardous effects on aquatic ecosystems by introducing an appropriate risk assessment system. To address these circumstances, the Ministry of the Environment (hereinafter referred to as “MOE”) has introduced a new regulatory system based on aquatic risk assessment in March, 2003 with the two-year preparation period for enactment.

2. Background of introduction of new regulatory system

2.1 Current circumstances around ecological risk assessment

The new Basic Environment Plan (Cabinet Decision as of December 22, 2000) requires that all economical and social activities should be performed within limits that allow the structures and functions of ecosystems to be maintained so that the value of the ecosystem is not reduced. In addition, it requires that chemical substance management should be promoted considering appropriate assessment and management of effects on the ecosystem caused by chemical substances including agricultural chemicals.

Agricultural chemicals will require more thorough care in their handling and/or use than other chemicals from the viewpoint of effects on the ecosystem. This is because they are developed in order to control pests and weeds in such open fields as the upland and paddy. Intensifying the regulatory assessment system of agricultural chemicals in Japan in consideration of substantial preservation of the ecosystem is an urgent issue in order to realize a sustainable community.

2.2 Problems of former regulatory system

Since 1963, a 48-hour median lethal concentration in carp less than 0.1ppm had been used as “the Standard to Withhold Registration” of agricultural chemicals used at paddy fields. This cut-off criterion was used in registering agricultural chemicals from the viewpoint of preventing hazard to aquatic organisms. However, the Standard had the following problems;

- a) It focused only on toxicity to carp that is less susceptible to chemicals and did not evaluate effects on other fish species, *Crustacea* (e.g. shrimp) and algae (e.g. laver).
- b) It was established not for each active ingredient but for all as a uniform standard regardless the type of active ingredient. Additionally, the exposure concentration to organisms in the environment was not considered in the risk assessment .

c) It was not applicable to agricultural chemicals used in areas other than paddy fields (e.g. upland fields and orchards).

2.3. Actual state of ecological effect caused by agricultural chemicals

MOE has investigated the effect of agricultural chemicals on the ecosystem through field surveys in Japan. This field effort is outlined as follows;

a) Decreased number of individual organisms and species observed in some field surveys. However, it was not possible to determine whether this resulted from the natural cycle (e.g. emergence) or use of agricultural chemicals. Separate determinations and evaluations of the effects of agricultural chemicals were difficult in the current field survey due to effects of environmental factors especially climate changes including rainfall and problems of setting unaffected reference area.

b) However, the results of some toxicological studies on aquatic organisms using water collected from rivers after application of agricultural chemicals, showed that concentrations of the agricultural chemicals in these water exceeded the EC₅₀ (median effective concentration for immobilization) value of Daphnia and 100% immobility of Daphnia was observed in bioassays of these samples using Daphnia. These effects were also observed in larger rivers suggesting potential effects of agricultural chemicals on aquatic organisms living around farmland.

With those results, it would be concluded that agricultural chemicals cause certain effects on the ecosystem in Japan to some but unclear extent notwithstanding difficulties to determine and assess separately the effect of agricultural chemicals from other factors in the field survey.

3. Revision of the Standard of Withhold to Registration

3.1 Basic viewpoints to revise the former Standard

Considering the above-mentioned circumstances, MOE revised the former Standard in view of the following basic points;

a) More species should be assessed.

b) The evaluation approach should include comparison of the toxicological endpoint to the exposure concentration.

c) Agricultural chemicals used in upland fields and/or orchards in addition to paddy field should also be evaluated.

In this evaluation, sufficient measures should be taken considering various conditions of Japanese environmental conditions such as rainfall, aspects of the river, situation of the ecosystem, and characteristics of farmlands as well as considering harmonization with existing aquatic risk assessment schemes established in Western countries.

3.2 Outline of the revised Standard

3.2.1 Goal to be achieved and concept of the Standard

At present, quantitative isolation and definition of the degree of effects on the ecosystem caused by agricultural chemicals are difficult in the actual environment. It is reasonable to set a goal in risk management by revising the Standard to reduce the possible adverse effects on the aquatic organisms by agricultural chemicals less than present state at least in the public water supply area such as rivers with the water environment standard point.

Ecological effects of an agricultural chemical should be assessed by comparing a predicted environmental concentration (PEC) during short periods following a single application of the agricultural chemical proposed for registration to the value of the Standard derived from its acutely effective concentration (AEC) on aquatic organisms. When the PEC exceeds the value of the Standard, the proposed use pattern shall be changed to mitigate the risk otherwise the registration shall be withheld.

3.2.2 Derivation of AEC and determination of value of the Standard

The target species are representative organisms of fish, invertebrates (*Crustacea*) and algae. The acutely effective concentration (AEC) is derived from these toxicological studies conducted according to the test guidelines, which the Ministry of Agriculture, Forestry and Fisheries prepared in conformity to OECD Test Guidelines. In this step, the uncertainty factor (1-10) is introduced considering the sensitivities among species (Table 1). The minimum AEC among fish, invertebrates and algae would be set as value of the Standard of the agricultural chemical concerned. In determining the value of the Standard, expert judgment should be required.

Table 1. Derivation of the Standard

Test species	<ul style="list-style-type: none"> ○ Fish: Killifish (<i>Oryzias latipes</i>) or Carp (<i>Cyprinus carpio</i>) ○ Crustacean: <i>Daphnia magna</i> ○ Algae: <i>Selenastrum capricornutum</i>
Endpoint	<ul style="list-style-type: none"> ○ Fish: 96 hr-LC₅₀ ○ <i>Daphnia magna</i>: 48 hr-EC₅₀ ○ Algae: 72 hr-EC₅₀
Uncertainty factor	<ul style="list-style-type: none"> ○ Fish: 10 ○ Crustacean: 10 ○ Algae: 1 <p style="margin-left: 20px;">(Less than 10 would be applicable according to sensitivity analysis for fish and crustacean.)</p>
Value of the Standard	Minimum AEC(AEC _f = 96 hr-LC ₅₀ ×1/10, AEC _d =48 hr-EC ₅₀ ×1/10, AEC _a =72 hr-EC ₅₀ × 1)

3.2.3 Derivation of PEC

For derivation of a PEC, an environmental model is established reflecting Japanese environmental and agricultural conditions. In this model, 100km² of basin are proposed as a whole country area, where 500 ha of paddy field and 750 ha of upland is calculated in proportion of their total actual areas to the whole country area. One agricultural chemical would be applied in 10% of the paddy field and/or 5% of the upland field. These rates (i.e., 10% and 5%) are derived from 80 percentile of coverage (i.e. the rate of application area to whole paddy or upland area) of main agricultural chemicals used in recent years. River area would be 2.0 km², 60% of which are occupied by a main river and 40% by branch rivers. Flow rate of the main river would be 3 m³/s. The agricultural chemical applied to fields would enter branch rivers via

spray drift and/or run-off and reach the main river. A PEC is calculated at the lowest reaches of the main river (Fig. 1) basically according to formula (1).

Prediction point

Fig.1 Image of environmental model for derivation of PEC

$$PEC = \frac{M_{runoff} + M_{Dr}}{F \times T_e} \quad (1)$$

Here, each term means as follows;

PEC : concentration of agricultural chemical at prediction point (g/m^3)

M_{runoff} : amount of agricultural chemical at prediction point via run-off(g)

M_{Dr} : amount of agricultural chemical at prediction point via drift(g)

F : flow rate of main river (i.e. $3 \text{ m}^3/\text{sec}$)

T_e : exposure time (sec) ; equivalent to the exposure time of toxicity study from which the value of the Standard is derived (i.e. 96, 48, 72 hrs in case of fish, *Daphnia* and algae, respectively)

In calculating a PEC, tiered derivation procedures are adopted. With these procedures, a conservative PEC is to be estimated in the first tier without considering dissipation (e.g. adsorption to the ridge and river sediment, hydrolysis and photolysis in water), but in the latter tiers a refined PEC is to be estimated taking account of the dissipation (Table 2). However, test guidelines of dissipation studies for the higher tiered PEC are not prepared for the present and will be established before the enactment of the new scheme.

Table 2. Exposure scenario (route and data used)

Exposure Route	Application site (application pattern)	Tier 1	Tier 2	Tier 3
Runoff	Paddy	Theoretical Calculation	Small scale dissipation study data	Paddy field dissipation study data ^a
	Upland	Constant rate (0.02%)	Runoff study data ^a	-
Drift to river	Paddy (Ground application)	Rate in drift table ^b	Rate in drift table ^b	Paddy field dissipation study data ^a
	Upland (Ground application)	Rate in drift table ^b	Field study data ^a	-
	Aerial application	Rate in drift table ^b	Rate in drift table ^b	Rate in drift table ^b (only paddy)
Drift to ditch (only paddy)	Ground application	Rate in drift table ^b	Rate in drift table ^b	Rate in drift table ^b
	Aerial application	Constant rate (100%)	Constant rate (100%)	Constant rate (100%)

^a Test guidelines to be prepared

^b Not specified here

4. Conclusion

The Standard to Withhold Registration of agricultural chemicals has been revised from the viewpoint of the preservation of aquatic ecosystem. The values of the Standard could be also available as monitoring indicators at post-registration phase. Before its enactment date of April 1, 2005, we will prepare test guidelines of field dissipation studies for calculation of higher-tiered PECs. In addition, we would start to investigate possibilities of more appropriate toxicity studies and/or approaches to reduce the uncertainty associated with derivation of the Standard. These future tasks are under consideration. The introduction of this risk assessment procedure into the regulatory system is expected to reduce risks of agricultural chemicals to the aquatic ecosystem in Japan.

The revision of the Agricultural Chemicals Regulation Law in Japan

Background

It is stipulated in The Agricultural Chemicals (hereafter referred to as ACs) Regulation Law (the Law) that any person/party (i.e. manufacturers, importers, etc), who would like to sell a pesticide in Japan, must get registration of a pesticide from the Minister of AFF prior to its marketing.

The Law was established in 1948 and has thereafter contributed to make agricultural production stable and prevent any adverse effect to human health and environment caused by pesticide use.

Recently, it happened that some retailers were found to have been importing and selling unregistered ACs in Japan and this fact has increased people's anxiety on food safety. Consequently, to cope with these situations and reduce health risk, the Law was amended on December 11, 2002 and enacted on March 10, 2003. (In the case of (4), it was amended on June 11, 2003 and will be enacted on June 10, 2004)

2) Main point of the amendment

(1) Revision of the registration system in relation to the manufacture or importation of ACs

Under the existing provisions of the Law, only the persons who manufacture, process or import ACs to distribute for business purposes are required to register. So the current amendment extends the application to the persons who manufacture, process or import ACs to distribute for non-business purposes for the restriction on the activity of self-manufacturing or private import of ACs.

(2) Revision on the notification system relating to the distribution of ACs

Under the existing provisions of the Law, only the persons who distribute ACs for business purpose were required to make a notification. Hereafter, not only the persons but also all persons who distribute or provide ACs shall notify the Prefectural governor of their name, address and other necessary matters under amended Law.

(3) Reinforcement of the restriction of deceptive advertisement by persons who act as agency for the importation of the ACs

(4) Obligation of the labeling that any herbicide for non-agricultural use shall not be used for agricultural purpose.

Non-agricultural herbicides, although, some of them are registered, are sold for such as parking area, flood wall and railroad, etc. But it is a big concern that they are also applied for agricultural-use instead of the registered ones. So avoiding the use of non-registered herbicide for agricultural purpose, the manufacturer must label from the point of food safety that non-agricultural herbicide shall not be used for agricultural purpose. In addition, the distributor/retailer must also display those labels at the place in their shops where anyone can easily be aware of them.

