

# The Australian Agricultural and Veterinary Chemicals Management System



A Report to Government  
by the APVMA on recent  
reviews of the system –  
June 2003



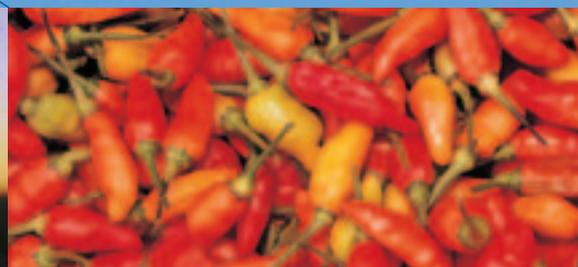
**Australian Pesticides &  
Veterinary Medicines Authority**

This Report was prepared by the APVMA as a formal contribution to the policy development process. It has been submitted to the Product Safety and Integrity Committee (PSIC) who will be providing a response to government on the Radcliffe and Allen Reports, through the Primary Industries Standing Committee (PISC) / Primary Industries Ministerial Council (PIMC).

## Contents

<b>Executive Summary</b>	<b>1</b>
<b>Summary of Proposals for Government Consideration</b>	<b>3</b>
<b>1. Introduction</b>	<b>4</b>
<b>2. Background</b>	<b>5</b>
2.1 National Strategy for Agricultural and Veterinary Chemicals	5
2.2 The AATSE Report	5
2.3 The Allen Report	6
2.4 ABARE Outlook Conference Workshop	6
2.5 National Chemicals Taskforce Report to the EPHC	7
<b>3. Issues</b>	<b>8</b>
3.1 Regulatory and Assessment Operations	8
3.2 Control of Use	8
3.3 Availability of Chemicals	9
3.4 User Accreditation and Training	11
3.5 Feedback and Monitoring	12
3.6 Public and International Confidence	13
3.7 Agvet Systems Structure – Links and Interfaces	14
<b>4. Conclusions</b>	<b>16</b>
<b>Glossary of Terms</b>	<b>17</b>

*Note: On 5 March 2003, the former National Registration Authority for Agricultural and Veterinary Chemicals (NRA) changed its name to the Australian Pesticides and Veterinary Medicines Authority (APVMA). For simplicity, the name APVMA is used exclusively in this report, including references to the organisation that predate 5 March 2003.*



# Executive Summary

The current registration and compliance system for agricultural and veterinary chemicals in Australia has been operating since 1992. It is generally agreed that since that time it has operated in a very effective manner and that the goals of public health and environmental protection are being met, while still allowing agvet chemical users access to vital production aids. However, the system must evolve if it is to meet future needs and challenges.

A number of recent reviews of the agvet chemicals management system have been conducted. A national strategy by the Agriculture and Resource Management Council of Australia and New Zealand, reports by the Australian Academy of Technological Sciences and Engineering, the Allen Consulting Group and the Environment Protection and Heritage Council National Chemicals Taskforce have all considered the management of agvet chemicals in depth and drawn some similar conclusions. To consolidate this breadth of information and enable stakeholders an opportunity to raise additional issues, the Australian Pesticides and Veterinary Medicines Authority (APVMA) conducted a workshop in conjunction with the ABARE Outlook Conference 2003.

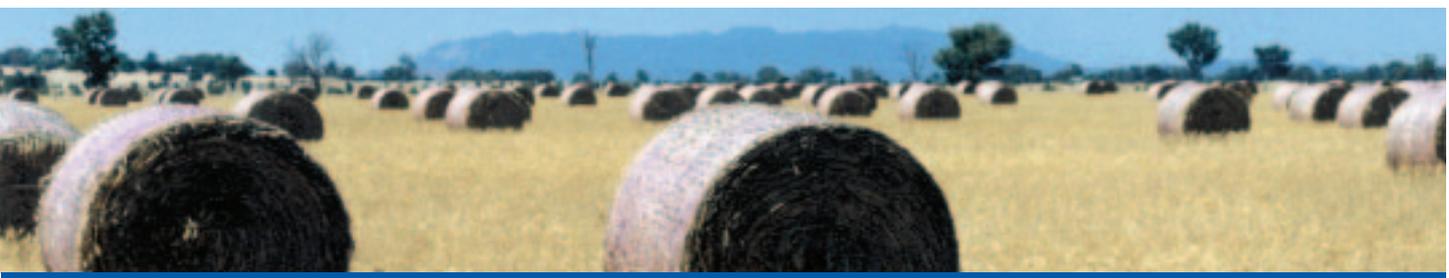
This report draws together the key issues identified from the reports and the workshop, and aims to provide a consolidated basis from which there can be informed consideration of the issues by government, stakeholders and the community. The agvet chemicals management system faces a range of future challenges. Seven principles have been identified that are considered essential to the design of an effective Australian agvet chemicals risk management system to meet these challenges. They are:

1. A seamless system.
2. Strong feedback loops.
3. Flexibility to respond to emerging issues.
4. Provision for continuous improvement.
5. Confidence in the regulatory and management process.
6. Effectiveness and efficiency.
7. International confidence.

There is general agreement that the current assessment and approval system is effective, and its strengths should be retained. However, the following structural shortcomings have been identified as coming between the current and future ideal system:

- Varying approaches to control of use between States / Portfolios.
- Lack of overall policy integration, formal links and interfaces.
- Fragmented and limited monitoring of outcomes.

Proposals for addressing these shortcomings are discussed in the following report.



In the broad area of control of use, there is widespread agreement about the need to achieve harmonised usage outcomes between different States / Territories as a priority, and to present a national coherent and integrated system to overseas markets/regulators.

It is also regarded as important that, in future, chemical assessment registration processes should become even more efficient and effective. Failure to do so will inhibit development of new chemicals, support of older chemicals and in particular, registration of minor use chemicals. Australia is seen to be particularly disadvantaged as its chemical use amounts to only 2% of the total world market, placing it low in the priorities of a globalised industry. Data Protection would also encourage the faster introduction of new innovations in agvet chemicals to Australia.

The necessity for strong feedback loops has been identified. This will enable the system to respond quickly to results of the application of registration decisions and to new and emerging issues, and also to provide greater transparency. As a consequence, monitoring the outcomes from use of agvet chemicals was rated as a very high priority. There is currently insufficient monitoring to provide confidence in and feedback for the system.

