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A Strategic Review for the National Registration Authority for Agricultural and Veterinary Chemicals

A National Risk Management System for Agvet Chemicals

Positioning For The Future

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Preface

This Report has been prepared by The Allen Consulting Group on behalf of the Project Steering Committee:

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The Consultants have sought to bring a strategic perspective to an inherently complex area involving a number of stakeholders. We wish to record our appreciation to the Steering Committee, the organisations who provided written responses to the Issues Paper we released at the start of the consultancy, and the individuals both in Australia and overseas who made time available for interviews.

The Steering Committee commend the recommendations for further consideration and action by all relevant decision-makers.

This Report was funded by the NRA.

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Executive Summary

Agvet chemicals will remain important to agriculture

Sales of agricultural and veterinary (agvet) chemicals in Australia are running at about A$1.6 billion per annum, which represents around 7 per cent of the cost of agricultural production.[1] Notwithstanding the developments in prospect in biotechnology and genetic engineering, the increasing demand by consumers in developed countries for organically grown food, and the move in some Northern European countries to directly reduce the use of agvet chemicals, we conclude that over the next 10 to 15 years the use of agvet chemicals will remain an important part of the tool box of instruments available to agricultural producers.

Pressures for change

There will be, however, pressures for change to the system that regulates registration and use of agvet chemicals. Changing community attitudes, the expansion of scientific knowledge and international efforts to achieve a higher degree of commonality by regulatory agencies each provide impetus for change. In the light of the major shocks associated with BSE and foot and mouth disease in Western Europe and Japan in recent years, it cannot be ruled out that new shocks will have to be dealt with in the coming 10 to 15 years.

Importance of retaining international acceptance for agricultural products

Australia is a major exporter of agricultural products into world markets, and especially the markets in North America, Japan and Western Europe (close to half of Australia's agricultural exports go to these markets), but it is not a member of either NAFTA or the EU, which means that Australia needs to be particularly sensitive to international changes in regulatory practices for agvet chemicals. Australia needs to have in place a regulatory system for agvet chemicals, which is robust and internationally credible. The system must be capable of successfully handling issues about agvet chemical residues or agvet chemical use relating to trade, public health and the environment. High standards for managing agvet chemicals are needed if Australia’s food exports are to retain acceptance in world markets.

The need for reform

The recent study by the Australian Academy of Technological Sciences and Engineering reached the judgement that the assessment, registration and labelling of agvet chemicals appears to be generally a rigorous process that uses internationally accepted principles of risk assessment.[2] However, the assessment, registration, and labelling of agvet chemicals is only one, albeit an important, element of the agvet chemicals risk management system. Other aspects, such as control of use, training and accreditation of users, stakeholder engagement and confidence, and information access are also important. The

[1] ABARE (2001), Australian Commodity Statistics.

[2] Australian Academy of Technological Sciences and Engineering (2001), Pesticides Use in Australia: A Review, sponsored by the Australian Research Council, p270.

performance of the total agvet chemicals risk management system depends on the way all the elements are operating and fit together.

To provide an optimal framework will require the evolution of the agvet chemicals risk management system to meet the following realities:

- Changes in community attitudes to food safety and the environment which reflect rising levels of wealth, increasing dissemination of knowledge, and changing perceptions of risk and concerns about perceived regulatory failures in other countries, eg Western Europe.
- Technological advances which make possible the availability of new products for primary industry, new measures for testing the impacts of agvet chemicals, and new production techniques for agricultural producers.
- Developments in regulatory methodologies and approaches in the US and the EU which tend to set the tone for regulation of agvet chemicals in developed countries and, increasingly, emerging countries.

These realities require that Australia's regulatory system has the capacity to respond appropriately to changes in its environment and the needs of stakeholders.

To test the adequacy of the existing agvet chemicals risk management system we have identified seven design principles, which we believe ought to be present in a world leading agvet chemicals risk management system for Australia. These design principles are listed in Table ES1.

Table ES1

DESIGN PRINCIPLES FOR AN IDEAL SYSTEM

Principle One	A Seamless System
Principle Two	Strong Feedback Loops
Principle Three	Flexibility to Respond to Emerging Issues
Principle Four	Provision for Continuous Improvement
Principle Five	Confidence in the Regulatory and Management Process
Principle Six	Effectiveness and Efficiency
Principle Seven	International Confidence

Source: The Allen Consulting Group

In the light of experience with the total system for the management of agvet chemicals since the establishment of the NRA, taken together with the consideration of the key drivers for the next 10 to 15 years, a strong case can be made that a package of reforms is needed to take the Australian system to the next level so that it is better able to meet the challenges expected in the medium to longer term. Without such reforms, the agvet chemicals risk management system is exposed and poorly positioned to respond to a major adverse agvet chemical related event, which potentially places in jeopardy significant parts of Australia's agricultural exports to markets in leading developed countries worth $13 billion annually.

The Strategic Review concludes that Australia does not possess a world leading agvet chemicals risk management system as it does not satisfy the design principles for an ideal system. Significant progress was made in 1995 with the establishment of the NRA; however, this will not be sufficient to ensure Australia's response to current and future pressures in the agvet chemicals area.

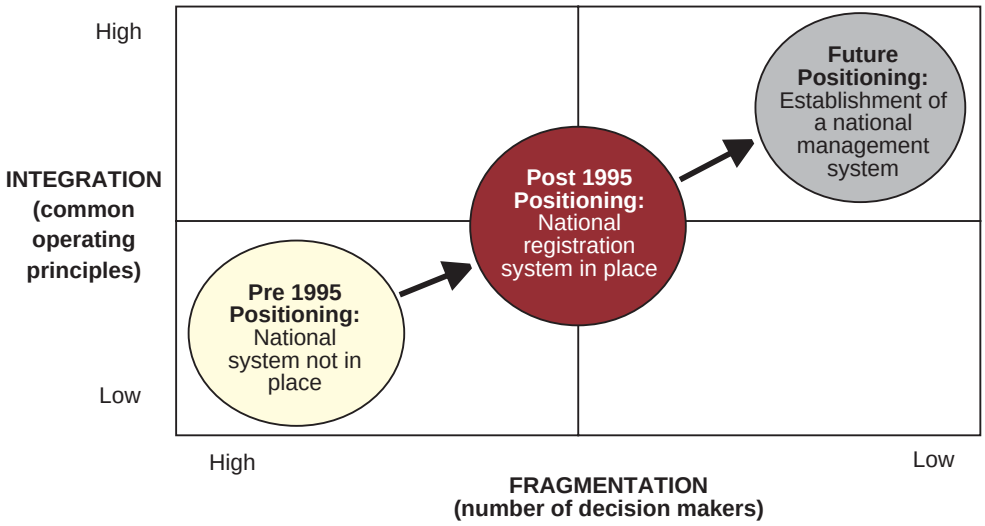
We have reached the judgement that the time has come to embrace the need for taking the existing system of agvet chemicals to a new and much more effective level. We believe that while business–as–usual plus incremental change can move the current system forward, improvements will not be general enough or happen sufficiently quickly to eliminate the risk of Australia facing a major adverse event in the next 5–10 years.