(5) Reinforcement of the prohibition of the use of ACs

Under the existing provisions of the Law, restrictions on the users of ACs are limited to certain designated ACs. However, no one can use those ACs of which label is not true or proper on the current amendment. In addition, a standard, to be complied with by the ACs users is established to ensure a safe and proper use of ACs. The standard contains target crop, frequency, rate and PHI etc.

(6) Increase of penalty fee, etc

Penalties for those who violate any regulations concerning the manufacture, import, distribution or user of ACs were amended as follows:

For natural person: imprisonment up to three years or fine not exceeding One million Japanese Yen(10,000 dollar, 8,000 euro).

For juristic person: fine not exceeding One hundred Million Japanese Yen (1,000,000 dollar,800,000 euro).

**IR-4 Program, Providing Reduced Risk Products to Minor Crop Growers Through Partnerships
with USDA, EPA, and the Crop Protection Industry
Daniel Kunkel, Robert Holm, and Jerry Baron, IR-4 Headquarters,
Rutgers University, New Brunswick, NJ.**

Mission Statement

The IR-4 Mission is to provide pest management solutions to growers of fruits, vegetables and other minor crops. People who benefit from IR-4 are minor crops growers, food processors and consumers.

Summary

Over the past decade, the agrochemical industry has developed a range of new, safer products. These newer crop protection tools are much more selective against target pests, exhibit low human toxicity and have minimal impact on the environment. The EPA recognized this trend and created a classification of Reduced Risk for compounds that meet these strict criteria. IR-4 recognized these trends as well, and in its 1995 strategic plan focused on the new, Reduced Risk chemistries. When the Food Quality Protection Act (FQPA) was enacted in August of 1996, IR-4's strategy was already being implemented and in the subsequent six years over 70% of IR-4's research program has focused on Reduced Risk or lower risk active ingredients as shown in Table 1.

As a means to accelerate the registration of newer reduced risk chemistries, IR-4 has as its goal a 30-month completion schedule on newly initiated high priority projects. IR-4 submits more than 100 petitions (data packages) per year to EPA, requesting that new MRL's be established on minor crops. IR-4 is speeding access of these new products to minor crop growers. A recent initiative of IR-4 is to develop residue data on new products at a much earlier stage. To maximize success in obtaining MRLs from the EPA, IR-4 is committed to identify new chemistries likely to be registered by industry and will develop parallel minor crop registration data to coincide with those from the companies seeking EPA registration on major crops. The result of this initiative will be new registrations available for minor crops at the time of the initial registration for major crops. EPA's 2003 workplan is an excellent example of IR-4 initiatives, where three new products include IR-4 submissions requesting MRLs for minor crops.

Other initiatives that IR-4 has implemented include the IR-4/EPA Technical Working Group, where many new ideas have resulted in hundreds of new registrations on minor crops via scheduling submissions and actively participating in the development of EPA's Work Plan. Reduced data sets or use of surrogate data support expanded registrations. The group also plays a major role in EPA's work share program with California's Department of Pesticide Regulation, where nearly thirty new minor use data packages are reviewed each year for EPA. The group has also worked with Canada's Pest Management Regulatory Agency (PMRA) for the first successful completion of an EPA/PMRA joint review of a minor use.

Table 1. IR-4 Reduced Risk Programs Since Food Quality Protection Act

Year	Total Studies	Reduced Risk*	% Reduced Risk	New Registrations
1996	151	20	13	80
1997	150	45	38	1
1998	163	78	48	58
1999	151	82	54	313
2000	131	104	79	567
2001	124	96	77	564
2002	95	79	83	538

* Reduced Risk = Classified Reduced Risk products as well as products with lower risk characteristics.

IR-4 Food Use Program Operation

Interregional Research Project Number Four (IR-4) was established in 1963 by the United States Department of Agriculture (USDA) to obtain regulatory approval for crop protection chemicals on fruits, vegetables, herbs and other specialty crops when the economic incentive for the private sector, the chemical company registrants, often limits their financial investment. The Directors of the State Agriculture Experiment Stations provided the stimulus for the establishment of IR-4. The fundamental problem was growers of the fruits, vegetables, herbs and other specialty crops (collectively called minor crops) do not always have legal access to safe and effective pest control technology.

IR-4 operates as a unique partnership between the State Universities (also known as land grant universities) system in the United States, USDA, commodity growers and crop protection chemical companies to accomplish its goal to provide crop protection solutions for minor crops. The IR-4 Project is managed by a headquarters staff which is located at Rutgers University in New Jersey, a USDA-Agriculture Research Service (USDA-ARS) coordinator in Beltsville, Maryland, and four regional offices that are associated with University of California-Davis, California; University of Florida-Gainesville, Florida; Michigan State University-East Lansing, Michigan; and Cornell University-Geneva, New York. All these units operate independently under the umbrella of the IR-4 Project Management Committee (IR-4 PMC). The IR-4 PMC meets on a regular basis to review the status of on-going programs, develop policy and procedures, set operational budgets, develop strategic plans and ensure that the programs overall goals are being met. Stakeholders have a strong voice in IR-4 management through the efforts of the Commodity Liaison Committee (CLC). The CLC serves as a bridge between IR-4 and the growers of minor crops to assure that the program continues to focus on significant pest management problems. They also serve a role to provide guidance and advice on ways in which the program can best serve the needs of minor crop commodity producers. Another important CLC role is to support federal IR-4 funding and budget support initiatives to help secure stable of resources. The Chair of the Commodity Liaison Committee serves as a non-voting member of the Project Management Committee.

Most requests for IR-4 assistance come from federal and state researchers/extension scientists involved in minor crop pest management. IR-4 also receives requests directly from growers and/or organizations representing a commodity. The only IR-4 stakeholders prohibited from submitting requests are representatives of agricultural chemical companies. A request for assistance consists of the completion and submission of a simple one-page Project Clearance Request (PCR) form. Completed forms can be submitted electronically via the IR-4 web site at <http://www.cook.rutgers.edu/~ir4>. Upon receipt of the completed PCR, IR-4 personnel will determine if the proposed use already registered. If not, an enquiry

will be sent to the agricultural chemical company, that holds the US registrations for the requested chemical, to determine if they are willing to cooperate with IR-4 to obtain the regulatory clearance of the pest control tool. Finally, IR-4 questions the US Environmental Protection Agency (US EPA) to determine if there are any regulatory impediments known that may delay or result in denial of the registration. If the company is willing to register the proposed use once IR-4 develops the appropriate data the proposed use is regarded as “Researchable” and is considered in the research project prioritization procedures.

As IR-4 does not have sufficient resources to conduct research on all proposed researchable projects. IR-4 sponsors a “Food Use Workshop” that is the cornerstone of the IR-4 prioritization process. This is an open forum where over 200 minor crop growers, commodity organization representatives, agricultural chemical company representatives, and federal and state research/extension scientists attend and participate. At the workshop, every potential project is discussed in detail and its importance is considered on the basis of such factors as the availability and efficacy of alternatives, pest damage potential, performance of the proposed chemical, and its compatibility with integrated pest management programs. IR-4 will conduct research on the highest priority projects identified at this workshop, approximately 100 studies (chemical/crop) per year.

In order to conduct this research, IR-4 has established 31 field research centers at strategic locations throughout the United States. IR-4 conducts an average of 100 projects on food crops every year. Over 85% of these projects consist of magnitude of residue studies. The remaining studies are designed to provide data to the registrants that the proposed use is safe and effective. This aspect of the IR-4 research plan comprises of nearly 700 field trials. IR-4 also has a network of four regional, three ARS and five satellite analytical laboratories that determine the amount of residues remaining in the crop. All these field centers and analytical laboratories operate under GLP. All data from IR-4 sponsored studies are transferred from the field sites and/or analytical laboratories to the IR-4 Headquarters. Before the data are transferred, they are subjected to both quality control and quality assurance audits. These quality checks have helped ensure that IR-4 has achieved some of the lowest number of review cycles of any data submitter to US EPA. Once at IR-4 Headquarters, the Study Directors critically review the data and reformat it into a style required for submission and review by the co-operating agricultural chemical company and the US EPA.

The first step in obtaining the regulatory clearance for a proposed IR-4 food use is for IR-4 to submit the data to the US EPA. Upon receipt, US EPA Registration Division personnel perform a preliminary review for completeness of the data and start discussions with scientists in the Health Effects Division to schedule a comprehensive review of the IR-4 and supporting data from the agricultural chemical company. The data are reviewed and if they show that clearance of the use would not expose consumers or the environment to unreasonable adverse effects, the EPA publishes a tolerance as a Final Rule in the Federal Register. This tolerance is the maximum residue limit (MRL) of the agricultural chemical in or on the crop that is considered safe and legally acceptable.

Since the IR-4 Project started in 1963, it has been responsible for residue data and other petitions to support over 6,500 food use clearances, more than 9,900 ornamental or non-food crop clearances and supported research on biopesticides that has resulted in over 300 biopesticide clearances. This is a tremendous accomplishment when measured against the level of funding and the efforts of the crop protection industry. The IR-4 supported clearances account for approximately 50% of all food use approvals granted by the EPA and for over 50% of the Agency’s ornamental approvals.

Food Quality Protection Act or FQPA in 1996

The passage of the Food Quality Protection Act or FQPA in 1996 set in motion a new set of challenges which had been foreseen, in part, by the 1995 IR-4 Strategic Plan. That plan recognized the trend of new, safer, Reduced Risk chemistries being developed by the crop protection industry and their potential value to minor crop agriculture. These products are extremely safe to mammalian systems as well as birds, wildlife, aquatic species and beneficial organisms making them ideal for use in integrated pest management (IPM) systems. IR-4 started integrating these new products into its 1996 program; over 10% of the projects that year involved those safer chemistries. This trend has continued and has reached the 70-80% level the past three years. This focused effort has given the program a high level of credibility with the EPA in partnering with them to implement the mandates of FQPA.

IR-4 Partnerships

The IR-4 Project continues to pride itself in being a model of interagency cooperation for a federally funded program by forming partnerships with the land grant university system, commodity organizations and minor crop groups, our USDA funding agencies (CSREES and ARS), the Crop Protection Industry and the EPA to bring the latest crop protection solutions to minor crop growers. The various stakeholders/customers and the partnership initiatives with them by IR-4 are noted below:

Crop Protection Industry

IR-4 would not have new products to make available as crop protection tools for minor crop growers without the cooperation of the biopesticide and chemical companies who discover, develop, register and market their new technologies. In spite of many mergers, acquisitions and reorganizations, the industry has continued to closely work with IR-4 to develop minor crop strategies for their new products. IR-4 also discusses ways that companies may maximize the potential of their new technologies for minor crops and makes them aware of market opportunities as presented by minor crop stakeholders through Project Clearance Requests and other direct inputs to IR-4. An initiative started in 2002, which should pay big dividends in future years, was to share future petition submission strategies with registrants and to encourage them to disclose their EPA petition priorities to IR-4. This allows our Registration Team to prioritize and optimize with the EPA a maximum number of petitions (both IR-4 and registrant) around each active ingredient resulting in the best possible outcome for all partners (IR-4, EPA, registrants and growers).