In this respect, the APVMA is implementing an adverse experience reporting program for agricultural chemicals (to complement the current program for veterinary products), which will significantly improve health monitoring, and PSIC has begun a project to review and improve outcomes measurement. There is unanimous

agreement on the priority need for improvement and maintenance of domestic and international confidence in the regulatory system. This requires credibility and confidence built by visible measures of system performance and achievement of objectives, supported by transparency of decision-making and consultation.

It is important for efficient management of agvet chemicals that Australia has a seamless system. This requires a structure that ensures effective integration and a uniform approach between the elements of registration, control of use and communication. Four alternative approaches to achieving a seamless agvet chemicals management system have been proposed, based on either horizontal or vertical integration. There is no clear stakeholder agreement that we need to change to one of these models.

There appear to be advantages in (and strong support for) retaining the current framework while applying an agreed system of National Operating Principles and following through with the other suggestions and recommendations arising from the various reports. However, when considering the way forward, system adaptations and developments to meet this should be guided by debated and agreed design objectives and principles, based in turn on agreement about desired outcomes and measures of these.

Based on discussion from the above-mentioned reports and from the Outlook Workshop, a number of proposals are presented for consideration by government and other stakeholders in assessing reform requirements in the Australian system for agvet chemicals management. There is generally broad support for the proposals. A summary of these proposals is shown on the following page.



# Summary of Proposals for Government Consideration

The following summary of proposals, arising from the cited reports and the Outlook Workshop, are presented for consideration by government and other stakeholders in assessing reform requirements in the Australian system for agvet chemicals management.

## ***There is broad support for the following Proposals:***

1. Develop and implement National Operating Principles and Agreed Performance Outcomes for control of use of agvet chemicals and improved feedback mechanisms. These principles may include adoption of best management practices (3.2.2).  
Consider whether further structural changes would provide a net benefit (3.7.3).
2. Explore the possibilities for use of harmonised assessment methodologies through links with industry, industrial chemical registration agencies and international organisations (3.3.3).
3. Increase training and supervision for agvet industry operators as a strategy to maintain access to higher risk chemicals. Particular focus should be placed on determining and implementing the drivers for behavioural change. Consideration should also be given to training for non-English speakers (3.4.1).
4. Revise chemical labels and develop policies to encourage increased use of clear directions and plain English text (3.4.2).
5. Develop and implement an improved feedback mechanism for the agvet chemical system to help guide decision-making and monitoring priorities (3.5.1).
6. Establish a national comprehensive and harmonised residue monitoring program for food and the environment and provide for wider dissemination of results (3.5.2).
7. Establish a comprehensive and integrated pesticide use reporting system, database and adverse effect registers, focusing especially on human health and the environment, building on the work currently carried out by the National Residues Survey, FSANZ, State / Territory governments and the APVMA. The program should include arrangements for data sharing and access and coordination of the timing and type-selection of samples (3.5.3).
8. Improve transparency and credibility in decision-making, including wider dissemination of information about registration applications and decisions and other information on chemicals, and consider other measures to improve public confidence (3.6.1).

9. Encourage the development of risk reduction strategies in all aspects of agvet chemical management including the use of QA, HACCP, and stewardship programs in the agvet chemical industry to meet required outcomes (3.6.2).
10. Improve the current structural arrangements for agvet chemical registration and control, including formalised and improved linkages with relevant agencies and stakeholders (3.7.1).
11. Consider whether there should be more formal and more visible provision for input from the Health, OH&S, and Environment portfolios on strategic decisions about the forward planning of agvet chemicals management (3.7.2).

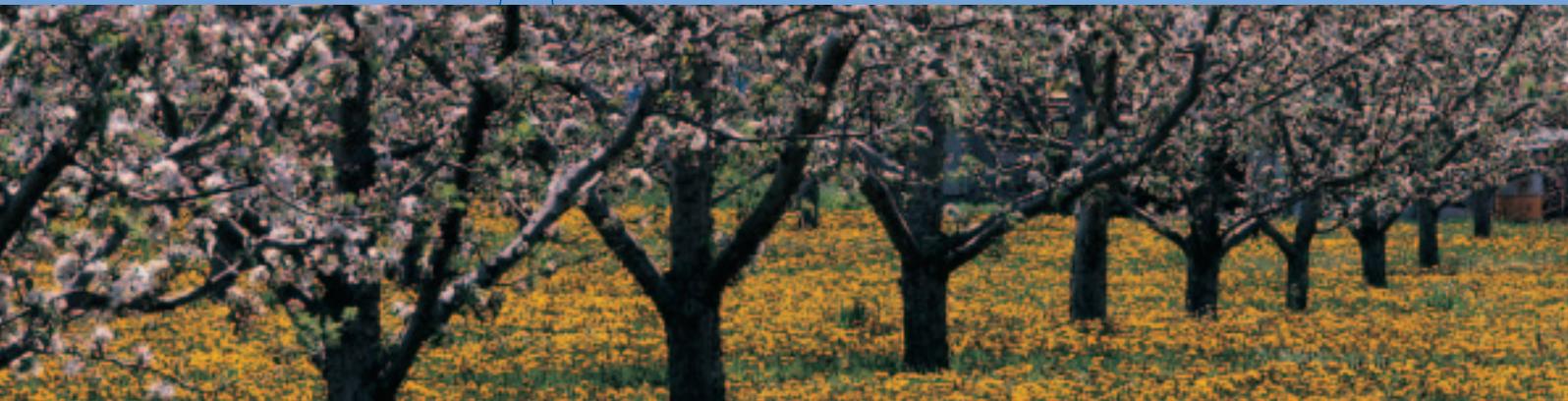
## ***The following Proposals, or how they may be achieved, do not have full consensus:***

12. Reduce the complexities of the National Registration Scheme to provide the APVMA with the capability to amend legislation more quickly, in response to emerging issues (3.1.1).
13. Ensure State/Territory legislation regarding use of pesticides achieves harmonised outcomes within the limits imposed by environmental and climatic differences (3.2.1).
14. Consider the adoption of more efficient and effective chemical assessment processes to reduce the costs of regulatory compliance (3.3.1).
15. Consider arrangements to facilitate more rapid approval of minor use and 'reduced-risk' agvet chemicals (3.3.2).
16. Facilitate implementation of improved data protection arrangements to encourage faster introduction of new innovations in agvet chemicals to Australia (3.3.4).
17. Develop and test contingency plans to protect health, environment and trade in the event of an agvet residue emergency (3.6.3).