The reform package

The nature of the repositioning of the system for the management of agvet chemicals is shown schematically in Figure ES1. Prior to the introduction of the National Registration System, the agvet chemicals risk management system was characterised by a low degree of integration and a high level of fragmentation which was inherent in an essentially State based set of arrangements. The properties of the overall system were considerably improved by the establishment of the National Registration System. However, further reform is needed to move the agvet chemicals risk management system to the desired high level of integration and low level of fragmentation required for a world leading system.

Figure ES1

POSITIONING OF THE AGVET CHEMICALS MANAGEMENT SYSTEM



Source: The Allen Consulting Group

In terms of structural reform options, after considering potential horizontal and vertical integration models, the Consultants consider that a vertical integration model, based on a newly created Australian Pesticide Safety Authority (APSA), taking responsibility for the key elements of the agvet chemicals risk management system (registration and labelling; control of use; training and accreditation) is the preferred option for the future.

The establishment of the new authority with wide responsibilities is a fundamental step to putting in place a world leading agvet chemicals risk management system in Australia. While a necessary development, it is not sufficient in itself to achieve the desired result. The Consultants have therefore identified a set of complementary proposals aimed at giving full effect to the seven design principles identified for an ideal system.

The Consultants realise that reform will require strong commitment by the Commonwealth and State Governments. The stakes involved and public expectations are high. Agvet chemicals must be viewed in terms of protecting public health, the environment, and occupational health and safety, and their role in underpinning Australia's valuable export markets for agricultural products. Moving ahead along the lines proposed will yield benefits well beyond any associated costs.

Chapter One

The Study

1.1 Background

Agricultural and veterinary (agvet) chemicals play an important role in Australia's highly export oriented agricultural production sector, which in 2000/2001 exported goods worth A$30 billion. The leading elements of the sector include grains, meat and dairy products. Agriculture plays a significant role in regional Australia, whether in the tropical north or in the more temperate southern parts of the continent.

Agricultural exports represent between 60 and 70 per cent of the value of agricultural production.[3] While agricultural exports go to many countries, the greater part is exported to North America, Japan and Korea and Western Europe, all of whom possess rigorous, science-based systems for regulating the use of agvet chemicals and for determining maximum residue limits in locally produced and imported food products.

Sales of agvet chemicals in Australia are running at about A$1.6 billion per annum which represents around 7 per cent of the cost of agricultural production.[4] The expansion of sales of crop protection products (which account for the greater part of agvet chemical sales) in most developed countries is tending to increase at the same rate as GDP suggesting that the market for them is essentially mature in these countries.[5]

Agvet chemicals are not the only tool available to assist agricultural producers to manage the health of their crops and livestock products, but they have been found in many industries to be an essential part of agricultural management practices. The recent study by the Australian Academy of Technological Sciences and Engineering quoted a US study which found that the return to agricultural producers from employing a dollar's worth of agvet chemicals is up to four dollars in terms of crop and livestock savings.[6]

However, over the last 20-40 years, it became increasingly apparent that the practical use of agvet chemicals can also have undesirable consequences for human health, the environment and the occupational health and safety of agricultural workers (eg DDT, dieldrin, 2,4,5-T). In response, over the past 10-15 years, there has been an increased awareness leading to the use of softer chemicals and other measures. Also, OECD countries have established systems to regulate the introduction of agvet chemicals into the market and to control their usage.

In Australia's case, until a little over 10 years ago, registration of agvet chemicals was a State responsibility. In 1991, following the *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals* in the previous year, the Commonwealth, State, and Territories agreed to establish a

[3] ABARE (2001), Australian Commodity Statistics.

[4] ABARE (2001), Australian Commodity Statistics.

[5] Agrow Report (2001), The Global Crop Protection Industry in 2010, PJB Publications Limited

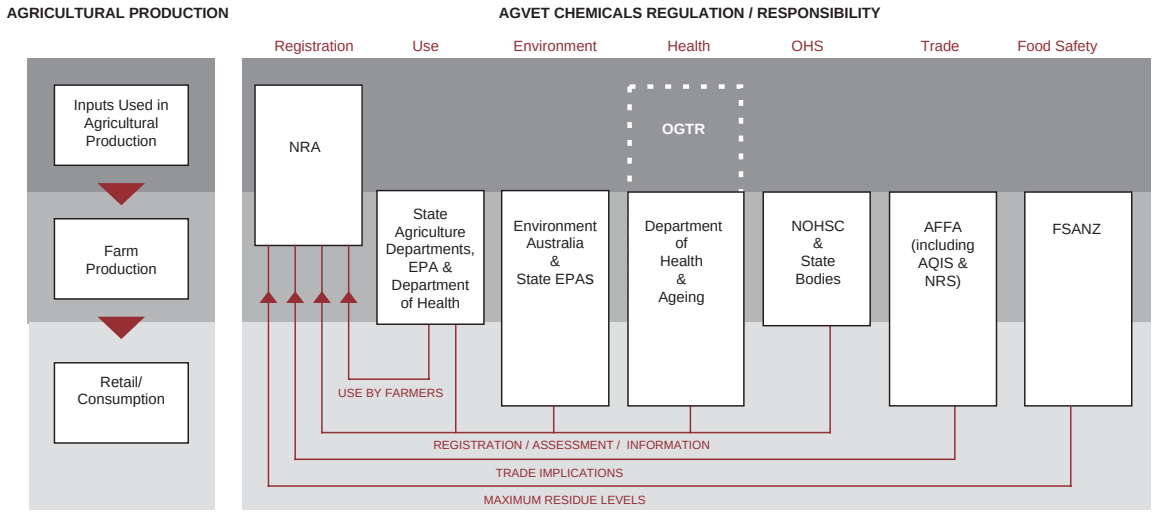
[6] Australian Academy of Technological Sciences and Engineering (2001), Pesticides Use in Australia: A Review, sponsored by the Australian Research Council.