PA

IR-4 started a Technical Working Group (TWG) partnership with the EPA in 1999 that allows IR-4 and EPA to work together more efficiently. Through quarterly meetings, IR-4 keeps EPA informed of their planned submission schedule which is in turn used by EPA to develop their work plans. Much efficiency has been realized through these planning sessions, such as: IR-4 developing a new petition format that is easier for EPA to review, moving to electronic submission of data packages, expansion of crop groups and the use of surrogate data, especially for certain reduced risk products that lend themselves to easy residue predictions. EPA has also developed a streamlined reduced risk request for IR-4 in situations where the product has already received reduced risk on another crop. EPA and IR-4 has also had a number of personnel exchanges/sabbaticals to build efficiencies. The development of the Agencies Annual Work Plan evolves over an 8 or 9 month period that generally results in 50% of the EPA's Work Plan since 1999 involving new uses for existing products with IR-4 projects. In 2003, of the 54 products that are currently registered and are on the 2003 EPA Work plan for new uses (registration expansion), IR-4 is the sole submitter on 20 and is the joint petitioner with the registrants on another 17 active ingredients. IR-4's

involvement with 68.5% of the products on the EPA's 2003 Work Plan is a good example of the scope of the program. IR-4 is also active in the new registration area where they are the sole submitter for one new active ingredient (quinoxifen) included in the 19 on the 2003 Work Plan and has ongoing research work on another 12 active ingredients resulting in a 63% involvement in new product registrations. The EPA partnership initiative was expanded to the Biopesticide and Pollution Prevention Division (BPPD) in 2001 and has evolved into regular Technical Working Group Meetings to explore more efficient ways to improve biopesticide registrations.

California's Department of Pesticide Regulation (DPR).

The IR-4/DPR partnership which was initiated in 2000 with one IR-4 petition as part of a DPR work share program with the EPA continued to grow to a level of 30 IR-4 petitions. This work share project involves about 10% of the EPA's annual workload of new uses for currently registered products and are about 20% of the IR-4 petitions submitted at the Agency. This program has been the major contributing factor in doubling the IR-4 contributions to the EPA's Work Plan from 25% in 2000 to 50% in 2002. DPRs continued commitment to maintaining the level of petition work share support in 2003 and 2004 in spite of severe budget cutbacks in California and at DPR demonstrates the importance of this program which greatly benefits not only California minor crop growers but also their counterparts throughout the U.S.

Health Canada's Pest Management Regulatory Agency (PMRA).

PMRA completed its first IR-4 work share petition with the EPA in 2002. The Canadians have been partners with IR-4 since 1996 and have made major contributions by conducting over 90 field residue trials on our priority projects since then. The Canadian government made a major funding commitment to minor crop growers in 2002 through PMRA and Agriculture and Agri-Food Canada which will set up six Field Research Centers, three GLP Residue Laboratories and a Minor Use Center in addition to expanding the PMRA minor crop review capabilities including a Minor Use Team Leader. This commitment has allowed the Canadian Team to expand their support of IR-4 projects to over 60 field residue trials in 2003 as part of our prioritization program and should lead to more minor crop registration for both U.S. and Canadian minor crop growers resulting in fewer trade irritant issues.

In the final analysis, IR-4's strategic plan has worked to successfully provide new reduced risk products for minor crop growers as they begin to transition from the higher risk products as part of the implementation of the FQPA.

IR-4 Program, Providing Reduced Risk Products to Minor Crop Growers Through Partnerships with USDA, EPA and the Crop Protection Industry



IR-4 Program, Providing Reduced Risk Products to Minor Crop Growers Through Partnerships with USDA, EPA, and the Crop Protection Industry


**Dan Kunkel
IR-4 Project Headquarters
New Brunswick, NJ**



The IR-4 Mission

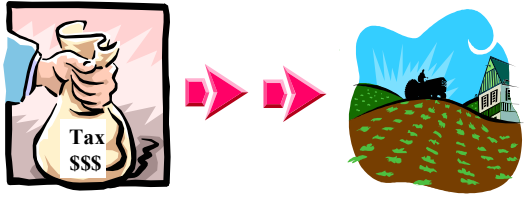

To provide pest management solutions to growers of fruits, vegetables, and other minor crops for the benefit of consumers, growers and food processors.





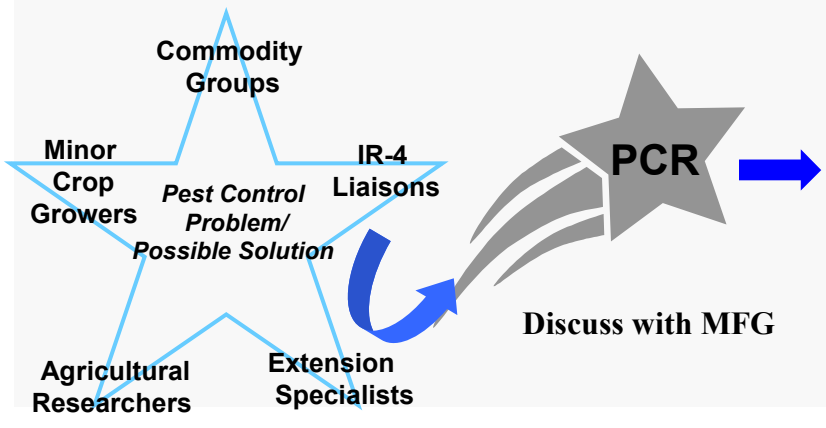
USDA IR-4 State Land Grant Universities

Interregional Research Project Number Four (IR-4) is the only publicly funded program that conducts research and submits data to to US Environmental Protection Agency to support the registration of pest control solutions.

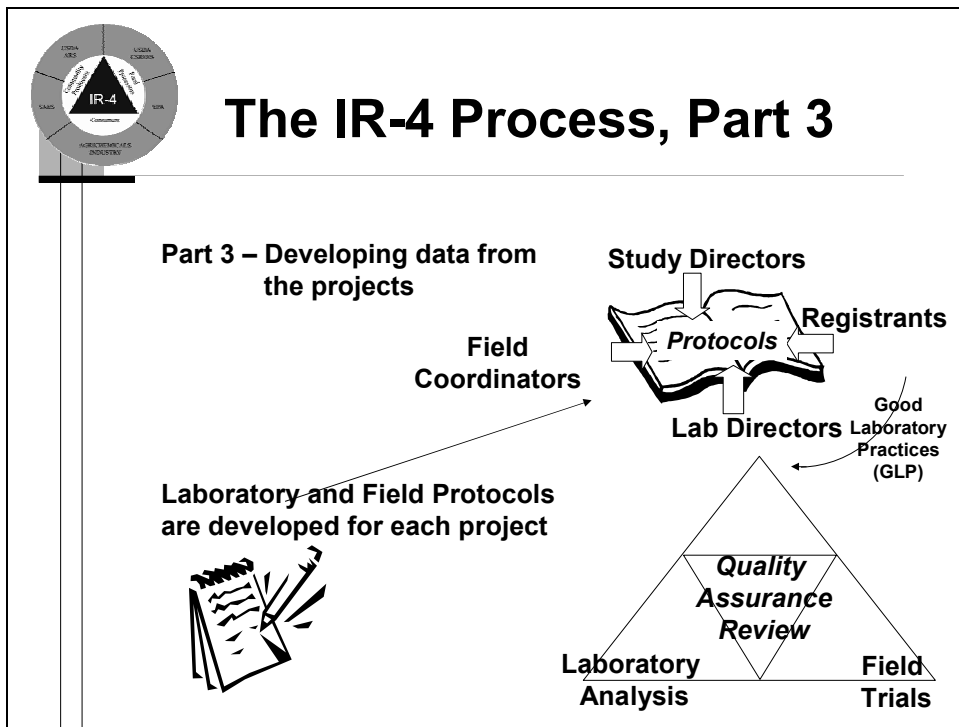
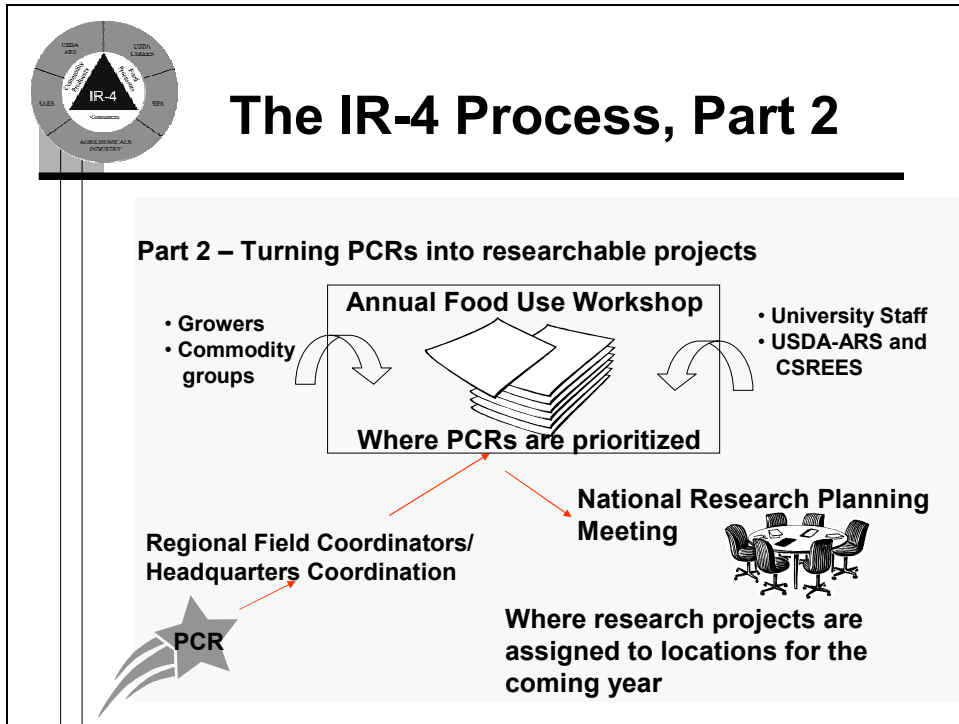