# 1. Introduction

The current consolidated national approach to agricultural and veterinary chemical registration (National Registration Scheme) was implemented following a 1990 Senate review of agvet chemicals. Since the Australian Pesticides and Veterinary Medicines Authority (APVMA) was created ten years ago as a result of this review, many changes have occurred. In the face of future challenges it is now time to consider what needs to be done to ensure that Australia has the best system to meet future needs.

The purpose of this report is to consolidate and discuss a substantial body of recent work regarding the future of the agvet chemicals management in Australia. The report identifies key themes and issues from this recent work, highlights areas of consensus and points of difference, and suggests issues for consideration by government and other stakeholders.



## 2. Background

There have been a number of recent reports (discussed below) that are relevant to agvet chemicals management in Australia. These have been, or are being considered by government and other stakeholders. For example, the reports by AATSE and The Allen Consulting Group are currently being considered by the Product Safety & Integrity Committee (PSIC) / Primary Industries Standing Committee (PISC). PISC will prepare a response to government through the Primary Industries Ministerial Council (PIMC).

### 2.1 National Strategy for Agricultural and Veterinary Chemicals

In 1998 the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ) endorsed a National Strategy for Agricultural and Veterinary Chemicals, seeking to maximise the contribution of agvet chemicals to national prosperity while minimising undesirable impacts on human health, the environment and trade.

The *Goal* of the strategy was “*Best practice management of agricultural and veterinary chemicals to achieve ecologically sustainable and socially acceptable food and fibre production in Australia*”. The following *Objectives* would enable this goal to be achieved:

- Integrated farm, forest and natural resource management.
- Reducing reliance on chemicals.
- More effective assessment, approval and availability of chemicals.
- Risk reduction in the use of chemicals.
- Minimise risks to human health.
- Minimise risks to the environment.
- Residues in food and fibre meet needs of customers and importing countries.
- Enhance market access for primary products.
- Safe disposal of unwanted chemicals and containers.

The National Strategy has since been transformed into a risk management framework underpinning the PSIC's priority policy areas of work.

### 2.2 The AATSE Report

A decade on from the 1990 Senate review of agvet chemicals, the Australian Academy of Technological Sciences and Engineering (AATSE) considered that a new review was warranted in view of trends in use, pesticide impacts on health and environment, regulatory effectiveness and the looming impact of genetically modified material.

Their report, '*Pesticide Use In Australia*' was handed down in 2002 following input from individuals within universities, CSIRO, State and Commonwealth departments, environmental interests and private enterprise.

The report, which considered only the rural use of pesticides, concluded (among other things) that agrochemicals are essential to food production and have undoubtedly helped producers to remain competitive in international markets, there is little feedback on quantities of pesticides used or on adverse effects, and State and Territory regulations need closer harmonisation.

The report recommended that:

- Australia should establish a comprehensive and integrated pesticide use reporting system.
- Best Management Practices should be more widely adopted by pesticide users.
- State-based regulations regarding use of pesticides should be better harmonised.
- Adverse effects registers should be established for pesticide impacts on both human health and the environment.
- More needs to be known about the effects of pesticides on Australian native species and ecosystems.
- Information about pesticide use, pesticide properties, and data from residue surveys should be more readily accessible.
- Producers and consumers need to be more aware of the role of the APVMA.

## 2.3 The Allen Report

In 2002 The Allen Consulting Group was commissioned by the Board of the APVMA to report on changes that may be required to the Australian agvet chemicals management system to meet expected challenges over the next 10 to 15 years. In preparing this report, there was extensive consultation with stakeholders in Australia, and with overseas organisations.

The Allen report “*A National Risk Management System for Agvet Chemicals – Positioning for the Future*” (September 2002), identified a number of substantial future challenges. These included changing community standards in response to rising awareness of risks and regulatory failures, technological and scientific advances such as GM technologies, the trend to greater international harmonisation of regulation, increased development costs for new chemicals and the loss of access to chemicals for the small (in global terms) Australian market.

The report identified seven principles considered essential to the design of an effective Australian agvet chemicals risk management system, as follows:

1. A seamless system.
2. Strong feedback loops.
3. Flexibility to respond to emerging issues.
4. Provision for continuous improvement.
5. Confidence in the regulatory and management process.
6. Effectiveness and efficiency.
7. International confidence.

Four reform options for structural integration were proposed. Two of the options propose horizontal integration, either through a new, more encompassing agency or a single Commonwealth Department. The other two options propose vertical integration, under a new agency (Allen’s preferred option), or alternatively by incorporating a set of National Operating Principles to the current framework.

## 2.4 ABARE Outlook Conference Workshop

With the three reports at hand and some apparent consensus on the issues related to agvet chemicals management, a workshop was held as part of the ABARE Outlook Conference (5 March 2003). The Workshop was also the official public launch of the Allen report.

There were presentations from the APVMA, stakeholder and community representatives to discuss strategic issues of relevance to their stakeholder groups. There was opportunity for discussion by workshop participants, and to identify missing components, areas of agreement, points of difference, matters for development and a way forward.

Dr Alison Turner [CEO APVMA] outlined the issues facing agvet chemicals management, and discussed the strengths and shortcomings of the current system drawing on the findings of the Allen report. She provided a system view of national risk management and identified three key components:

- Risk Assessment and Marketing Authorisation (Registration), which is managed by the APVMA with formal links to other Commonwealth and State agencies.
- Control of use, which is exercised by individual State / Territory governments within varying portfolios (i.e. Agriculture, Health, Environment), so there are inevitably different expectations and emphasis about prime outcomes and control of use.
- Monitoring of outcomes, which is highly fragmented. Examples include the National Residue Survey, the FSANZ Australian Total Diet Survey, and some State and industry-based residue monitoring programs. There is little overall coordination of the monitoring results, and there is little formal monitoring of health, environmental and agricultural outcomes.