National Registration Scheme for Agricultural and Veterinary Chemicals. This scheme required the agreement and passage of legislation in the jurisdictions, which among other things, allowed for the establishment of the National Registration Authority for Agricultural and Veterinary Chemicals (the 'NRA').[7]

Notwithstanding the 1991 agreement, it took until 1995 before the NRA was fully operational. Since that time, the NRA has been responsible for agvet chemicals up to and including the point of sale; the State and Territories for control of use of agvet chemicals past the point of sale. This function is exercised either by Departments of Agriculture, Environmental Protection Agencies, or Departments of Health. In some States more than one agency is involved.

Figure 1.1

JURISDICTIONAL RESPONSIBILITY FOR AGVET CHEMICALS



Note: While the NRA seeks input from various regulatory agencies, the NRA has legislative responsibility for health, environmental and occupational health and safety issues in so far as they relate to the registration of agvet chemicals.

Source: The Allen Consulting Group

The national scheme for the registration of agvet chemicals has now been operating for almost seven years and in this context the NRA has commissioned this review.

1.2 Terms of Reference

The NRA plays a critical role in the regulatory oversight of agvet chemicals by evaluating registering and regulating agvet chemicals. The NRA evaluates agvet chemicals to ensure that the product is safe for people, animals and the environment and that it won't pose an unacceptable risk to trade with other nations.[8] If an agvet chemical meets the NRA's standards it may be registered for use in Australia.

Implementing the NRA charter requires consideration of a number of influences ranging from community attitudes, changes in technology, changes in agricultural practice and changes in the agvet chemical industry itself. To

[7] The ***Agricultural and Veterinary Chemicals (Administration) Act 1992*** established the National Registration Scheme in 1993. It also set out the NRA's role as an independent statutory authority undertaking the Commonwealth's responsibilities under the scheme and provides the NRA with its full range of powers.

[8] As set out in the NRA's governing legislation

continue to provide an optimal regulatory framework will require the evolution of the regulatory system to meet the following realities:

- Changes in community attitudes to food safety and the environment which reflect rising levels of wealth, increasing dissemination of knowledge, and changing perceptions of risk and concerns about perceived regulatory failures in other countries, eg Western Europe.
- Technological advances which make possible the availability of new products for primary industry, new measures for testing the impacts of agvet chemicals, and new production techniques for agricultural producers.
- Developments in regulatory methodologies and approaches in the US and the EU which tend to set the tone for regulation of agvet chemicals in developed countries and, increasingly, emerging countries.

These realities require that Australia's regulatory system has the capacity to respond appropriately to changes in its environment and the needs of stakeholders. Against this background and in the light of the fact that it is now more than 10 years since the landmark Senate Select Committee Report, it is timely to consider how well the system is working and in particular what are the issues relating to the future management of agvet chemicals in Australia.

Accordingly, the NRA has commissioned The Allen Consulting Group to undertake:

- an in–depth analysis of the factors that are likely to have a defining influence over the availability, supply and use of agricultural and veterinary chemicals in Australia in 2015 that are safe, effective and without harm to people, the environment and trade;
- a detailed analysis of the objectives, role and key elements of a future regulatory framework that will effectively respond to the factors identified above, particularly given the important role of regulation in delivering expected outcomes;
- an assessment of issues, trends and options that government, industry, chemical users and consumers will be asked to consider in undertaking their respective responsibilities; and
- an identification of key issues and concerns that may need to be addressed progressively towards 2015.

The purpose of the review is to:

- propose a national system for agvet chemicals regulation that would be more appropriate to serve Australia's national interests over the next 10–15 years;
- fulfil the function of the NRA "to encourage and facilitate the introduction of uniform national procedures for control of the use of chemical products'; and
- determine how the NRA can best contribute to this improved national system.

The terms of reference go further than simply reviewing the NRA's current regulatory responsibilities. While the NRA has acknowledged that it does not have primary responsibility for reform and policy making in this area, a review of this nature is intended to provide an objective, authoritative resource with which future policy decisions can be referenced.

1.3 Structure of the Study

The report is based on four main elements:

(a) A review of the literature on agvet chemicals and the regulation of these products. Major studies have recently been done in the US and Europe on the outlook for pesticides in the next ten years which have been highly relevant to this study.

(b) The responses received from a range of interested parties to the Issues Paper released by The Allen Consulting Group in March 2002.

(c) The views put to the consultants in a round of face–to–face meetings with the key stakeholders.

(d) The views put to the consultants in meetings with the regulatory authorities and interested organisations in Washington, Brussels and London, which took place in the second half of March, 2002.

This Overview Report is structured in the following way:

- The key drivers for agvet chemicals and the regulatory system are discussed in Chapter Two.
- International developments in the regulation of agvet chemicals are discussed in Chapter Three.
- Implications for the Management of agvet chemicals are outlined in Chapter Four.
- The consultant's conclusions and proposals are set out in Chapter Five.

The consultants wish to acknowledge the contributions that have been made to this report by a number of stakeholders and organisations, which have responded to the Issues Paper. The views expressed in the report are those of the consultants.

Chapter Two

Key Change Drivers

In the light of a review of the literature on agvet chemicals and their regulation, an extensive consultation process with stakeholders in Australia, and discussions with regulators and stakeholders in the US, EU, and the UK the consultants have concluded that the six key change drivers for the management of agvet chemicals are:

- community attitudes;
- technology;
- agvet chemical industry;
- agricultural industry;
- trade; and
- regulation.

The importance of trade and access to export markets for Australian agricultural producers means that international factors as well as domestic factors are critical in considering the future influences on the management of agvet chemicals in Australia. International factors are considered both within this and the following chapter.