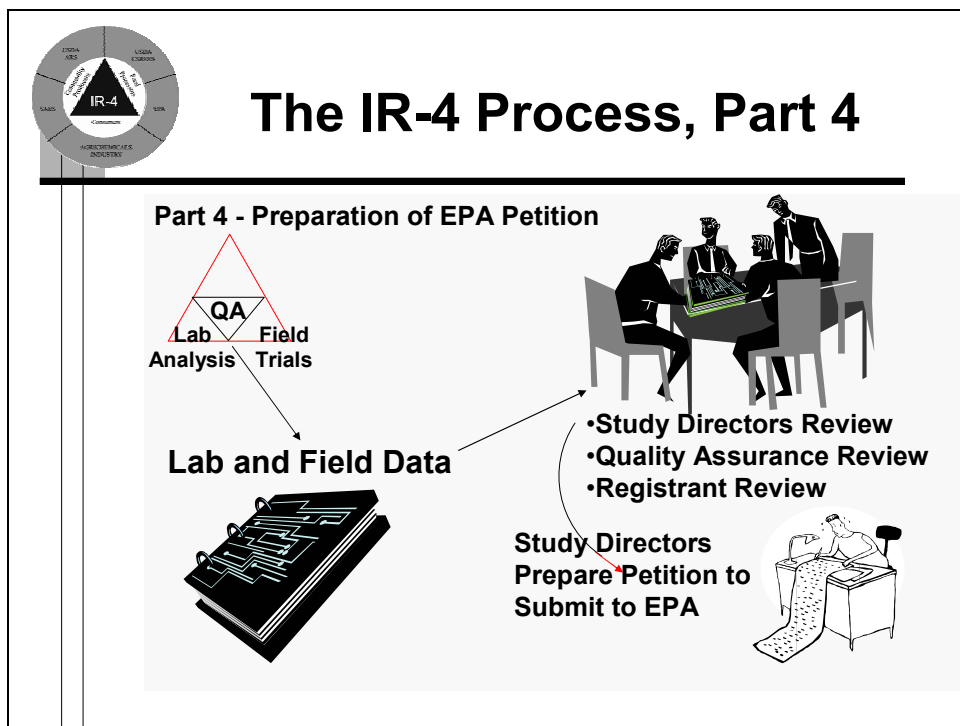
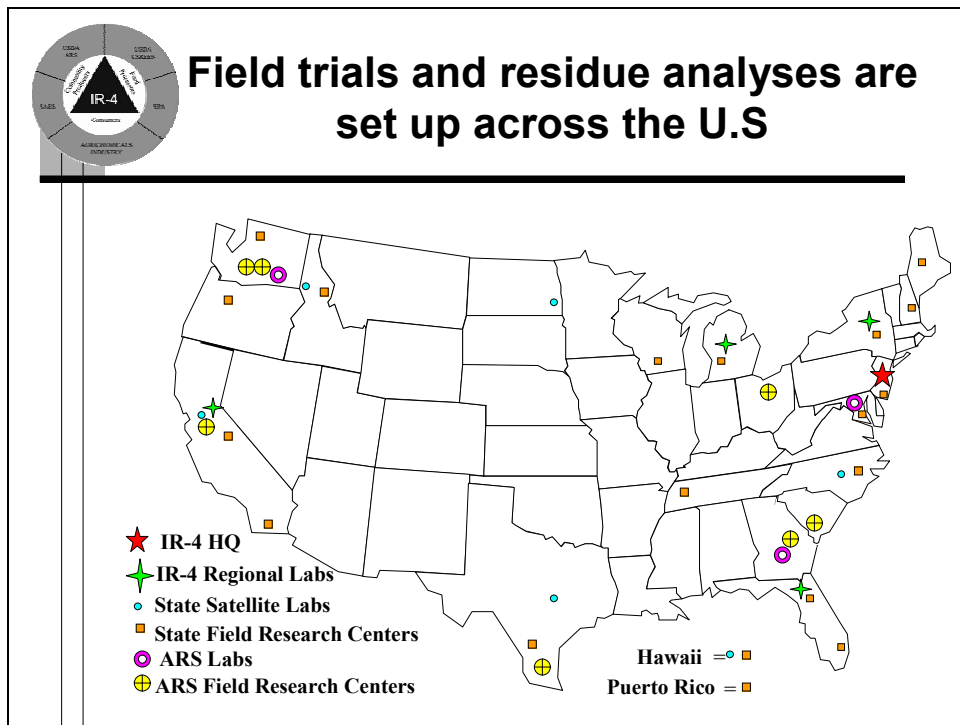
The IR-4 Process, Part 1

Part 1 – Submitting the Project Clearance Request Form (PCR)



Discuss with MFG







Product Registration



The petition is sent to **EPA**




where it is reviewed.



If everything is in order, a MRL is granted (for food use products) and a registration follows.



A new product is now available for minor use.



IR-4's Risk Reduction Strategy

- Designed to ensure that a selection of existing and new pest control products will be available for specialty crops in the future.
- Work closely with growers and industry and partner on developing data for minor crops
- Expedite minor use registration (i.e. IR-4 research before first registration)



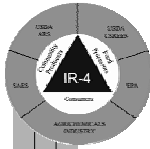
IR-4 Program Since FQPA

- **Since FY 1997 EPA's OPP has dramatically increased its decisions related to IR-4 submissions due to:**
 - **IR-4 focus on "reduced risk" and other new chemistries**
 - **OPP's commitment to IR-4 in the priority work plan**
 - **Creation of the Minor Use Technical Working Group (TWG)**



EPA PRIORITIZATION

- 1) Methyl Bromide alternatives**
- 2) Reduced risk - OP alternatives**
- 3) Other reduced risk candidates**
- 4) OP alternatives, not reduced- risk**
- 5) Vulnerable crops**
- 6) **IR-4 Petitions****
- 7) Minor Crop Uses submitted by registrants**
- 8) Trade irritants**
- 9) Other registrant identified actions**



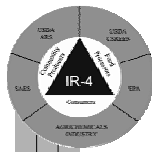
Other Regulatory Partnerships

- California
 - Completed 3rd year on EPA Workshare Program
 - Significant Impact! (20% of IR-4 Clearances)
 - Continuing in 2003 despite budget cuts
- Canada
 - PMRA completed 1st joint EPA Workshare project
 - Significant Canadian Government Minor Crop Funding initiative (\$~10 million/year)
 - More joint programs via CHC and A&AFC



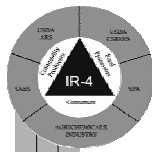
IR-4/Industry Relations

- Major Headquarters effort on meetings
- Great support from IR-4 Liaisons and company staff
- Strong Financial Commitments
- Innovative partnerships
 - Quinoxifen
 - BAS 500/510/516
 - Syngenta commitment



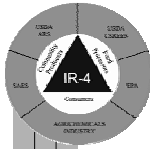
Number of New Uses Associated with EPA Approvals

- Prior to 1976, each petition submitted resulted in approx. one approval
- With use of crop groups, new petitions average about five approvals per petition
- We expect this number to increase in the future.
 - Establishment on new crop groups
 - Expansion of crop groups
 - Use of super crop groups



Super Crop Groups

- Reduced Data Sets for Reduced Risk Chemistries
 - Spinosad (165 uses)
 - Azoxystrobin (129 uses)
 - Glyphosate (over 200 uses)
- Saved IR-4 an estimated \$1.5 million in direct research costs
- More to come, surrogate data petitions, utilizing logical associations, Canadian data, etc.



Results of Crop Grouping Symposium

Categories	Current	Added	Total
Commodities	508	553	1061
Crop Groups	19*	19	38
Subgroups	18	72	90
Definitions	20	29	49
Ornamentals	0	900	900
Ornamental Groups	0	12	12

*** Crop Group 20 - Oilseed is approved by HED ChemSac but not yet published**



Economic Support for IR-4

- **Direct Contributions – Approx. \$15.76 MM**
 - CSREES Grant \$10.67 MM
 - Regional Research \$0.48 MM
 - ARS \$3.61 MM
 - Gifts \$1.0 MM
- **Indirect Contributions – At least \$15 MM**
 - Employee Benefits
 - Utilities
 - Land Rental
 - Other miscellaneous research costs



IR-4 Biopesticide Program

- Regulatory Assistance
- Funding research
 - Early Stage (25%)
 - Advance Stage - efficacy data to expand biopesticide labels (75%)
 - IR-4's strategy for 2003 was to encourage research to integrate biopesticides in rotation with conventional materials
 - Pest Resistance Management
 - Residue Management



New Biopesticides

- Numerous new products in development
- Possibilities for conventional & organic systems
- However
 - Companies have not cooperated with Land Grants
 - Researchers have bias "Biopesticides Don't Work"
 - Many companies are small "Mom & Pop" organizations who are funded by venture capitalists
 - Companies do not have extensive regulatory experience-Problems with EPA clearances

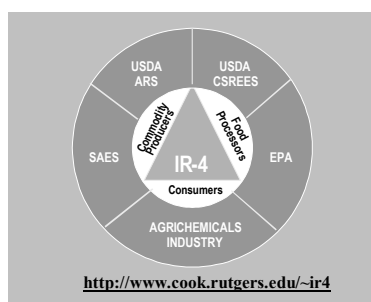


Methyl Bromide Alternatives

- Jack Norton/Program Manager
- Originally strawberry & tomato research
- Shifting emphasis to other minor crops in need: peppers, vine crops, cut flowers, bulbs and ornamentals
- Member of Methyl Bromide and Critical Use Exemption Task Forces
- Recognition from Steve Johnson/EPA



Thank you!



THE MINOR USE PROGRAM

Funding provided by USDA (CSREES and ARS) and the SAES

Minor Uses and Pesticide Risk Reduction
Germany Bonn, October 2003
Federal Ministry for Consumer Protection, Food and Agriculture

Addressing minor use problems

Germany has operated a smooth and efficient system to close crop protection gaps in minor uses since the middle of 2000. As a basis, relevant organisational structures had been set up at the ministerial level (national working group on minor uses, shortly termed AK-LÜCK, set up in 1991), at the crop protection services of the federal states (minor uses work group of the states, with eight sub-work groups, set up in 1993) and at authorities dealing with the authorisation of plant protection products. The procedure to close minor use gaps is also soundly founded on co-operation with manufacturers of plant protection products (round table-talks), with farmers' associations, the processing industry, food markets, horticulturists and farmers.

The federal states' annual work group on minor uses and round-table talks with industry provide the major platform for solving minor use problems.

Legal basis: there are three possible procedures for minor uses:

1. Authorisation procedure according to Article 15 of the Plant Protection Act (PPA): company submits application for a product authorisation (rare case).
2. Special minor use approval procedure extending the uses of an authorised plant protection product (PPP) according to Art. 18, 18a PPA (main way).
3. Special minor use procedure for a personal permission to apply a pesticide, according to Art. 18b, granted by the federal states for very small crops only.

Preconditions for minor use approvals:

1. The plant protection product in question must be authorised (approval parallel to authorisation is possible),
2. Approval has to be in public interest,
3. Available data must give evidence that there are:
 - no negative effects on the health of humans and animals and on the ground water,
 - no unacceptable effects on the environment or endocrine functions of humans and animals,
4. Applicant has to confirm effectiveness and that there are no unacceptable effects on plants.

Minor use approval procedure in Germany (Art. 18, 18a PPA)

Apart from the **Working Group on Minor Uses**, the following parties are concerned with the minor use approval procedure:

1. Companies (authorisation holders, also as applicants),
2. Authority granting authorisations: Federal Office of Consumer Protection and Food Safety (BVL),
3. Authorities of consent:
 - Federal Biological Research Centre for Agriculture and Forestry (BBA) – evaluating efficacy, plant safety, benefit of PPP
 - Federal Institute for Risk Assessment (BfR) - evaluating toxicology, residues, protection of consumers and users
 - Federal Environmental Office (UBA) – evaluating natural balance.

In most cases, an application according to § 18a PPA can only come after a heap of preparatory work. In that, the BBA is dealing with the following:

Co-ordination of the Working Group on Minor Uses

Organisation of annual meetings of the subgroups

- Discussion of test results of efficacy and residue studies,
- Making a working plan for efficacy and residue field studies,
- Making proposals for application forms,
- Listing of old and new minor use gaps,
- Discussing ways to close these minor use gaps.

Organisation of “round-table discussions” with several companies, the authorisation authority, authorities of consent and heads of working groups on minor uses to clear up:

- all problems before the beginning of the official approval procedure
- division of labour
- possibilities to early include new developments of PPP in minor use program
- Preliminary examination of all approval application forms
- actual minor use gap/public interest
- correctness of content
- completeness of necessary data

The actual application is made after a first scrutiny of the matter in question. The ensuing procedure consists in the following steps:

- Official evaluation of all application forms for approvals by BVL in consent with UBA, BBA and BfR, hearing of the authorisation holder to get his agreement (if he is not the applicant) and hearing of the Expert Committee (SVA) before decision
- Information of applicant and/or authorisation holder about approval decision
- Publishing of all granted approvals in the Federal Gazette with notice that liability lies with the user

Time required is between 13 weeks up to about 4 months.

Funding of minor use approvals in Germany

Germany has no special funds for minor uses. Efficacy trials and field studies for residue behaviour made by minor use sub-groups are free of charge (ownership by AK-LÜCK).

The essential problem in execution of efficacy and residue trials as a basis for applying for uses which require special residue studies is the payment of analyses of residue samples. Heads of minor use subgroups collect money for payment.