Dr Turner concluded that while the current modular system works quite well, a number of areas have been identified where improvements are desirable. However, when considering the way forward, system adaptations and developments to meet this should be guided by debated and agreed design objectives and principles, based in turn on agreement about desired outcomes and measures of these.



Lisa Corbyn [Director General of the NSW Environment Protection Authority and Chair, Environment Protection Council's National Taskforce, Chemical Management] presented a State and an environmental stakeholders perspective. She spoke of the need for a streamlined, cost effective system with an improved database, outcome monitoring and strong feedback loops. For safety and effectiveness, both occupational and domestic end users must have a proper understanding and education for the chemicals they are using.

Dr John Keniry [Chairman Ridley Corporation and a primary producer] presented an industry and a chemical user perspective. He noted that, to ensure food safety and quality in coming years, the business model for food production and marketing would be heavily based around supplier/purchaser certification of the system. The regulatory system for agvet chemicals must be consistent with this model. National systems for registration, control of use, training and accreditation are required to underpin credibility and ensure consistency in a globalised world. A collaborative approach between government, industry and users will ensure that Australia has access to the modern chemicals required to underpin competitiveness in world markets.

Dr Heather Yeatman [Associate Professor, Graduate School of Public Health, University of Wollongong] presented a consumer and public health perspective. She stressed the need for the agvet system to be built on honesty and openness, with public interest and public health as first priority. Dr Yeatman pointed out that consumers do accept risks every day, however their basis for judging risks incorporates a wide range of issues. Evidence on which to base their decisions about risks needs to reflect such broad concerns to be credible. Given time and information the community do incorporate new technologies into the framework of their 'social rules'.

Consumers also like to know that public interest is paramount over trade. The use of trade imperatives to justify use of chemicals is seen to be in the commercial

interests of international conglomerates. Social benefits of employment and income generation in a community are rarely presented.

### **Workshop participant input**

Workshop participants raised a number of issues, primarily related to communication, credibility and confidence in the system:

- The consultative interface between APVMA and small companies should be improved to encourage innovation and facilitate marketing of 'soft' chemical products. Improved data protection arrangements also need to be legislated.
- Users and consumers require an identifiable contact point within the system.
- There is concern that many agvet chemicals and products are still not monitored and that there is a gap between chemical registration and proper use.
- Funding arrangements for monitoring should be identified along the lines of the existing shared State / Commonwealth arrangements for the National Pollution Inventory.
- In anticipation of any future breakdown of the food safety system, Australia should develop and test contingency plans for emergencies.

## **2.5 National Chemicals Taskforce Report to the EPHC**

The Environment Protection and Heritage Council (EPHC) National Chemicals Task Force has recently submitted a report 'Toward Ecologically Sustainable Management of Chemicals in Australia' that addresses the issues associated with ecologically sustainable chemical management.

The Taskforce report found that good linkages are required in the necessarily complex Australian institutional and legislative agvet framework. The Taskforce has identified enhanced monitoring and investigation as key areas for action to improve our understanding of environmental impacts.

The Taskforce considered 'best practice chemicals management' and identified the same major issues listed in this report, namely, communication, understanding and assessing chemical risks, consistency of implementation, monitoring impacts and public availability of information. In particular the Taskforce concluded that 'there is a gap in the lack of a comprehensive environmental risk management framework for chemicals'.



## 3. Issues

It was clear from the workshop that there is broad agreement on the seven principles considered essential for an effective system, proposed in the Allen report (see section 2.3). These were seen as applicable to the entire agvet chemical management system.

Based on the 7 principles, the major issues raised in the reports and workshop are consolidated here for discussion and focussed consideration.

### 3.1 Regulatory and Assessment Operations

Australia currently enjoys a robust system for managing assessment and approval of agricultural and veterinary chemicals. Managed by an independent statutory authority, the APVMA, the system has a number of strengths:

- Independent decision making, supported by strong legislative criteria that ensure that public health and environmental safety are paramount considerations.
- A track record of strong performance, which demonstrates 'worlds best' outcomes in terms of food safety and efficiency of process.
- Science based risk assessment and marketing authorisation (Registration).
- Strong linkages both directly, and through the Primary Industries Ministerial Council, to the Control of use function exercised by the States.

Commonwealth Health, Environment and OH&S portfolios are involved in the approval process through formal links and contracts under which they provide specialist advice to the APVMA. Although the final decision on any marketing authorisation rests legislatively with the APVMA, any of these advisory bodies can prevent registration if it is based on sound advice. State agriculture departments, and specialist bodies such as the Expert Advisory Group on Antibiotic Resistance (EAGAR) also provide risk assessment advice to the APVMA.

Legislation governing the APVMA's activities is relatively new, rigid about what the APVMA can or cannot do, but provides some flexibility on decision-making. It is well linked with complementary legislation in each State and Territory.

There is general agreement that the assessment and approval system is effective and these strengths should be retained. The AATSE report found that 'assessment of pesticides by the APVMA appears to be a vigorous process that uses internationally accepted principles of

risk assessment' and 'assessments —are indicative of a careful scientific approach. It is important that this leading-edge proficiency be maintained'.

The structural shortcomings identified as coming between the current and ideal systems are:

- Varying approaches to control of use between States / Portfolios increase the difficulty of providing a national risk management strategy for each product registered.
- Lack of overall policy integration in the overarching policy framework.
- Need for improved formal links and interfaces to improve communications flows.
- Fragmented and limited monitoring of outcomes, with lack of quality feedback to the APVMA.

In addition, the Allen report noted that the complexities of the National Registration Scheme which established the APVMA as a Commonwealth / State endeavour has in some respects meant that the ability of the APVMA to amend legislation to respond quickly and flexibly to emerging issues has been constrained.

#### PROPOSAL 3.1.1

**Reduce the complexities of the National Registration Scheme to provide the APVMA with the capability to amend legislation more quickly, in response to emerging issues.**

### 3.2 Control of Use

Stakeholders and reviewers are concerned at a perceived lack of consistency in implementing national assessment and registration decisions. Inconsistent implementation prevents a good understanding of how and where chemicals are used, rendering it difficult to determine if risk assessment strategies are effective, and leaving Australia open to trade difficulties through inconsistencies in production of export commodities.

The EPHC Taskforce report notes that both the APVMA and NICNAS base their assessment (and registration) on certain usage assumptions but controlling jurisdictions do not consistently ensure that chemicals are used within these parameters.