2.1 Community Attitudes

Community attitudes to the use of agvet chemicals, particularly as they relate to food safety and the environment, are becoming increasingly important.[9] With higher incomes and better education, consumers are demanding more information about the content of food products, assurance about the integrity of food chains, and where possible choice in the products that are available. This trend is further compounded by the fact that Australia's population is ageing, with retiring baby-boomers enjoying more free time to assess issues of health and safety.[10] Also, the use of mass communication technologies makes it easier for such issues to be discussed and issues or concerns to be raised.

Community attitudes to the use of agvet chemicals centre on a desire to reduce risk, particularly since there is little choice about their use and ultimate consumption unless lower risk organic substitutes are available. Given some quite spectacular perceived failures in the regulation of food quality in Europe, eg Bovine Spongiform Encephalopathy (BSE), Foot and Mouth Disease (FMD), Listeria, etc, consumers are no longer prepared to accept at face value assurances from regulators about the appropriateness of current regulatory

[9] In a survey conducted by Quantum Market Research in 2001 for Biotechnology Australia it was found that pesticide use was the second greatest food concern behind food poisoning. Source: Survey results available at www.biotechnology.gov.au/global_support_for_GM_foods_10_May_2001.doc

[10] Population projections by the ABS predict that by 2015, more than 14 percent of the population will be at retirement age (over 65 years). Source: ABS catalogue number 3222.0 2000.

standards if those assurances are based on closed, in-confidence regulatory processes.[11]

Consumers are increasingly looking for guarantees that their food is of the highest quality possible and is safe to consume. Such risk aversion is leading in Western Europe for pressures to adopt a far-reaching interpretation of the precautionary principle for use in the regulatory process.[12]

There has also been growing public concern about the impact on the environment of agvet chemicals. Intensive agriculture practices are increasingly being considered to have a detrimental effect on the environment.[13] The potentially adverse effects of agvet chemicals, combined with the occurrence of spray drift, tend to dominate the environmental concerns regarding agvet chemicals.[14] In particular, the environmental concerns regarding agvet chemicals tend to concentrate on the pollution of ground and surface waters and the impacts on biodiversity.

Changing community attitudes, and the growing interest in the quality of the food chain and its environmental sustainability is reflected not just in pressure on regulators but also on food sellers. For example, in the UK the leading supermarket chains have developed their own set of production requirements for their suppliers, which have both food safety and environmental protection aspects.

Conclusion

For the foreseeable future, non-government organisations will maintain pressure on regulatory bodies in relation to pesticide and veterinary medicine products and will focus on: food safety, health issues (such as resistance to antibiotics), scientific uncertainty, environmental concerns (including agricultural intensification), labelling, and boundary issues (eg the impact of fertilizers).

2.2 Technology

Agvet chemicals are being impacted like most other R&D based activities by the significant advances that are taking place in science and technology. For example, new breed technology, and in particular the biotechnology revolution and the possibilities opened up by genetic engineering have major implications for both crops and crop protection and animal health products. New computer controlled, robotic laboratory procedures are enabling the rate of search of new molecules to be increased very significantly.

The introduction of new agvet chemicals has seen a shift away from old style, broad-spectrum products to more targeted, softer chemicals that have a lesser impact on the environment, and health and safety of the community.[15] One

[11] For example, the UK Food Standards Agency, created in 2000 to protect the public's health and consumers' interests in relation to food, operates under the key guiding principles of being open and accessible, putting the consumer first and being an independent voice.

[12] Originally the precautionary principle was designed to aid risk management. Where the available science was highly suggestive of a particular adverse effect then regulators should not wait to have scientific certainty before acting. To many now, this principle is taken to mean that unless a product is proved safe with certainty then regulators should err on the side of caution and not approve the use of a product until scientific evidence is available.

[13] OECD (2001), Indicators for Agriculture: Methods and Results , Volume 3.

[14] Based on concerns by leading advocacy groups such as Pesticides Action Network, World Wide Fund for Nature and Greenpeace.

[15] Australian Academy of Technological Sciences and Engineering (2001), Pesticides Use in Australia: A Review, sponsored by the Australian Research Council.

example of this is in the area of bio-pesticides, which have grown in importance and use, as is evidenced by the priority placed on their registration by the US Environmental Protection Agency (EPA).

However, there is concern that the rate of development of new chemicals may be slowing due to industry consolidation and the cost of registration. In general, the top international agvet companies spend approximately 10 percent of sales on R&D.[16] In contrast though, R&D expenditure in Australia has decreased from 4.2 percent of sales in 1991 to 3 percent of sales in 1998.[17]

Significant advances are being made in the development of genetically modified and non-genetically modified crops. Progress has been made in the introduction of genetically modified plants in the US but in Western Europe community resistance has seen a moratorium imposed on the introduction of new GMOs. However, moves are currently underway in the European Commission to create conditions in which the moratorium can be lifted. Nevertheless, progress with the introduction of GMOs in both Western Europe and for that matter the US is likely to be slower than was expected a few years ago.[18]

Furthermore, there is a concern that the introduction of some herbicide or pesticide tolerant GMOs may lead to greater use of chemicals rather than less. For example, the performance of Monsanto's round-up ready Soya beans encouraged more rather than less agvet chemical use. Yet at the same time, some GM Crops have led to a reduction in pesticide use, such as the introduction of Monsanto's Bt Cotton applications aimed at Helicoverpa spp.[19] Notwithstanding mixed signals about the implication for agvet chemicals from the introduction of GMOs, it is clear that any increase in agvet chemical use will be increasingly challenged by opponents of GMOs as well as those concerned about agvet chemical use.

Technology is also impacting on the regulatory process, with assessment methodologies incorporating new technologies such as computer modelling and better measurement techniques. Regulators are now able to respond better to new community concerns, such as endocrine disruptors, chemical cocktail effects, and cumulative effects. At the same time though, concerns have been raised that the regulatory process does not respond adequately to technological developments. If the regulatory requirements for local manufacturers are more onerous than those applying to imported goods, then this may drive local manufacturers offshore to low cost countries such as India or China.

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16 Agrow Report (2001), The Global Crop Protection Industry in 2010, PJB Publications Limited

17 Avcare (2000), Data Protection for Agvet Chemicals: What You Should Know!

18 However there may be a rapid expansion in new non-genetically modified breeds such as triazine tolerant (TT) canola.

19 The recent Australian Academy of Technological Sciences and Engineering (2001), does not provide a definitive answer on the degree to which herbicide tolerant crops may reduce herbicide use, but suggests that this reduction is determined by the ability of a producer to manage weed resistance within such production systems.