Costs for Residue analyses in the past two years:

	2001	2002
Vegetable crops	383.000 Euro	326.000 Euro
Fruit crops	141.000 Euro	80.000 Euro
Medicinal and aromatic plants	77.000 Euro	40.000 Euro
Total	601.000 Euro	446.000 Euro

If the use is in public interest, the BVL waives fees in more than 95 % of approvals.

Results

The past three years have seen big progress in closing minor use gaps. We were able to grant approvals according to § 18a of the Plant Protection Act for

- 121 fields of use in 2000,
- 308 fields of use in 2001,
- 407 fields of use in 2002,
- 266 fields of use in 2003, so far.

This trend will continue. Also, approvals must be renewed when the product authorisation on which the approval is based ends. The number of minor uses which are applied for from the beginning, that is at the same time as the main intended uses of a product, is still small, though the chemical industry is willing to include such minor uses in their original applications. The problem is that companies have only little prospect of profit with minor uses. Liability also plays a role for applications according to § 18a of the Plant Protection Act.

Liability is also not completely clarified in Austria. Austria is taking over authorisations and approvals made in Germany, but does not have Germany's legal framework for these matters. Most recently, a company paid damages (as fair dealing) because crop plants showed damage after use of the company's product. The farmer has to care for this in Germany.

Statistics of applications and approvals according to § 18a Plant Protection Act

	Number of uses	
	Applied for	Actually approved
Arable crops	168	162
Vegetable growing/fresh herbs	522	404
Fruit growing	183	126
Medicinal, aromatic and spice plants	132	53
Others	208	180
Total	1213	925^{*)}

^{*)} About 50 uses more will be approved after setting of MRLs

Identifying opportunities for risk reduction

Approvals to close minor use gaps help to minimise risks of plant protection product uses for consumers and the environment. Data proving that use of the product in question is efficient and harmless to humans, environment and crop plants is therefore a prerequisite for an approval to be given. If residues can occur, it is necessary to conduct residue trials to prove that residues in harvested crop will not exceed legal limits (maximum residue levels). Should this be the case, trial results may be used to apply for revision of maximum residue levels.

This procedure makes sure that agriculture and horticulture have tested products available for their needs and reduces the pressure to use products illegally. This provides protection to both producers (legal management, products are marketable) and consumers and environment (tested uses, calculable risk).

The range of usable plant protection products will be sharply reduced in many member states of the European Union after 27 July 2003, when old authorisations of 362 active substances expire at a time, because they have not been included in Annex I of Council Directive 91/414/EEC. Germany is less concerned about this problem because many of the old substances have no longer been authorised anyhow. The working group on minor uses has since long before worked intensively to solve minor use problems, which has relieved pressure of that problem.

Identifying ways for more co-operation between governments and stakeholders

On the national level

Germany has achieved a high level of co-operation between the government and industrial stakeholders, which is reflected both in the working group on minor uses and its sub-groups and in the “round-table talks” with the agrochemical industry. These show a high degree of co-ordination and co-operation. Officials have been put in charge of minor use problems both on a state level and on the national level. Big manufacturers of plant protection products have also named staff members who are looking after minor uses in particular, some even have working groups for that. A number of small companies, too, have their own minor use people.

On the international level

Co-operation on EU level

A technical working group on minor uses was set up at EU level in March 2003 as a prerequisite for international co-operation in that field. Each member state has sent one representative to that group.

Main tasks are:

- Stimulating work and data sharing,
- Co-ordination of residue work,
- Stimulating more harmonisation of procedures,
- Recommendations for research (also for alternatives),
- Improvement of principles for extrapolation (residues and efficacy) and harmonisation of uses.

The founding meeting has fixed as first steps:

- Identification of minor use gaps in each country,
- Identification of the 5 most important gaps in EU,
- Work plan on efficacy and residues (work and data sharing),
- Building up a database for residues, and later for efficacy work,
- Naming a contact person for minor uses in each country.

Germany has compiled lists of the most important minor use problems which remain to be solved to meet the above objectives. The federal states also started to compile all efficacy and residue trials and the results of residue trials in a joint database, which is updated annually after consultations among the institutions carrying out trials. This database is the basis for exchange of data within the EU.

In the framework of bilateral co-operation, Germany has sent UK in 2002 a list of all residue trials which may be used in an exchange of data. Negotiations about data exchange are also conducted on national level.

International co-operation

Long-term co-operation with:

- IR-4 Project in USA (residue studies financed by the government and supported by universities): exchange of residue results for checking up comparability, exchange of working programmes,
- Horticultural Development Council in UK: exchange of working programmes, efficacy and residue data,
- Austria: Austria takes over authorisations and approvals from Germany, participation in efficacy and residue trials and all meetings of minor use work groups.

Conclusions

Minor uses will remain a challenge for agriculture, legislators, authorisation authorities, research, and the chemical industry.

Solving problems requires:

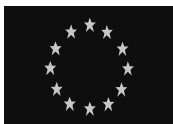
- Authorised PPPs (basic prerequisite),
- Close co-operation between all involved institutions and persons on the national and international level,
- Mutual recognition of authorisations and approvals,
- Exchange of results, documents and information regarding minor uses,
- Co-ordination of trial projects,
- Development of international databases,
- Strong support of applicants by authorities.

**Minor Uses in EC Canice Nolan
European Commission DG Health & Consumer Protection**



Minor uses in EC

Canice Nolan
On behalf of Wolfgang Reinert
European Commission
DG Health and Consumer Protection



Dir. 91/414/EEC, Art. 9(1)

Application of authorization of a plant protection product shall be made by [...] the person responsible for first placing it on the market in a Member State [...] where the plant protection product is intended to be placed on the market.

Official or scientific bodies involved in agricultural activities or professional agricultural organizations and professional users may request that the field of application of a plant protection product already authorized in the Member State in question be extended to purposes other than those covered by this authorization.

**Member States shall grant an extension of the field of application of an authorized plant protection product and shall be obliged to grant such an extension when it is in the public interest to the extent that:
[...] the intended use is minor in nature, [...].**



Criteria for evaluation

1. The use is meant for more than one Member State.
2. The active substance is authorised at least in the respective zone (Northern/Southern).
3. The owner of the a.s. agrees and intends to keep the formulation needed to address the Minor Use on the market for a while.
4. If relevant: at least one accepted MRL exists in at least one relevant crop and the ADI fits.
5. Sufficient indication of efficacy and selectivity exists.
6. The intended application replaces one 'essential use'.
7. Generated data will be freely shared between Member States.
8. The use closes a gap in the resistance management in order to prevent an endangering of a sustainable use in IPM.
9. The use is necessary for reasons of agricultural efficiency and/or necessary for the continuation or development of integrated crop management in the relevant crop.



Expert Group on Minor Uses

- The need for an expert group on Minor Uses has been clearly identified during 2002.
- In June 2002, COM establishes an expert working group 'Minor Uses'; further meetings follow in September and December 2002. This group comprises experts from BE, DE, FR, NL, PT and UK.
- New Structure from March 2003:
 - Minor Uses Steering Group
 - 2 Minor Uses Technical Groups (Northern/Southern Zone)
 - each comprising Member and Accessing States as well as key stakeholders (industry, producers and environment)
 - each led by one coordinator; the coordinators of both groups are in permanent exchange
- Next meeting: 9-11 December 2003



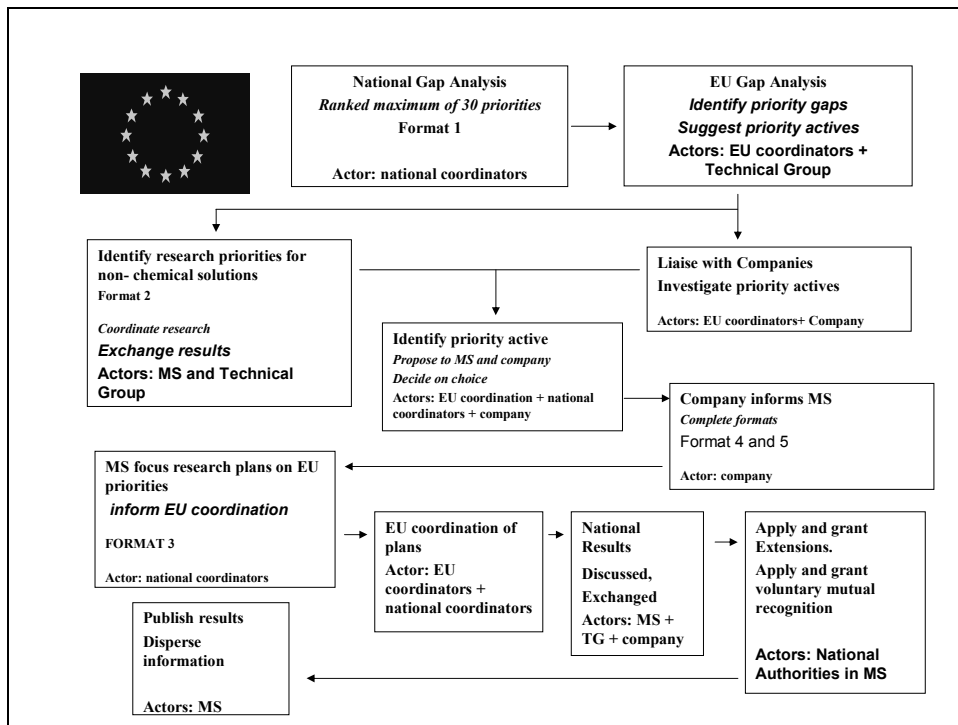
Activities taken so far

- **In a detailed questionnaire has been circulated to Member States.**
- **Each Member State identified the 5 most concerning Minor Uses, respectively.**
- **The ‘Flies-Project’ has been started**
- **The following draft schemes have been developed:**
 - **strategy paper in the implementation of the programme.**
 - **for a feasibility study on a harmonised Minor Uses database.**
 - **for a residues database.**



Activities for the future

- **Support the wider use of ‘mutual recognitions’.**
- **Reconsider the actual residues extrapolation rules and explore scope for flexibility.**
- **Examine the practice of efficacy extrapolation in Member States and explore the scope for a common approach.**
- **Improve the harmonisation of uses between Member States by analysing and comparing the definitions on key elements like ‘approved use’, ‘pest’ or ‘crop’.**
- **Compile information available from the use gap analyses already done on national level in several Member States.**
- **Issue an EU-wide, harmonised ‘catalogue of uses’.**



Risk management in minor use crops: Australian agricultural industry experience.
Kevin Bodnaruk, AKC Consulting, Australia

INTRODUCTION

The Australian agriculture sector is characterised by a large number of minor crops, which are poorly represented on the labels of registered chemical products. In the past this lack of representation has presented significant problems to the industry. Issues contributing to this situation include loss of uses through chemical reviews, emerging crops, state control-of use legislation, quality assurance programs and the disinclination of manufacturers to register minor uses. The APVMA¹ has legislative criteria that allow it to approve minor use via permits if satisfied that the use would not cause an undue hazard to people (directly or through food residues), the environment, plants and animals. The use must also be effective and not prejudice Australia's trade². In order to satisfy APVMA requirements industry applicants must undertake a degree of risk management in the advancement of any minor use proposal. The current approaches towards risk management and minor use utilized by the major industry groups involved, QFVG, CPA & JAY4³ are comparable and outlined below.

CURRENT APPROACH

The major industry groups all use formalised processes for the collection of minor use requests, e.g., web site based nomination or written forms. These nominations or requests can be received from growers, advisers or researchers. Prior to inclusion in their respective programs the nominations will undergo preliminary screening. The screening processes used by the different groups vary somewhat but in general terms are similar. The procedure followed is iterative and involves the systematic collection of any additional information required and consultation with various stakeholders such as researchers, advisers and growers, to characterise the proposed use.