There is no consistency in which portfolio (i.e. Health, Environment or Agriculture) exercises control of use in individual States / Territories. Inevitably there are different expectations about outcomes and in the quality of links with portfolios impacted by agvet outcomes. The Allen report notes that 'the current fragmented nature of responsibility for the overall management of agvet chemicals limits the extent to which overall confidence in its effectiveness can be developed'.

There is broad agreement about the need to achieve harmonised usage outcomes within the limits imposed by environmental differences. AATSE recommended evaluation of current control of use mechanisms and adoption of State / Territory legislation which achieves harmonised outcomes, noting that over sixty pieces of legislation concerning management of agvet chemicals remain on the statute books. The EPHC Taskforce report suggests that 'a clearly articulated, cross-sectoral commitment to common principles and coordinated approaches could potentially bring substantial benefits to human health and the environment while leading to more cost effective regulation and risk management'.

While various State / Commonwealth councils are currently addressing some of these issues, significant benefit would accrue from the development of National Operating Principles with agreed performance outcomes. These could, in effect, put the flesh on the legislative bones and provide the necessary and agreed framework for harmonised agvet chemical implementation and performance outcomes. An inbuilt audit system would provide the feedback for continuous improvement.

***The substantial debate in the last year or so about antibiotic use in animals has shown that, in some States, very little is known in Health portfolios about the overall agvet chemical management system and the role of Commonwealth health agencies in risk assessment and management.***

#### PROPOSAL 3.2.1

**Ensure State/Territory legislation regarding use of pesticides achieves harmonised outcomes within the limits imposed by environmental and climatic differences.**

#### PROPOSAL 3.2.2

**Develop and implement National Operating Principles and Agreed Performance Outcomes for control of use of agvet chemicals and improved feedback mechanisms. These principles may include adoption of best management practices.**

### 3.3 Availability of Chemicals

Concern has been expressed about the future registration of chemicals. The National Strategy, EPHC Taskforce and The Allen Group all recommended more efficient and effective chemical assessment processes be adopted.

At issue is the cost of testing chemicals against increasing regulatory requirements, which inhibits development of new chemicals, support of older chemicals and, in particular, registration of chemicals for minor uses. This is of significant concern for most stakeholders. As Dr Keniry reported at Outlook, 'industry needs access to the most modern chemicals to underpin competitiveness in world markets'

AATSE reported that there has been a move from broad spectrum and generally more toxic pesticides to targeted, more efficacious and less toxic or 'softer' products, and this should be supported. However, as noted in the Allen report 'A consequence of increased regulatory hurdles and continual review programs has been that agvet companies have been less willing to undertake the expense of registering some minor use agvet chemicals'.



*In Europe, 320 actives will be withdrawn by mid 2003 because chemical companies find it unprofitable to carry out the testing required to support their use. Australia with less than 2% of total world market for agvet chemicals could face loss of 'essential' chemicals without comparable alternatives as we assume lower priority in a globalised chemical industry.*

It has also been reported that international harmonisation of agvet chemical management systems is becoming inevitable, and offers potential economies. There are a number of international fora for discussion and establishment of harmonised chemical regulatory processes, eg. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), Codex and Organisation for Economic Cooperation and Development (OECD) to which Australia should stay attuned.

A number of ways to improve the speed and cost effectiveness of chemical assessment have been suggested:

- Utilise harmonised assessment methodologies and standards, including those developed in international fora such as VICH, Codex and OECD, and integrate health / environment assessment methods.
- Improve the consultative interface between APVMA and small companies to encourage innovation and facilitate marketing of softer chemical products.
- Provide special approval processes for 'soft' (reduced-risk) or 'minor use' pesticides based on predetermined limits such as volume used in any twelve month period or evidence of prior approval by overseas regulators in circumstances, which are similar to conditions likely to be found in Australia.
- Financial support similar to that given in the USA to assist minor growers seeking data for continued registration would be of assistance.

#### **PROPOSAL 3.3.1**

**Consider the adoption of more efficient and effective chemical assessment processes to reduce the costs of regulatory compliance.**

#### **PROPOSAL 3.3.2**

**Consider arrangements to facilitate more rapid approval of minor use and 'reduced-risk' agvet chemicals.**

#### **PROPOSAL 3.3.3**

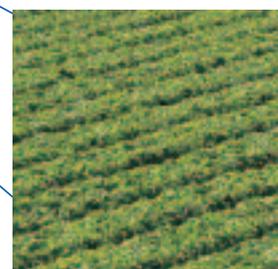
**Explore the possibilities for use of harmonised assessment methodologies through links with industry, industrial chemical registration agencies and international organisations.**

#### **Data Protection**

The need for improved data protection arrangements has been identified. Under current Australian regulatory arrangements, once the patent covering an active constituent has expired, other applicants may seek registration of generic or "image products" providing they can be shown to be identical with the pioneer product. In these circumstances, the APVMA does not require that a complete package of technical data be provided to duplicate existing knowledge of the product's performance and safety.

*VICH – Australia has observer status but has adopted most of its initiatives.*

*Codex and OECD – Australia actively participates as a full member of these fora.*



Under a proposed new data protection scheme for Australia, primary registrants would be granted either exclusivity for their data and/or will be able to seek compensation for access to their data by generic registrants for a specified time. This would provide a primary registrant sufficient time to recoup their commercial investments through product sales without competition from image products, or through negotiated compensation from secondary registrants. It is considered that this would encourage the faster introduction of new innovations in agvet chemicals to Australia.

#### PROPOSAL 3.3.4

**Facilitate implementation of improved data protection arrangements to encourage faster introduction of new innovations in agvet chemicals to Australia.**

### 3.4 User Accreditation and Training

There is wide agreement that with increased sophistication of agvet chemicals, the need for operator safety and growing consumer concerns, there should be greater focus placed on training and accreditation systems for users of agvet chemicals. In particular, the Allen report and Dr Keniry have recommended that ways should be explored to utilise commercial requirements, for example endorsement of QA and HACCP systems, and stewardships schemes through national standards.