Conclusion

Over the next 10 to 15 years, technological advances will allow for development of safer and less toxic agvet chemicals. At the same time, the development and use of GMOs will be slower than originally expected in the late 1990s. Hence the regulatory system must remain open to new agvet chemicals and the continued use of traditional agvet chemicals.

2.3 Agvet Chemical Industry

Over the last decade the global agvet chemical industry has gone through a period of consolidation, which has seen the number of major companies reduce to fewer than 10, with these firms generating over 90 percent of total global sales.[20] There are approximately 760 firms operating in the Australian market, but in practice about 30 companies account for 90 percent of the value of sales of agvet chemicals. Smaller companies, many of which are Australian owned, are important in the production of niche products.

The global agricultural chemical market is estimated at approximately $US30 billion. The Australian market represents approximately 1.8 per cent of world agricultural chemical sales and 1.4 per cent of veterinary chemical sales.[21] In this context, Australia is a small player with limited influence on the decisions of multinational agvet chemical companies, particularly in the area of agricultural chemicals, which account for 78.5 percent of the total sales of all agvet chemicals in Australia.[22]

As a result of consolidation virtually all research and development in the creation of new agvet chemical molecules is now conducted in either the US or in Europe, mainly for northern hemisphere climates and pests. For Australia, this raises important issues about how quickly new products developed elsewhere are made available in Australia and whether such new products suit Australian conditions.

The danger is that further consolidation of the global agvet chemicals industry, which is in prospect, may result in Australia being seen as a small commercial market and therefore not of sufficient importance to justify registration of new chemicals or re-registration of older chemicals, except in those areas where the demand for such chemicals in Australia is similar to the demand in the Northern Hemisphere and is relatively large, eg grains and meat.[23] For example, it has been argued that chemicals like isoproturon and alachlor, which are registered in the US and EU, are not available in Australia due to the relatively small potential return in Australia, particularly given Australia's proprietary rights granted under data protection rules.[24] The net effect is that Australian producers may not have access at reasonable prices and in a reasonable timeframe to some agvet chemicals, including vaccines, that are proven to be effective and are being used in other countries.

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20 It is interesting to note that the Australian company Nufarm is now the 10th largest agvet chemical company in the world, with sales of around $200 million per annum.

21 In 1999, 7,014 products with a total of $2,217 million agvet chemicals were consumed in Australia.

22 Veterinary products represent only 21.5 percent of the product sales but almost 45 per cent of the total number of products registered in Australia. Based on NRA registrations and sales figures 2001

23 View expressed by VMDA, Avcare, Meat and Livestock Australia, and Australian Apple and Pear Growers Association.

24 View expressed by the Western Australian Agriculture Department.

Conclusion

Consolidation of the world agvet chemical industry is likely to continue, which raises questions about Australia's ability to enjoy access to the latest agvet chemicals, particularly if multi-national companies focus on significant international markets in the US and Europe.

2.4 Agricultural Industry

Agvet chemicals are extremely important to Australian farmers, as is evidenced by the rapid increase in pesticides sales in Australia over the last twenty years.[25] Their use includes farming, forestry, horticulture and animal production, and has allowed agriculture to remain one of Australia's biggest export industries and contributors to economic growth, with produce exported to a range of markets, including Japan, Korea, North America and Europe.[26]

There has been a great deal of restructuring in Australia's agricultural industry over a long period and the restructuring is expected to continue. One of the major trends has been for a reduction in the number of farm units and an increase in their average size – this change is being driven by the economics of producing agricultural products to be competitive on global markets.[27]

Farms are becoming businesses rather than family operations. Associated with this trend has been an increase in the level of expertise in the farming community as they have moved to embrace new technologies and practices such as personal computers, geo-positioning systems, integrated crop management systems, and more sustainable agricultural practices.

At the same time, there has been a long-term shift within broad acre agriculture away from wool production where the number of sheep has fallen by 30 percent over the last decade toward increased cropping where the value of cereal grains has increased by 90 percent over the same period. Concurrently, growth has also been taking place in horticultural industries covering a wide range of areas. The expansion of the grape industry linked to the growth of Australia's wine industry, which has doubled production in the last ten years, has been the outstanding example.[28]

At the same time, even within production types, Australian agriculture is becoming more intensive. For example, the area planted to irrigated rice increased by about one third from 1990-91 levels, the area planted to irrigated cotton has nearly doubled, and within livestock production, the number of beef cattle in feedlots increased from 252,000 in March 1990 to 572,000 in March 2000.[29]

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25 This has been paralleled by a steady increase in the real total investment in pesticides (that is, total sales of pesticides as a proportion of total farm area). Source: Australian Academy of Technological Sciences and Engineering (2001), Pesticides Use in Australia: A Review.

26 Top exporters include wool, wheat, beef, veal, and dairy products, all of which rely heavily on the judicious use of agvet chemicals. The total value of exports of agricultural produce to North America, Japan, Korea and the EU is around $12.7 billion representing 43.5 percent of the total value of all agricultural goods exported. Source: ABARE (2001), Australian Commodity Statistics, p21.

27 ABARE (2001), Australian Commodity Statistics, p25.

28 ABARE (2001), Australian Commodity Statistics, p145.

29 Martin, P., Lubulwa. M,Chapman. L. and Love. G, (2001),'Farm Performance: future of farming – the challenge of change, in *Outlook2001*, Proceedings of the National Agriculture and Resources Outlook Conference, Canberra 27 February – 1 March, vol 2, *Agriculture*, ABARE, Canberra.

A consequence of this change has been movement from traditional agricultural industry, which was a relatively light user of agvet chemicals to modern and diversified agricultural industries, which use agvet chemicals more intensively.

Further growth in Australia's agricultural industry is likely to be driven by export growth rather than by production to supply the relatively slow growing domestic market. An imperative for Australia's agricultural industry is to obtain and retain access to important agricultural markets overseas. This will require that they are highly productive and produce high quality products. As discussed earlier, this in turn will require that they have appropriate access to agvet chemicals.

In recent years there has been a growth in Australia of farmers who have been converting to organic production methods. While this growth is likely to continue, it is not expected that organically produced food will become a substantial part of total agricultural production in the foreseeable future.