At this time specific issues relating to a compounds use (efficacy), trade (export MRLs), regulatory status (proprietary or generic), consumer (dietary exposure), user (occupational health) and environmental safety are considered. However, the criteria used to assess possible impacts are comparative in nature and can provide only a coarse assessment.

The types of criteria used for the key areas of risk are outlined below.

- Dietary exposure: Does an MRL exist on a related crop domestically or on the crop internationally?
- Trade: Does an MRL exist for the pesticide/crop combination in export markets avoiding potential non-tariff barriers to trade?
- Environmental exposure: Is the application method identical to a currently approved use for that product?
- Occupational health: Is user exposure likely to be any different to currently approved uses for that product?

¹ Australian Pesticide and Veterinary Medicines Authority

² http://www.apvma.gov.au/minor_use/general.shtml#Environmental%20safety

³ Queensland Fruit and Vegetable Growers, Crop Protection Approvals and the JAY4 Grains project.

- Efficacy: Is the proposed use pattern likely to be efficacious and sustainable, e.g., does it control the pest/disease or weed on another crop(s), if so does the pest/disease or weed behave in the manner, is crop safety an issue or is a resistance management strategy needed?
- Regulatory status: If the product is generic the lack of data protection can be a disincentive for manufacturer support, i.e., risk of little or no return on investment.

Following the initial assessment and prior to submission, liaison with the APVMA is undertaken to identify any areas of specific regulatory concern and confirm data requirements as requirements for minor uses are often reduced⁴. Particularly if existing data is available from manufacturers, JMPR monographs or other sources. On the basis of this liaison further consultation with stakeholders occurs to determine priority. This prioritisation is based on industry need, resource requirements, manufacturer support and fit with the industries long-term strategy. At this point a decision is taken whether to continue.

A proposed minor use may not proceed to application for a number of reasons. These may include:

- a particular concern may be raised by the APVMA that could either
 - disallow the use ;
 - result in prohibitive data requirements; or
 - result in regulatory controls that could make the use impractical;
- due to the lack of manufacturer support a use is unlikely to ever progress to a label extension, the relevance of this constraint may vary dependant upon crop status; or
- the proposed minor use may not be compatible with an industry stated pest management strategy, i.e., promotion and development of Integrated Pest Management.

To date when an application has been made the predominant requirement has been for residue data, to enable the APVMA to establish an MRL and carry out dietary exposure assessments. However, the APVMA is increasingly requiring efficacy and crop safety data which can be problematic in emerging crops. Residue data is most usually collected from GLP studies, while not a requirement for minor crops are needed for minor uses in major crops.

When data is required trials are established to reflect the GAP from either the proposed use or the GAP from another similar crop in which the pesticide is approved, and can often involve both single point and residue decline. The number and type of trials has been dependant upon the availability of data from other sources, e.g., manufacturers or similar crops. More recently an attempt is being made to determine harvest intervals required to achieve non-detectable residue levels in vegetables. This is being done with the aim of providing harvest interval data for either exported commodities where no international MRLs exist or to meet customer, e.g., supermarket, requirements. The data is then submitted to support a permit or used in the progression of the minor use to a registered label claim.

FUTURE NEEDS

As indicated much of the risk management approach followed by industry is comparative and currently utilises limited criteria. Increasingly this approach is being found wanting by the regulatory authorities.

⁴ Residues and minor crops. NRA Information Sheet January 2000.

Often resulting in significantly greater data requirements than anticipated or an involved and extended evaluation process.

A set of guidelines for determining minor uses currently exist in Australia, however, they provide little or no information on the identification or assessment of potential risks and their possible management. The availability of simplified risk assessment methodologies coupled with generic guidelines or indicative thresholds indicating the level of regulatory control that may be required for a given pesticide x crop use would allow industry groups to more critically assess minor use proposals prior to submission.

A review of the minor use definition could also be of value. At present the prime determinants are acreage and or frequency of use. Broadening the scope of the definition to include other factors could be a positive development in risk management. For example, the current IUPAC⁵ project on minor crops⁶ has suggested using levels of consumption or dietary exposure as potential criteria for identifying minor uses.

Of further benefit would be the classification of pesticides on the basis of risk profile, using such categories as low, medium or high. This categorisation could be based upon a range of criteria, e.g., dietary intake, environmental exposure and occupational health and safety. This would provide industry an opportunity to better assess and manage potential risks by differentiating between pesticides on the basis of their risk category, with lower risk compounds given preference.

Finally progress regarding data protection would also be of value. While not specifically relevant to risk management per se an extension of current data protection could provide an environment more conducive to data generation by manufacturers. Such a scenario would be of benefit as a consistent problem in assessing and advancing minor use is the lack of relevant data and the cost of its generation.

Industry groups increasingly have to accept responsibility for managing and resourcing minor use of pesticides in Australia. They have to consider risk in a complex regulatory environment but are currently ill equipped to do so. The development and provision of more effective risk assessment tools, such as simplified risk assessment methodologies, pesticide categorisation and a broadened minor use definition would enable industry groups to develop and implement more effective strategies for risk management and mitigation in minor use.

⁵ IUPAC – International Union of Pure and Applied Chemistry.

⁶ Project 2001-039-1-600 *Methods for setting interim MRLs for minor-consumption crops*.

Risk Management in Minor Use: Ag Industry Experience
K Bodnaruk, Australia

Risk Management in Minor Use:
Ag Industry Experience

K Bodnaruk

OECD Seminar on Minor Uses and
Risk Reduction

Minor Use

Lack of access to products

- Emerging crops
- Chemical reviews
- Control of use
- Quality Assurance schemes
- Manufacturer reluctance

OECD Seminar on Minor Uses and
Risk Reduction

Current Approach

- Producer groups involved
 - QFVG, CPA, JAY4 & PIBs
- Formalised request collection & vetting
 - Both online and written
- Consultation
 - Researchers, advisers & producers

OECD Seminar on Minor Uses and
Risk Reduction

Current Approach

- Risk management
 - Comparative in nature
- Criteria used:
 - Dietary exposure
 - OH&S
 - Environment
 - Efficacy
 - Trade
 - Regulatory status

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Risk Reduction

Current Approach

- APVMA liaison
 - Determine data requirements

- Further stakeholder consultation
 - Prioritisation
 - Data generation

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Risk Reduction

Future Needs

- Guidelines expanded
 - Simplified risk assessment methodologies

- Definition revised
 - Broaden scope, e.g., dietary consumption

- Pesticides categorised
 - Identify reduced-risk products

- Data protection

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Risk Reduction

Experiences and Perspective from within the Food Processing Industry
Alan Kale, Crop Technical Advisor, Heinz Wattie, New Zealand

Good Morning Ladies and Gentlemen. I am Alan Kale. My current role is that of Crop Research Manager at the Hastings site of Heinz Wattie.

The views I am presenting this morning are my views. **Not those of the company or the process sector.** But they are drawn from the twenty years of observations from within this industry.

As a little introduction, Heinz Wattie is one of the major food processors in Australasia, procuring approximately 200,000 tonnes of raw seasonal fruit and vegetables, across more than 30 crop types, grown by 7-800 growers, in various regions of New Zealand. All of these growers, including our Organic growers, rely on pesticides as an option to manage weeds, pests, and diseases in their crops.

So how do you **reduce the risk** associated with the use of these pesticides, and how does this relate to Minor uses?

There are three main factors involved.

- **Elimination of unnecessary use**
- **Substitution of less risky options**
- **Use of Non chemical control measures**

The process is the same whether it is a major or minor use crop. The issue for the Minor use crop is that there is less money available to pay the development costs associated. But I am sure you all knew that already.

It also depends on how serious you are about **reducing actual risk**, not just achieving an imposed political use reduction target.

From a New Zealand Horticultural Processing Perspective, **no sensible risk reduction policy** can be formulated without first establishing current use patterns for pesticides, and what actual risks arise from such use.

This cannot be done using gross national figures, because the information becomes so diluted as to be meaningless, and does nothing to identify actual risk. To be effective and sustainable (in both economic and environmental terms) **risk reduction should be approached in a systematic way**, collecting information at very local levels (broken down by use, environment/crop type/region. Each use pattern, within each crop type, needs to be understood. Only then, can appropriate practical options (action plans) be developed for each; that growers can find acceptable and utilise.

When growers perceive no threat from changes, then you get buy in from them, which leads to effective change for everyone in terms of risk reduction.

This is not an easy, quick fix option, but is necessary to obtain **real** risk reduction long term.

This is the approach Watties have been fostering with our growers. We first research and develop workable alternatives for them before requiring a change in their practices. This has for many years, included co-funding chemical registrations, basically because no one else would. This approach has led to

major reductions in pesticide usage for our crops. An example of this is the insecticide usage in our process tomatoes. The table below shows the changes that have taken place. The program of change started in the late 1980's. It has taken time to develop and implement, but (as indicated by the last 4 years figures) the current low usage is pretty stable.

A Comparison of Insecticide Usage on Tomatoes.

Average number of Active Ingredient Applications per Block

Insecticide	1980's	1999	2000	2001	2002
Total Num	12	0.52	0.42	0.38	0.21
OP	9	0.00	0.00	0.00	0.00
Bt	0	0.21	0.05	0.00	0.00
SP	1	0.20	0.05	0.02	0.06
Soft	0	0.27	0.35	0.30	0.16

This brings us back to the three factors mentioned earlier.

The majority of the change in the tomato example came from only applying chemicals when it is necessary to do so (eliminating unnecessary use).

This reduction was further enhanced by using introduced parasites (classic IPM non chemical control measures). The final stage has been to develop a floating threshold assessment technique to further minimize use.

The third part has been a change in pesticide type. This has involved getting pesticides registered which have a mode of action more specific to the pest and more benign to predators and the general environment.

But the ability to reduce levels to this extent may not be the case for other crops, and it may not always stay this way for tomatoes either.

Over recent years, New Zealand has suffered an increased number of new pest incursions, with no sign of this abating.

This situation is when the concept of using **pesticide reduction as a target goal in itself, breaks down**. It is not flexible enough to allow for future changes in use patterns, caused through uncontrollable factors such as new pest introductions, climate change, and seasonal weather variation. **The concept of Elimination of Unnecessary use, does, and therefore should be used.**

In New Zealand all crops would be considered minor use in the global context of chemical use. But some are more minor than others. It is these crops in particular where the **chemical registration process, has been impeding Risk Reduction progress**. The process has been very expensive, and slow, becoming bogged down under new legislation. We should continue to have a centralized system of independent approval, but need to develop a much more responsive and inexpensive system for product registration (covering both organic and conventional). The assessment should focus more on food safety and less on efficacy.

New Zealand also needs to develop a **rapid response process** for emergency use. Other countries have Special Use Permit approval procedures. New Zealand has nothing in place to handle a situation where a grower needs to control a pest urgently (to avoid total crop loss), but has no registered effective option to use.

In conclusion, to highlight some of the points I have made today, here is a quick summary.

- A lot of Risk Reduction is already taking place.
- Processors can be instrumental positive change agents, through their direct links to grower use.
- Elimination of Unnecessary Use should be the target goal, not simply reduction of chemical use.
- Facilitation of an inexpensive, responsive, chemical registration process is critical to successful risk reduction for minor crops.
- Need to put in place a rapid response (2-3 day) approval process for emergency use (SUP).