The APVMA together with the National Farmers Federation (NFF) and Product Safety and Integrity Committee (PSIC) have been examining the feasibility of a national chemical user training and accreditation scheme. The scheme would identify the risk level of chemicals on the basis of complexity of use, as a focus to minimise impact. Skills required by a user of higher risk chemicals would be determined against the Australian Qualifications Framework (AQF) competency standards and set at a higher level than that required for current ChemCert / Farmcare certification.

This scheme, if implemented, would:

- Promote competencies and training as a basis for risk reduction in the use of agvet chemicals.
- See the supply of higher-risk agvet chemicals restricted to users who were competent to use them.
- Enable suitably skilled farmers to retain access to certain higher-risk chemicals.
- Have a balance of industry self-regulation and regulation at state and national level, and be strongly supported by industry and users.

#### PROPOSAL 3.4.1

**Increase training and supervision for agvet industry operators as a strategy to maintain access to higher risk chemicals. Particular focus should be placed on determining and implementing the drivers for behavioural change. Consideration should also be given to training for non-English speakers.**

#### *Labelling and foreign language translation*

There is increasing pressure on farmers and users to increase competency levels in the application of agvet chemicals. AATSE reported that 'Communication with growers and provision of consistent technical information in plain English, or in some cases in more appropriate languages, remains a problem'. Speakers at the workshop raised the difficulties of non-English speakers and those with low literacy and numeracy skills. To this end, it is noted that simplified labelling is required, in plain English, with better grouping of information on the label, and non-English explanations attached or readily available.

#### PROPOSAL 3.4.2

**Revise chemical labels and develop policies to encourage increased use of clear directions and plain English text.**



### 3.5 Feedback and Monitoring

All of the reports and a number of speakers at the Outlook Workshop discussed the need for strong feedback loops. This would enable the system to respond quickly to results from the application of registration decisions and to new and emerging issues. It would also provide greater transparency.

Feedback through monitoring for chemical residues in food and the environment provides a measure of the effectiveness of application control and correct use. However as Dr Turner emphasised at Outlook, this element is highly fragmented with responsibility for monitoring residing in many portfolios. The National Residue Survey presently provides partial coverage of primary products, but has its emphasis on export produce and is limited by full cost-recovery obligations. State surveys and the Food Standards Australia New Zealand (FSANZ) Australian Total Diet Survey provide additional information, but even with this there is very little formal monitoring of health and environmental outcomes, and surprisingly little organised monitoring/evaluation of agricultural outcomes. Certainly, the current monitoring system of both environmental and health outcomes in Australia is inadequate to provide a sufficient level of public confidence or the information that is required to improve the agvet system.

Obtaining and collating information on quantitative usage of chemicals by crop / species and region has been identified as a priority in both the AATSE and EPHC Taskforce reports and by a number of speakers at Outlook. The EPHC Taskforce noted 'a lack of information about the health and environmental impacts of chemicals in Australia' and that 'more needs to be known about the effects of pesticides on Australian native species and ecosystems'.

***There is no significant coordinated monitoring of Australian produced foodstuffs. The National Residues Survey covers mainly meat and grains and is voluntary except where required for market access by an importing country. The Australian Total Diet Survey is conducted biannually and a significant portion of it covers imported products as found on supermarket shelves. State Surveys provide some further information. None of the data from these surveys is integrated and readily available for risk assessment.***

Data that is collected is not necessarily readily available or coordinated and AATSE has recommended that Australia develop a cost effective, comprehensive and integrated pesticide use reporting system. Such a system and database would provide a clear understanding of what and where chemicals are used and would assist development of consistent monitoring priorities.

Every effort should be made to obtain existing data, coordinate the future data collection process between agencies, and investigate funding arrangements possible along the lines of the existing shared State / Commonwealth arrangements for the National Pollution Inventory.

The development by the APVMA of an adverse experience reporting program for agricultural chemicals, commencing mid-2003 (to complement the current program for veterinary products), will significantly improve health monitoring. For its part, PSIC has begun a project to review and improve outcomes measurement. Ultimately adverse effects registers should be established for pesticide impacts on both human health and the environment.

#### PROPOSAL 3.5.1

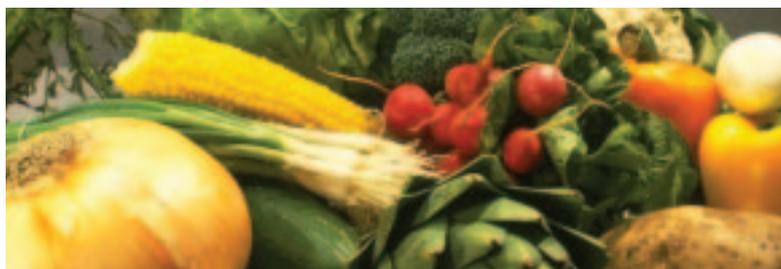
**Develop and implement an improved feedback mechanism for the agvet chemical system to help guide decision-making and monitoring priorities.**

#### PROPOSAL 3.5.2

**Establish a national comprehensive and harmonised residue monitoring program for food and the environment and provide for wider dissemination of results.**

#### PROPOSAL 3.5.3

**Establish a comprehensive and integrated pesticide use reporting system, database and adverse effect registers, focusing especially on human health and the environment, building on the work currently carried out by the National Residues Survey, FSANZ, State / Territory governments, and the APVMA. The program should include arrangements for data sharing and access and coordination of the timing and type-selection of samples.**



### 3.6 Public and International Confidence

The Allen, AATSE and EPHC Taskforce reports, and Outlook speakers all identified the improvement and maintenance of domestic and international confidence in the regulatory system as a priority. This requires credibility and confidence built by visible measures of system performance and achievement of objectives, and supported by transparency of decision making, placing the necessary information for making judgements into the public domain, with adequate provision for consultation by stakeholders and the community.

Dr Yeatman suggests the public become concerned when trade imperatives are used to justify the use of agricultural and veterinary chemicals. Trade, rather than being seen to offer employment and income, is then considered to be in the commercial interests of international conglomerates. Also raised in the reports and workshop were the lack of public understanding of the agvet registration and control of use system and the need for improved contact points.

Despite scepticism about the ability of scientists and regulators to manage risks from agvet chemical use, Australian consumers still overwhelmingly trust the food system. The system remains credible and has not yet been challenged by a major food scare such as those that have occurred in Europe. The Australian system is not as transparent as that of the USA. For example, unlike USFDA, APVMA due to legislative restrictions, cannot publicly disclose what applications for registrations it is considering.