Conclusion

In the foreseeable future, agvet chemicals will remain important for Australian agricultural producers. Growth of the industry will come from export markets and to be competitive producers will need to have access to agvet chemicals.

2.5 Trade

The Australian agricultural sector is highly export oriented. Traditionally, agricultural trade has been heavily influenced by both agricultural protectionism in Western Europe, North America and Japan and the regulatory framework for food safety including registration and usage of agvet chemicals and the establishment of MRLs for such chemicals in particular food products. These issues are extremely important for the development of Australia's agricultural exports.[30]

Recent events in Western Europe have highlighted that community concerns are driving changes in food regulations in important export markets. Such community concerns have resulted in pressures being placed on the EU and member states to adopt the precautionary principle in regulating matters relating to food safety, including trade, and to include provisions based upon it in international agreements. At this stage, it is too early to say whether the EU will be successful in including factors other than science results in international agreements in the face of opposition from North America and the world's leading exporters of agricultural products.

The political environment in which agvet chemicals are being discussed at international levels, particularly Europe, threatens to make food import regulations more complex and burdensome for Australian exporters and less predictable for both exporters and regulators. This reflects the move to incorporate subjective measures into the regulatory process such as the

[30] As evidenced by the recent announcement by the Government in its *Growing Stronger – AFFA 2002-03* to allocate $102.4 million to develop a five-year 'National Food Industry Strategy'.

precautionary principle, factors other than science, and a greater weighting for consumer preference for reduced risk and enhanced certainty.[31]

Unpredictability in the regulatory process is especially challenging for both agvet companies and agricultural producers because of the additional time and cost involved in an evolving regulatory environment for registration. The challenge for Australia will be to assess the appropriateness of incorporating regulatory reforms in the US or EU, as they relate to agvet chemicals, into the national registration system. Given that the EU stands alone in its move toward subjective assessment measures, Australia should be extremely cautious before adopting the EU regulatory model, with reform only after the benefits have been clearly demonstrated.

In the light of complexities in the registration process, there is a disposition by major regulatory agencies to share/contain the costs of regulation and to harmonize processes, with this involving agreement on standard data sets, and establishment of lead regulators.[32] However, for a relatively small country like Australia that is both a regulatory and technology taker, there is a question as to whether Australia is disadvantaged by not having sufficient influence in the international arena where these decisions are made – both for political and commercial reasons.

While trade friction issues may be resolved through the WTO mechanisms, there are grounds for concern that the pressure of public opinion on food safety issues can undermine compliance with the main WTO agreements - the Sanitary and Phytosanitary Measures Agreement (SPS) and the agreement on Technical Barriers to Trade (TBT) - which endorse the use of international standards for matters such as import controls relating to food safety.[33] The recent EU beef hormones case has highlighted how food safety concerns have undermined the science-based regime that these trade agreements currently endorse.[34] Although these pressures have been most evident in Europe, they are likely to become equally strong in Japan and the US.

Apart from developments at the multilateral level, there has also been a significant trend in recent years to the establishment of major regional trade blocks. For example, the North American Free Trade Agreement now takes in the US, Canada and Mexico. At the time of writing, Australia is seeking a free trade agreement with the US. In the longer term, there is also the possibility of Australian negotiating free trade agreements with other major export markets in Asia. To the extent that Australia is successful in these endeavours, there will be opportunities for Australia to negotiate standards and systems that are mutually acceptable.

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31 In 2000, the EC adopted the precautionary principle as part of its agricultural chemical approval process as well as adopting a proportionate approach to regulation which is focused on the impact of a regulatory decision, such as the value of life, rather than being based on risk and risk management.

32 This is evidenced by the work that at is being undertaken under the auspices of the OECD, VICH, and Codex.

33 In the period September 2001 to March 2002 there were 397 notifications by individual countries to amend their SPS border measures. This represents an increase of 230 percent on the previous year with the underlying rationale behind these notifications questionable and potentially protectionist.

34 Report of the Appellate Body: EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R and WT/DS48/AB/R (16 Jan 1998).

Conclusion

There is a complex set of institutions that influence the international trading environment for food products which have used agvet chemicals in their production. The push by the EU to write the precautionary principle into relevant international agreements is likely to continue, potentially adding a new and unpredictable element to the currently science–based approach to regulation of food safety.

2.6 Regulation

Many consider the registration process undertaken by the NRA to be close to world best practice.[35] The relatively small number of agvet chemical incidents and the absence of ongoing trade issues are often cited as evidence of a system working well.[36] Notwithstanding this, there are a number of trends in regulatory practices that could see significant changes to the role and function of the NRA and/or other regulatory agencies involved in the management and oversight of agvet chemicals.

Most notable of these trends has been a number of recent agreements to develop a national approach to related regulatory areas, namely food safety and the occupational health and safety. Both of these have involved coordination and cooperation between the jurisdictions to adopt a consistent legislative framework. In particular, the development of the Australian food regulatory model has seen:

- The establishment of a national food safety standing committee, with State and Territory representation, to determine policy direction.
- A commitment to the sharing of information and an efficient use of resources between jurisdictions.
- Coordination of the provision of information to external stakeholders, including consumer associations and other NGOs.
- A system that reports to a Ministerial Council, where decisions are based on a majority and no one party has a right of veto.

While this approach is not dissimilar to that taken to establish the NRA, the features of the national food safety regime provide a mechanism for ongoing regulatory improvement. Such efforts to ensure a national approach in the area of agvet chemicals have been difficult, as evidenced by the fact that a number of key strategies identified in the 1998 ARMCANZ report on the management of agvet chemicals have yet to be implemented.[37] However, recent initiatives by the Agricultural and Veterinary Chemical Policy Committee (AVCPC) to provide national policy and strategic direction for Australia's agvet chemicals risk management system may have greater success, particularly if the need for a national regulatory system is accepted by all jurisdictions.

A further trend in the development of regulation has been the adoption of the principles of good regulation developed under the National Competition Policy

[35] As seen in the Australian Academy of Technological Sciences and Engineering (2001), Pesticides Use in Australia: A Review as well as submissions from Avcare, AVDA, Commonwealth Government Departments and some State Departments.

[36] Although, it is noted that some commented on the fact that limited testing is being undertaken and that measurement issues tend to be re-active.