Minor Uses and Risk Reduction: an Industry Perspective
Gabriele Timme, Croplife

Minor Uses and Risk Reduction

An Industry Perspective

Gabriele Timme

OECD Minor Use Seminar, Canberra, Australia
04 November 2003

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Industry Position

As a Crop Protection Industry, we:

- **Acknowledge that the lack of tools to protect minor crops (or major crops where the problem occurs on a limited acreage) against pests, fungi and weeds is a problem impacting multiple stakeholders in the food supply chain**
- **Recognize that the lack of crop protection tools may lead to two equally unacceptable situations:**
 - **Illegal use of plant protection products not approved for the purpose**
 - **Loss of the agricultural production with downstream consequences from growers to consumers**
- **Acknowledge that we can **contribute** to finding solutions, however, **not** as the only stakeholder**

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Reasons for Aggravation of the Minor Use Issue (1)

- * **National/regional review programmes caused withdrawal of many existing compounds**
 - **EU / Review under 91/414**
 - 1993: 866 active substances authorized
 - 2003: ↻ 450 active substances still in the process
 - **USA / FQPA (as of September 30, 2002)**
 - Total products in reregistration: 8,617
 - Products reregistered: 1,637
 - Products cancelled: 3,806
- * **Consequence: Withdrawal of MRLs**
 - **USA / FQPA (1996 - 2002)**
 - Total MRLs reassessed: 6,499
 - MRL revocations: 1,930

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Reasons for Aggravation of the Minor Use Issue (2)

- * **Increased regulatory requirements #**
 - **140.000** compounds to be synthesized
 - **2** compounds for "development"
 - **1** compound reaches the market
- * **Increased political / economic pressure on pesticide industry**
 - **concentration / mergers of companies**
 - **focus on major markets**
 - **lack of return on investment**

The cost of new agrochemical product discovery, development and registration in 1995 and 2000 - A study by Phillips McDougall on behalf of ECPA and CLA (mean values for new CPP in USA and EU)

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Reasons for Aggravation of the Minor Use Issue (3)

* Increased time to launch in major markets

- 7 - 9 years from synthesis to submission
- 2 - 4 years until authorization granted
- **≥ 9.1 years**

* Increased costs

- Research 94 Million Dollars
- Development 79 Million Dollars
- Authorization 11 Million Dollars
- **Total costs 184 Million Dollars**
(1995-2000: increase of 21%)

The cost of new agrochemical product discovery, development and registration in 1995 and 2000 - A study by Phillips McDougall on behalf of ECPA and CLA (mean values for new CPP in USA and EU)

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Pesticide Industry Experiences (1)

* Major Issues

- Costs of efficacy and residue studies
(Minimum data package for line extension : \$ 150 K)
- Dietary risk concerns
(problems if risk assessment is not refined or specific ethnic groups are considered)
- Misuse of products on minor crops
(stewardship programmes necessary)
- Product liability
(legal situation requires involvement of applicant)

**Conclusion: case-by-case decisions at a company level
often driven by return on investment**

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Pesticide Industry Experiences (2)

- * **Minor crop / minor use /essential use programmes**
 - **US: IR4 Programme**
Good cooperation between Growers, Authorities, Academia and Pesticide Industry
 - **Germany: "AKLück"**
Good cooperation between "Technical Service", Authorities and Pesticide Industry
 - **NL/UK: off-label approvals**
 - **EU: Essential Uses**
Only for limited time period, until replacement authorized (max. end of 2007)

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Opportunities for Risk Reduction

- * **To prevent misuse, evaluate further options for extrapolations of residue data**
 - **expand crop grouping for efficacy and residue studies**
 - **use foreign residue data**
(especially in the light of the OECD zoning project!)
 - **accept residue data from studies with more critical GAP**
(beyond current practice of extrapolation rules, i.e. 25%)
- * **Generate consumption figures for minor crops**
(if not available yet)
- * **Refine the dietary risk assessment regarding "percent crop treated"**
(will reduce exposure level significantly)

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Proposals for Improved Cooperations

- * **Establish round-table discussions with all stakeholders to identify new opportunities**
- * **Consider ways of cost- or work-sharing, if pesticide industry has financial issues**
- * **Reduce requirements on efficacy and residues as far as possible for minor uses without compromising on safety**
- * **Establish fast approval procedures where appropriate**
- * **Don't grant authorizations for minor uses, if main data holder / applicant has a liability (efficacy, phytotoxicity) concern**
- * **Create other incentives (e.g. extension of data protection periods)**

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Jo Immig, National Toxics Network, Australia

'Minor Uses' and Pesticide Use Reduction

A Public Interest Perspective

Jo Immig

National Toxics Network Australia
for Pesticide Action Network International

National Toxics Network & Pesticide Action Network

- **National Toxics Network (NTN) Australia**

- **NTN** is a community based network with a common aim to reduce the chemical load on the environment and to promote environmentally responsible technologies and management systems.
- **NTN** aims to be a true network reflecting a diversity of approach with a solidarity of purpose.

- **Pesticide Action Network (PAN) International**

- **PAN** is a network of over 600 participating nongovernmental organisations, institutions and individuals in over 60 countries working to replace the use of hazardous pesticides with ecologically sound alternatives.
- **PAN** projects and campaigns are coordinated by five autonomous regional centres in Africa, Asia and the Pacific, Europe, Latin America and North America.

The public interest perspective

- The public interest perspective is essential to the 'minor use' debate as growing and distribution of food is fundamental to all of us.
- The focus of food production has dwelt for too long on chemical manufacturers, regulators and economists and has not taken seriously societal concerns about pesticide residues in food and degrading environments.
- The 'minor use' problem points to a deeper underlying issue regarding the way we farm and the damaged relationship the broader community has with the land.
- The community is becoming more aware and concerned about the negative impacts of industrialised farming, eg loss of biodiversity, pollution of waterways, soil degradation, and the collapse of farming communities around the globe.

'Minor Uses' & Pesticide *Use* Reduction

- 'Small and diverse' can't be catered for because it doesn't make economic sense for chemical manufacturers. Yet, diversity is the foundation of sustainability.
- It is essential the 'minor use' problem is coupled with pesticide *use* reduction to reduce the reliance and use of synthetic chemical inputs in farming.
- Increasing global trend towards sustainable food production with minimal or no synthetic inputs which produces nutritious and safe food while minimising impacts on the land and providing a sustainable income for farmers.
- More farmers are realising that chemical-intensive methods have left them with degraded lands, increasing resistance to pesticides and an ever diminishing tool kit to manage pests.

Problems with 'minor use' chemicals

- **No common definition for 'minor use'**
 - Lack of clarity creates the opportunity for the term to be misused to suit any purpose.
 - An accepted definition is necessary to be able to proceed with a coordinated regulatory approach.
- **Illegal chemical use**
 - Essential for farmers to have access to user-friendly, environmentally sound and economically viable solutions so they don't resort to unauthorised or inappropriate chemicals to protect their crops and animals.
 - As a minimum requirement we should be doing our best to ensure people are using 'legally approved' chemicals rather than doing things illegally.
- **Equity issues**
 - Equity issues are raised for those farmers who do the right thing and abide by the law.
 - 'Minor use' users already have a tough time getting access to products compared with the 'non minor users' which shouldn't be made even more difficult.

Off-label permits perpetuate the chemical paradigm

- **Off-label use permits perpetuate the chemical paradigm and don't comprehensively address the health or environmental impacts of pesticides or of sustainable farming livelihoods.**
- **Creates an uneven playing field and risks becoming a de-facto registration system, undermining the integrity of more rigorous regulatory processes for other chemical registrations.**
- **Farmers are locked into the pesticide treadmill.**
- **Administering and monitoring a complicated system of permits and temporary registrations is expensive.**
- **An *interim* system which makes 'minor use' more accountable and transparent, whilst still allowing the use of 'minor use' chemicals is required.**
- **Research and development can be partly achieved through increases in pesticide levies on industry.**

Protecting public health

- Legitimate questions have been raised about the health effects of the combination of pesticide residues we eat and drink on a daily basis over a long period of time.
- Extension of Maximum Residue Limits (MRLs) from one crop to another is problematic and not a valid process in many instances.
- For public health protection the exposure has to be calculated and checked against the Average Daily Intake (ADI) (chronic and acute).
- It is essential to also look at the combination of toxicity of certain groups of chemicals (organophosphates and carbamates or dithiocarbamates) and calculate a combination ADI.

Decision-making on 'minor uses'

- **Decision-making on 'minor uses'**
 - A panel of independent experts could do a first phase evaluation before applications get any further.
 - A streamlined registration process subject to an assessment of risks (such as toxicological, environmental, and health impacts). 'Minor use' could be delineated by an appropriately determined threshold, for example, volume used.
- **Transparency**
 - 'Minor use' chemicals should be intensively monitored in order to manage and evaluate the system.
- **Enforcement**
 - Enforcers have a big problem coming to grips with illegal use and introducing another layer of enforcement could be problematic, but is essential.
- **Partnerships**
 - 'Minor use' issues should not be left only to government, industry and growers, the whole food supply chain needs to be actively involved, including consumers and public interest groups.

MINOR USES' AND OPPORTUNITIES FOR PESTICIDE USE REDUCTION

A Public Interest Perspective

Jo Immig, National Toxics Network (NTN) Australia

on behalf of Pesticide Action Network (PAN) International

With special thanks to: Stephanie Williamson, PAN-UK, Hans Muilerman, PAN-Europe, Jane Worner, PAN-UK

National Toxics Network (NTN) is an Australian based community network with a common aim to reduce the chemical load on the environment and to promote environmentally responsible technologies and management systems.

NTN is a true network reflecting a diversity of approach with solidarity of purpose. NTN has interests in all aspects of toxic chemical pollution including regulation and assessment. NTN is the umbrella organisation for over 300 groups and campaigners across Australia as well as representatives from New Zealand and the South Pacific. NTN has been campaigning locally and globally for over ten years.

Recent pesticide related work:

- NTN was recently the ECO/NGO delegate to the OECD 35th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology held in Paris in June 2003;
- NTN has a representative on the Australian Pesticides and Veterinary Medicines Authority (APVMA) Community Consultative Committee;
- NTN is coordinating and developing a CD handbook and web site for the International POPs Elimination Network (IPEN) Community Monitoring Working Group to collect and disseminate information on community monitoring techniques, case studies as well as body burden sampling. The initiative is designed to support the implementation of the Stockholm Convention and the identification and selection of new persistent organic pollutants (POPs).

Pesticide Action Network (PAN) International is a network of over 600 participating nongovernmental organisations, institutions and individuals in over 60 countries working to replace the use of hazardous pesticides with ecologically sound alternatives. Its projects and campaigns are coordinated by five autonomous regional centres in Africa, Asia and the Pacific, Europe, Latin America and North America.

PAN-Europe is campaigning at the EU and Member State levels to ensure that the EU keeps to its commitment to achieve a significant reduction in pesticide use. Through its *Pesticide Use Reduction in Europe (PURE)* campaign PAN is working to ensure that the 6th Environmental Action Program (EAP) maintains the commitment to reduce pesticides. PAN is also working to set in place legislation to achieve pesticide use reduction throughout the European Union.

I am currently the representative for peak environment groups on the New South Wales Environment Protection Authority's (EPA) Pesticides Implementation Committee, which is developing new regulations and policies for pesticide risk reduction in NSW, setting a bench mark for control-of-use legislation across Australia. I also served as a member on the Australian Pesticides and Veterinary Medicines Authority's (APVMA), first Community Consultative Committee. I have authored two books with a focus on children and pesticide/chemical risks – *Toxic Playground: a guide to reducing the chemical load* and *Safer Solutions: Integrated Pest Management for Schools and Child Care Centres*.