In addressing food safety and quality Dr John Keniry advised that there are increasing trends both in Australia and overseas for the supplier/purchaser relationship to be underpinned by QA certification requirements. In coming years the business model for food production and marketing will be heavily based around certification of the system to ensure quality and consistency of product. The future regulatory system for agvet chemicals must be consistent with this model.

In respect to the current system there are a number of possible changes that would enhance confidence and transparency of operations:

- Legislative changes to allow APVMA to give prior notice of chemicals for which registration is being sought.
- APVMA should endeavour to make its role better known and more transparent to the general community.

*The lack of effective and timely management of the UK BSE outbreak and monitoring failures in Belgium that allowed dioxin contaminated feed into the food chain severely undermined public confidence in the control systems. Extensive and unmonitored use of chloramphenicol in food producing animals in China has had extensive negative impact on their export market.*

- Inclusion of an environmental, user, and consumer representatives on the APVMA Board would help to improve community consultation and meet community and international expectations.
- Information about pesticide properties and data from residue surveys should be more readily accessible.
- A national single point of contact that will allow ready access and minimal referral to other areas.

Australia has not faced a major public health crisis such as the BSE (mad cow disease) incident in the UK, dioxins in Europe or chloramphenicol in China. Experience has shown the need for proper planning and coordination if system credibility and proper environmental health outcomes are to be maintained in an emergency. In anticipation of any future breakdown of the food safety system, Australia should develop and test contingency plans for emergencies.

#### PROPOSAL 3.6.1

**Improve transparency and credibility in decision making, including wider dissemination of information about registration applications and decisions and other information on chemicals, and consider other measures to improve public confidence.**

#### PROPOSAL 3.6.2

**Encourage the development of risk reduction strategies in all aspects of agvet chemical management including the use of QA, HACCP, and stewardship programs in the agvet chemical industry to meet required outcomes.**

#### PROPOSAL 3.6.3

**Develop and test contingency plans to protect health, environment and trade in the event of an agvet residue emergency.**

### 3.7 Agvet System Structure – Links and Interfaces

It is important for efficient agvet chemicals management that Australia has a seamless system. This requires a structure that ensures effective integration and a uniform approach between the elements of registration, control of use and communication. As the overall objective is safe use of chemicals plus effective control of pests and diseases, there also need to be links to other areas of government such as Health (including OH&S) Environment, and Agriculture (including agricultural trade) at both State / Territory and Commonwealth level. Diagram 1 is a representation of desirable structural links in the Agvet Chemical Management System.

Current established links between Commonwealth (AFFA) and States on agvet policy matters serve to give direction and consistency to the standards of risk management and acceptability applied in the system, and to determine forward direction and future development. At the same time, operating links provide efficiency, robustness, and confidence that the system is working. There are well defined operational links based in legislation, between APVMA and State agencies responsible for control-of-use.

The APVMA has good formal links, through service level agreements, with Commonwealth Health, Environment and OH&S portfolios to provide risk assessment advice. But these portfolios are not directly involved in decisions about the forward direction of agvet management at a more strategic level, although their respective Ministerial Councils are represented on the PSIC. Consideration could be given to additional means of obtaining input from these portfolios.

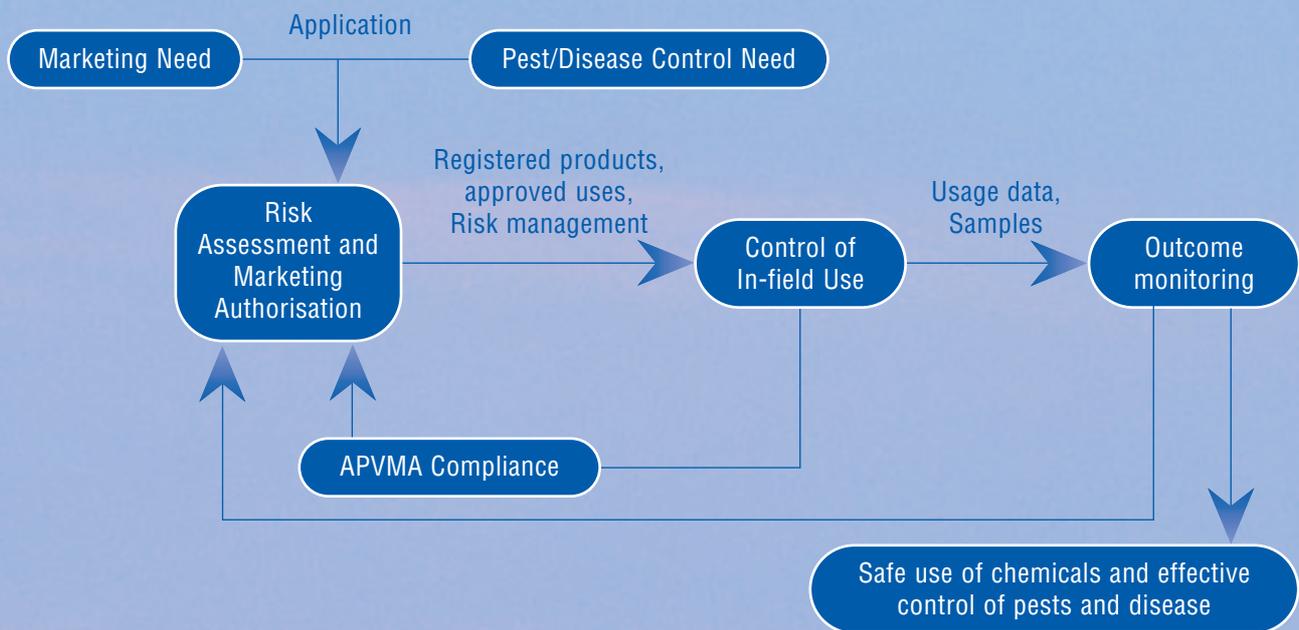
#### PROPOSAL 3.7.1

Improve the current structural arrangements for agvet chemical registration and control, including formalised and improved linkages with relevant agencies and stakeholders.

#### PROPOSAL 3.7.2

Consider whether there should be more formal and more visible provision for input from the Health, OH&S, and Environment portfolios on strategic decisions about the forward planning of agvet chemicals management.