[37] See the Agriculture and Resources Management Council of Australia and New Zealand (1998), A National Strategy: Management of Agricultural and Veterinary Chemicals.

by the Council of Australian Governments (COAG).[38] In essence these require that regulatory oversight focus on appropriately matching regulatory control to risk management, which regulation is the minimum necessary to achieve the desired outcome, and that regulation focuses on outcomes and performance rather than prescription. Applying these principles to the NRA could see a change in emphasis and a redirection of resources away from low risk registration towards high-risk issues, such as the re-registration program and enforcement provisions.

Along with principles of good regulation, legislative reform is increasingly requiring regulators to engage more with stakeholders and to ensure transparent, open access to decision making processes. This often involves holding public hearings, seeking submissions, and independent assessment of decisions by external parties. The consultation requirements in the legislation to establish the Office of Gene Technology Regulator highlight a possible future approach for the NRA.

Regulatory reform is also focussing on the reducing regulatory and compliance costs. The recent review into cost recovery by the Productivity Commission concluded that the NRA's current funding arrangements were inappropriate and that only non-core functions should be funded by user charges with core functions funded directly by Government.[39] In the light of this conclusion, pressure will mount for the Government to consider the appropriate funding mechanism for regulatory agencies like the NRA. Furthermore there may be a greater focus on how those funds are prioritised, with greater emphasis on matching funding to higher risk issues.[40]

Conclusion

Pressure for the reform of the national regulatory system for the management of agvet chemicals to ensure that regulation is optimal for Australia's needs will continue. Such pressure will focus on improving national coordination, stakeholder communication, matching regulatory oversight to risk management, and funding arrangements.

[38] COAG (1995), National Competition Principles

[39] Productivity Commission (2001), *Review of Cost Recovery by Commonwealth Agency: Inquiry Report 2001*

[40] This issue was raised in the NRA submission to this inquiry, which stated that staff believes that funding could be better matched to the risk profile of chemicals.

Chapter Three

International Perspective

Australia has developed a regulatory system for the management of agvet chemicals which in respect of its assessment of agvet chemicals is broadly consistent with best practice from overseas, but also attuned to Australia's special climatic and ecosystem circumstances and the presence of niche crops with special requirements.

Nevertheless, the reality that Australia has a highly export-oriented agricultural sector with a substantial proportion of exports going to the large markets in North America, Japan and Western Europe, means that it is critical that any review of drivers of the future management of agvet chemicals in Australia consider emerging issues in countries like the US and Europe. While the regulatory frameworks in place in the US and Western Europe are important in their own right, they are also important to the extent that these countries tend to be the regulatory leaders for many countries.

The fact that the major agvet chemicals companies are multinationals that operate across multiple regulatory jurisdictions also has implications for future directions in Australia's agvet regulatory system, particularly if multinationals increasingly lobby for Australian regulatory systems to be brought in line with regulatory systems in their major markets, eg the US and EU.[41]

It is clear that the regulation of agvet chemicals is changing in North America and Western Europe in response to external drivers, such as community pressures associated with the demand for high levels of food safety and the desire for an environmentally sustainable approach to agriculture.

The key messages for Australia from regulatory developments in North America and Europe can be usefully considered under the following headings:

- The future of agvet chemicals.
- Regulatory legitimacy.
- The whole food chain.
- Regulatory focus.
- Risk assessment versus risk management.
- International harmonisation.

3.1 The Future of Agvet Chemicals

In looking to the likely future significance of agvet chemicals to the agricultural sector, particular regard is needed for three main factors:

- the likely impact of breed technology and GMOs;
- the significance of the trend to organic foods; and

[41] This view was expressed both by Crop Life America, Croplife International, the UK Crop Protection Agency and Avcare.

- political intervention aimed at directly reducing the demand for and usage of agvet chemicals.

The potential for genetic engineering is very large and significant take-up has occurred, particularly in the US, in the use of GMOs. However, the future penetration of GMOs is likely to be slower than expected in both the US and the EU, where there is now a moratorium on the introduction of new GMOs. There are signs that the European Commission is seeking to have the moratorium reviewed on the basis of progress for the introduction of labelling and traceability requirements. Nevertheless, it is clear that in the next 10 to 15 years genetic engineering is not likely to seriously alter the overall position of agvet chemicals as a whole, although it may change the composition of agvet chemical usage.

The great bulk of the world's food requirements are met by agricultural producers using the complete toolbox of agvet chemicals. Nevertheless, the organic food movement is gaining momentum in many developed countries as consumers look for more choice. In Europe, Austria is considered to be a leader in consumption of organically produced food. There has also been growth in the consumption of organically produced food in the UK but such food still only accounts two percent of total food sales.[42] The combined domestic and export sales of Australian certified organic produce is estimated at $300 to $350 million per annum, which represents around 1 to 1.5 percent of agricultural production.[43] The upshot of this is that organic food production, while growing, is likely to remain a relatively minor component of total food production in the next 10 to 15 years.

A small number of countries in Northern Europe have taken action to directly reduce the usage of agvet chemicals by their agricultural producers. In some cases this has involved the application of significant taxes on pesticides. The UK government recently considered levying a tax on pesticides but subsequently decided not to proceed on the basis of a voluntary stewardship program developed by the UK Crop Protection Association and the British Farmers Organisation. There is no indication that such an approach to directly reduce pesticide use is likely to be adopted by the large agricultural producing countries in Western Europe, such as France, Italy, and Spain, nor in North America.

Having regard to these factors, our judgement is that agvet chemicals will continue to remain of critical importance to the agricultural produce of the developed world in the next 10 to 15 years. This view has been shared by recent major reviews of pesticides in both the UK and the US.

> " There is no doubt that the majority of our food will continue to be grown with the help of pesticides, at least for the foreseeable future"
>
> UK Curry Report (p90)[44]

[42] OECD (2001), Environmental Outlook 2001.

[43] The National Association for Sustainable Agriculture Australia Ltd. Website http://www.nasaa.com.au/main.html accessed 11 May 2002

[44] UK Curry Report (2002), Farming and Food a Sustainable Future, a Report of the Policy Commission on the Future of Farming and Food.