Public interest perspective

I am here today to represent the public interest perspective as a representative of NTN and PAN. The public interest perspective is essential to the 'minor use' debate as the growing and distribution of food is fundamental to all of us. In pure economic terms, the consumer drives the demand for produce and increasingly, *how* it is produced.

Perhaps the focus of food production has dwelt for too long on chemical manufacturers, regulators and economists and has not taken seriously societal concerns about pesticide residues in food and the degrading environment. As a result I believe we have lost something along the way about working with nature and working together as a community.

The 'minor use' problem perhaps points to a deeper underlying issue regarding the way we farm and the damaged relationship the broader community has with the land. I sense the community is becoming far more aware and concerned about the negative impacts of industrialised farming, for example the loss of biodiversity, pollution of waterways, soil degradation, and the collapse of farming communities around the globe.

The 'minor use' problem has brought us full circle. 'Small and diverse' can't be catered for because it doesn't make economic sense for chemical manufacturers. Yet, diversity is the foundation of sustainability and needs to be nurtured, not homogenised.

There seems to be no lack of consensus that there is a significant global problem with 'minor use' chemicals and the subsequent problems it raises for farmers and regulators. What is not given significant consideration however, is the real concerns the community has about the safety of food and the health impacts of pesticide residues and the impacts on the environment.

It is essential the 'minor use' problem is coupled with pesticide risk reduction, in fact, what I think we should discuss is pesticide *use* reduction. Tinkering around the edges with risk reduction isn't getting to the crux of the matter, which from my perspective is to reduce the reliance and use of synthetic chemical inputs in farming. It will be in the innovation and proliferation of ideas to address use problem that the long-term sustainable solutions to 'minor use' will be found. Like the NTN mission statement, we need a diversity of approach with solidarity of purpose.

From where I sit there seems to be an increasing global trend towards sustainable food production with minimal or no synthetic inputs which produces nutritious and safe food while minimising impacts on the land and providing a sustainable income for farmers. For instance, there is strong opposition from both farmers and the broader community to the introduction of genetically engineered crops and food. The more they find out about it, the more concerned they become. Aside from real questions about the unknown health, environmental and economic risks of gene technology, I think people just don't sit comfortably with yet another technology which aims to 'control' nature rather than work within its complexities.

I believe more farmers are realising that chemical-intensive methods have left them with degraded lands, increasing resistance to pesticides and an ever diminishing tool kit to manage pests. They are searching for new ways to farm, to be profitable and sustainable without costing the earth and at the same time the public is demanding clean green food.

No common definition for 'minor use'

There are many definitions for 'minor use' chemicals but no widely accepted one, making it difficult to determine what is meant by 'minor use'. It seems to be a misleading term that creates a blurred distinction

between so-called minor and major uses of chemicals. Perhaps it also infers that minor uses are of less risk. Other terms have also entered the dialogue such as 'off label use' which serves to confuse the issue further.

Lack of clarity in this area creates the opportunity for the term 'minor use' to be misused to suit any purpose. Leaving this question of definition open creates a major loophole and is potentially an easy way of authorising pesticides without doing the required tests and field trials.

In Australia, 'minor use' is defined in the *Agricultural and Veterinary Code Regulations (1995)* which states that "...minor use in relation to a chemical product or an active constituent, means a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)". There are guidelines which endeavour to place some boundaries around the rubbery bit - 'sufficient economic return'.

An accepted definition is necessary to be able to proceed with a coordinated regulatory approach to 'minor use' and to minimise misuse of the term by creating a common understanding of what is meant by it.

Illegal chemical use

I think we are all agreed it is essential for farmers to have access to user-friendly, environmentally sound and economically viable minor use solutions so they don't resort to unauthorised or inappropriate chemicals to protect their crops and animals.

Obtaining permission to use minor use chemicals is often a difficult and cumbersome task which takes time, forcing farmers to illegally use pesticides while they wait or until they get caught out. Illegal use is considered to be wide-spread and is not well documented or inspected. Fines, if imposed at all, are often limited and out of kilter with the potential or actual harm caused by the misuse of pesticides.

We should be trying our hardest to make sure that 'minor use' chemicals are not being used illegally. If farmers are going to use the chemical then it is best that there is a system that monitors this chemical use and that it is 'within the system'. As a minimum requirement we should be doing our best to ensure people are using 'legally approved' chemicals rather than doing things illegally.

This is of course a juggling act for regulators who must not endorse chemicals for which there is not enough data to be sure of their impacts, yet ensure there are options for farmers. There are possibilities here for greater cooperation with recommendations from other countries following a Prior Informed Consent (PIC) like approach, while recognising that environments and sensitivities differ from country to country. This approach, however, would need to be underpinned by the precautionary principle.

Equity issues

Equity issues are raised for those farmers who do the right thing and abide by the law. 'Minor use' users already have a tough time getting access to products compared with the 'non minor users' which shouldn't be made even more difficult. Minor use chemicals also get a double whammy in that because they represents small quantities of chemical it is often not feasible to undertake the data collection required for registration, and since it affects a small number of users the application may not be taken as seriously by regulators or acted upon as quickly as other applications.

Off-label permits perpetuate the chemical paradigm

Providing provisional approvals and off-label use permits perpetuates the chemical paradigm and does not comprehensively address the health or environmental impacts of pesticides or of sustainable farming livelihoods. It could lead to an uneven playing field and risks becoming a de-facto registration system, undermining the integrity of more rigorous regulatory processes for other chemical registrations.

Farmers are locked into the pesticide treadmill while they are waiting to gain or lose provisional approval which does not provide an environment conducive to innovation, independence or a move towards long term sustainability.

Administering and monitoring a complicated system of permits and temporary registrations is also expensive. It may prove more cost effective and sustainable if there is a regulatory directive to reduce pesticide use for integrated pest management to focus efforts on developing safer and more readily available non-chemical options.

In the meantime, we need an *interim* system which makes 'minor use' more accountable and transparent, whilst still allowing the use of 'minor use' chemicals. Often these chemicals are being requested by farmers who are trying niche and new products. At the same time we need to be exploring other commercial non-chemical options and fostering the linkages and partnerships which promote extension services and information sharing to assist farmers to move towards sustainable farming systems.

Research and development can be partly achieved through increases in pesticide levies on industry. This model applies in other industries where there is a recognised pollution problem and a change of technology and approach is required. For instance, the energy sector or the waste sector.

Priority must be given to preventative and integrated methods of pest management to minimise reliance on chemicals as the first line of defence. Granting of minor use permits could be coupled with conditions for integrated pest management (IPM) plans. The IPM plans would be developed and presented with the request and the request only granted if the IPM program is practiced by minor-use-farmers.

We need to investigate the incentives and disincentives that would encourage farmers to embrace non-chemical methods such as better costing of chemicals to reflect their real impact on the community and environment. As I mentioned earlier, consumers are also driving the demand for chemical-free food, so why not promote methods that enable farmers to provide it?

Protecting public health

While genetically engineered foods are currently in the limelight in terms of concerns the public has about food safety, there is still considerable concern about the effects of ingesting pesticide residues with our food, especially with respect to children's health. Legitimate questions have been raised about the health effects of the combination of pesticide residues we are exposed to, and then eating/drinking this chemical cocktail on a daily basis over a long period of time. It is particularly disturbing to note that human breast milk, for instance, has such a high level of pesticides that it would not be permitted to be sold packaged on supermarket shelves.

Extension of Maximum Residue Limits (MRLs) from one crop to another is problematic and not a valid process in many instances. There must be scientific evidence that MRLs in one plant family are relevant to another. An extra uncertainty factor is added in any MRL extension from one crop to another.

For public health protection the exposure has to be calculated and checked against the Average Daily Intake (ADI) (chronic and acute). It is essential to also look at the combination of toxicity of certain groups of chemicals (organophosphates and carbamates or dithiocarbamates) and calculate a combination ADI.

Decision-making on minor uses

Suggestions have been made in the EU that in order to prevent getting all kinds of unjustified and poorly argued 'minor use' proposals on a long list, a panel of independent experts could do a first phase evaluation before they get any further. This would also help other stakeholders better understand what is going on by creating a more acceptable and transparent approach.

Others have suggested a streamlined registration process which would be subject to an assessment of risks (such as toxicological, environmental, and health impacts). Minor use could be delineated by an appropriately determined threshold, for example, volume used.

Transparency

'Minor use' chemicals should be intensively monitored in order to manage and evaluate the system. A fully closed administrative system from producer to trader to co-operatives and farmers with special labels is required. A centralised database of individual pesticides, amounts, crops, and names of all traders and users should be developed and be available to the public.

Enforcement

Enforcement of laws around pesticide use is already a big problem and illegal use around the globe is rife. Law enforcers have a big problem coming to grips with illegal use and introducing another layer of enforcement could be problematic, but is essential. A centralised database could be helpful for administration and special labelling on 'minor use' chemicals stating the conditions under which the use is acceptable should also be considered.

An important consideration in conjunction with labelling is the problem of reading and the readability of labels as many 'minor use' chemical users may have literacy or language issues where they are simply unable to read the labels.

We are currently grappling with this issue on the NSW EPA Pesticides Implementation Committee where vegetable growers in the Sydney Basin have serious problems with access to 'minor use' chemicals for the wide range of vegetables they grow for the multi cultural population of Sydney. Not only is it difficult for the growers to make applications for minor use permits, but they have the added issues now of requirements for record keeping and mandatory training under new regulations which they must comply with to continue to have access to chemicals.

We all want growers to be viable, yet we don't want pesticides to be misused and to end up with produce on the market with high levels of pesticides. I believe efforts should be focused in helping the farmers, particularly the horticultural sector, adopt integrated methods and safer options to address the 'minor use' issue.

Partnerships

'Minor use' issues should not be left only to government, industry and growers, the whole food supply chain needs to be actively involved, including consumers and public interest groups. This is the perfect opportunity to re-connect the community with the production and distribution of food. One only needs to

look to the emerging number of 'farmers markets' around the globe to see that people want to be re-connected with their food supply and to help the farmer stay viable.

Food retailers also have a significant role to play, driven as they are by consumer demand for clean green produce. Indeed some food retailers are already developing their own standards for organic produce and entering into contracts with farmers to supply certified organic foods.

In considering the issues around 'minor use' we must also ensure we are mindful and assist newly emerging regulatory regimes for chemicals. If regulation of 'minor use' chemicals is problematic in countries with a longer history of regulation, imagine the difficulties of regulation/ approval/ enforcement in other countries? 'Minor use' policies in the OECD countries could assist other countries in coming to terms with 'minor use', despite the fact that they deal with very different issues of risk such as the general lack of appropriate application equipment. Jane Worner from PAN-UK recently came back from Ethiopia where the regulatory agency reported they get many applications for 'minor use' but simply don't have the capacity or resources to undertake the data collection exercise.

Conclusion

In summary, 'minor use' chemicals are a major problem which needs addressing before it gets further out of hand. The proliferation of 'minor use' permits bypassing the registration system simply because of the high cost of registration is not acceptable and poses significant unknown and unquantifiable risks in particular to the public. Simply stated chemicals should not be used for the purpose for which they were not intended or approved. We must get to grips with this problem by moving quickly to reduce the use of these chemicals and to replace their use with a safe system of integrated pest management. Clearly it would not be practicable to end the 'minor use' permit system overnight but as a first step we need greater regulatory control and a condition that those farmers applying to use chemicals unapproved for the purpose should be obliged to demonstrate that they are using or introducing integrated pest management before being given approval. Ultimately this unsatisfactory system of using chemicals not registered for the purpose should be ended altogether and replaced with a known and safe system of pest control.