**Diagram 1: Desirable structural links in the Agvet Chemical Management System**



### Structural Options

Four alternative approaches to achieving a seamless agvet chemicals management system were proposed in the Allen report. Two horizontally structured options proposed integration either under a new more encompassing agency, or within a single Commonwealth department. Allen's preferred option involved vertical integration under a new independent agency. An alternative was vertical integration through National Operating Principles, whilst retaining the current structural framework (see Diagram 2).

There has been no consensus on a particular model.

The horizontal integration options, whilst providing some benefits, do not satisfy all of the seven Principles. They do not achieve satisfactory policy links, and may simply replace the current system with a larger, more complex and less responsive organisation.

Similarly, a vertically integrated model under a single agency suffers predominately from the fact that it is difficult to encompass all the required elements in a single system. Large vertically integrated organisations have been found in practice to lack flexibility, responsiveness and transparency.

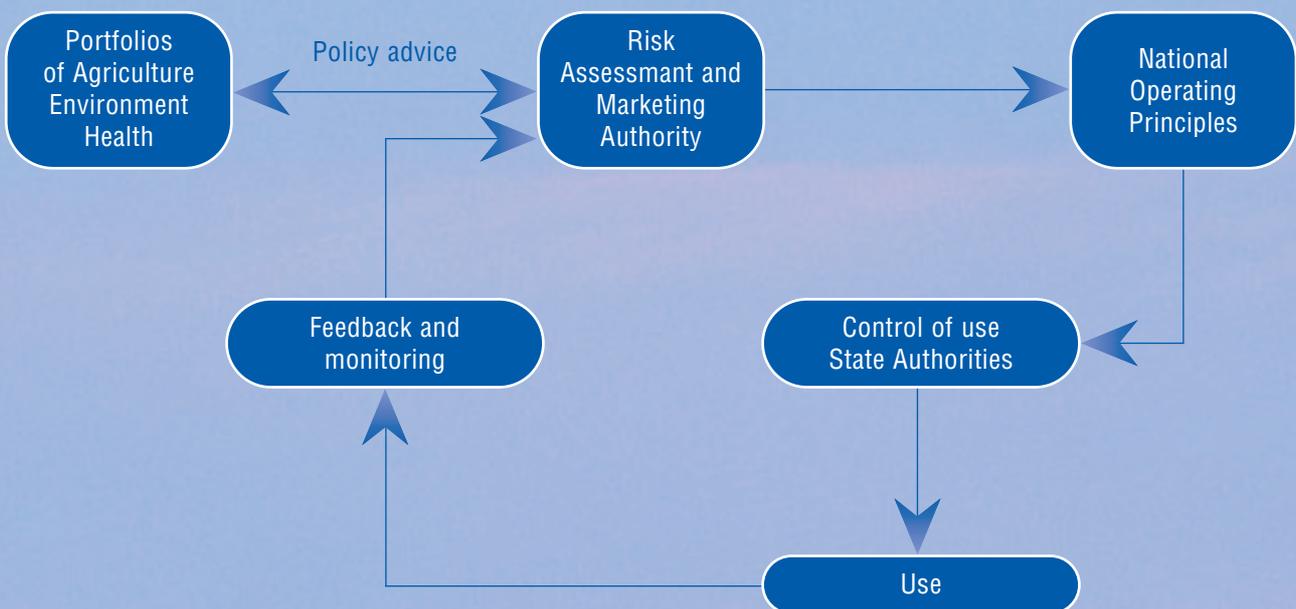
The creation of either a larger horizontal or vertically integrated organisation would also raise substantial State / Commonwealth issues and introduce new design and management difficulties. International precedent also does not support this direction.

However, the vertically integrated model with National Operating Principles (Diagram 2) and agreed performance outcomes may provide the optimal system. A system comprising the three main modules, regulation and assessment, control of use and monitoring, each with well-designed role and functions and with well-specified links and interfaces, could be expected to operate to best achieve the requirements of the seven Principles. Such a system with audits and defined reporting arrangements overcomes the disadvantages of the other options but gives uniformity of approach and good feedback. However, it does require commitment of all parties to the process and arrangements for continuing liaison on management and policy development.

#### PROPOSAL 3.7.3

Consider whether further structural changes would provide a net benefit. These should be guided by agreed design objectives and principles.

**Diagram 2: Vertical integration through National Operating Principles**



## 4. Conclusions

The agvet chemical management system faces substantial challenge over the next 10-15 years. While it is generally agreed that the current modular system has worked quite well, a number of areas have been identified where improvements to agvet chemicals management in Australia are desirable. With attention to the issues raised, the development of National Operating Principles and audit systems could provide a suitable long-term outcome. However, when considering the way forward, system adaptations and developments to meet this should be guided by debated and agreed design objectives and principles, based in turn on agreement about desired outcomes and measures of these.



# Glossary of Terms

AATSE	Australian Academy of Technological Sciences and Engineering
AFFA	Agriculture Fisheries and Forestry – Australia
Agvet	Agricultural and Veterinary
AQF	Australian Qualifications Framework
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand
APVMA	Australian Pesticides and Veterinary Medicines Authority (formerly the NRA – National Registration Authority for Agricultural and Veterinary Chemicals)
BSE	Bovine Spongiform Encephalopathy
EA	Environment Australia
EPA	Environment Protection Agency
EPHC	Environment Protection and Heritage Council
EU	European Union
FSANZ	Food Standards Australia New Zealand (formerly Australia New Zealand Food Authority)
HACCP	Hazard Analysis Critical Control Point
MRL	Maximum Residue Limit
NFF	National Farmers Federation
NICNAS	National Industrial Chemical Notification and Assessment Scheme
OECD	Organisation for Economic Cooperation and Development
OH&S	Occupational Health & Safety
PISC	Primary Industries Standing Committee
PIMC	Primary Industries Ministerial Council
PSIC	Product Safety and Integrity Committee (formerly the Agricultural and Veterinary Chemicals Policy Committee – AVCPC)
QA	Quality Assurance
USFDA	United States Food and Drug Administration
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

## **Acknowledgements**

**The contributions of Mr David Cox and staff of the APVMA in preparing this report are acknowledged.**



**Australian Pesticides &  
Veterinary Medicines Authority**