> "Overall, the Committee concluded that the Chemical Pesticides will continue to play a role in pest management for the foreseeable future, in part because environmental compatibility of products is increasing – particularly with the growing proportion of reduced-risk pesticides being registered with the EPA"
>
> US National Academy of Sciences Report (p3)[45]

3.2 Regulatory Legitimacy

Consumers in Europe and Japan have become increasingly concerned about food safety issues in Europe following a number of significant food safety scares relating to BSE, Foot and Mouth Disease, and Listeria. Highly public failures of intensive agricultural practices, have resulted in a loss of trust by European consumers in their domestic regulatory processes for agricultural production.

As trust in government process has been eroded, the legitimacy of European regulatory agencies has been subject to severe questioning and, in some cases, significant restructuring. Amongst other things, this has led to the decision to establish a European Food Safety Agency, the establishment in the UK of a Food Standards Agency, the merger of the UK Department of Agriculture Forestry and Fisheries with the Department of Environment to form the Department of Environment, Food, and Rural Affairs and the merger of the German Ministry of Agriculture with the Consumer Protection part of the Department of Health to form the Ministry of Consumer Protection, Food and Agriculture.

In contrast, in the United States the EPA and the FDA continue to enjoy significant community confidence.[46] To some extent this is due to the absence of any recent highly public food safety issue. However, this is also due to the fact that the EPA conducts its process in a more open and transparent manner and aggressively prosecutes breaches of its governing legislation.[47]

3.3 The Food Chain

While recent food scares in Europe have precipitated major regulatory changes, a trend for some time now in both the US and Europe has been the oversight of the food chain as a whole rather than just components of the production chain. The European Food Safety Agency and the UK Food Standards Agency have recently been given de facto authority to oversee the complete food chain. While in the US, the passage of the EPA's governing legislation, the *Food Quality Protection Act* in 1996, has seen the EPA take an overview/oversight role of the US food chain.

While Food Standards Australia and New Zealand (FSANZ) is responsible for national food safety regulation and oversight, its scope and jurisdiction is limited. As such, it is reasonable to say that no regulatory agency assumes or is granted a regulatory oversight role for the whole food chain in Australia.

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45 National Academy of Sciences Report (2002), The Future Role of Pesticides in US Agriculture.

46 The EPA is responsible for the regulation of agricultural chemicals and the FDA for the regulation of veterinary chemicals which are taken internally by animals. USDA is responsible for the regulation of veterinary chemicals which are applied externally to animals.

47 "Throughout its history the [EPA] has relied on a strong, aggressive enforcement program as the centrepiece of its efforts to ensure compliance with national environmental laws. Civil enforcement is one part of a broader program that includes both compliance assistance ... and criminal enforcement, which prosecutes those intentional or deliberate acts of non-compliance." Source: the Office of Regulatory Enforcement's website http://es.epa.gov/oeca/ore/index.html

In addition to government regulation, supermarkets (both in Australia and internationally) are implementing their own, and often more onerous requirements on agricultural producers, thus allowing retailers to market products as safe and of high quality.[48] However, the danger of leaving regulatory oversight to the market place is that controls may be based less on science than on marketing designed to placate consumer concerns at the expense of good science and optimal regulatory controls and hence result in unnecessarily higher agricultural costs.

3.4 Regulatory Focus

Regulatory change in the US and EU is driven both by external factors, such as consumer and environmental pressure, as well as internal pressures, such as government policies to continually improve and enhance the regulatory process.

The main programme for review being undertaken in the US is the re-registration program. This involves re-testing legacy chemicals that were approved without the benefit of today's technology and review processes. A similar review process is set to be undertaken in the EU and it is anticipated that it will lead to a significant reduction in the availability of some agvet chemicals. The current register is expected to decrease from around 800 actives to around 300.

The review will specifically examine the EU Pesticide Directive 91/414 and is likely to lead to the incorporation of comparative assessments, use of the substitution principle (ie the unilateral removal of older chemicals if new safer chemicals are available), a stricter interpretation of the precautionary principle, and enhancement of animal welfare, health and environment provisions.

A consequence of increased regulatory hurdles and continual review programs has been that the agvet companies have been less willing to undertake the necessary expense to register some minor use agvet chemicals, even for large markets like the US. To address this situation the EPA in the US operates a program (the IR-4 program), which provides financial support to assist minor crop growers to develop residue data for continued registration. Australia does not have such a program.

Science and non-science criteria will be incorporated in the registration process with the potential for new safer chemicals allowing for older chemicals to be deregistered. In the US, the scientific advisory panel is increasingly addressing policy issues and in the UK non-scientific experts are now included on several UK scientific committees.

Regulatory priorities are for registering safer chemicals. For example, Canada's proposed new *Pest Control Products Act* will require special protection for infants and children, as well as support risk reduction outcomes by encouraging the registration of lower-risk products.[49] However, given the resource

[48] In Europe the leading European food retailers have come together through the Euro Retailer Produce Working Group (EUREP) to establish an agreed approach to agricultural production standards and verification frameworks for fruits and vegetables. The document is EUREPGAP Fruits and Vegetables which incorporates good agricultural practice. First accreditation certificates were issued in 2001. In the UK leading supermarket chains such as Tesco, Marks & Spencers, Sainsbury's and Safeway are all members of EUREP and applying practices consistent with EUREPGAP to their suppliers in both the UK and internationally.

[49] Taken from Canada's Pest Management Regulatory Agency web site. http://www.hc-sc.gc.ca/pmra-arla/english/aboutpmra/about-e.html.

requirements to review legacy chemicals and the need to prioritise new chemicals there can often be a backlog of registrations. This is compounded by an ever-increasing demand for certainty and safety in the approval of new chemicals.

A relatively recent regulatory initiative in both the US and EU has been the focus on chemical cocktail and cumulative effects. Given the difficulty in analysing these issues, the need for sound scientific measures has dictated the use of probabilistic modelling. At present, the NRA does not use these models.

3.5 Risk Assessment versus Risk Management

A common feature of the regulatory process in the US and Europe relates to the gap between risk assessment, which is undertaken by the central government, and risk management (chemical registration, labelling and control of use), of which control of use is conducted at the state or member state level.

At this stage, a fully coordinated approach to the management of agvet chemicals does not exist in either the US or Western Europe, however, action has been taken in both jurisdictions to improve coordination. For example, in the US, the EPA uses money to influence risk management (control of use) by the various states. However, in general, financial grants tend to be small in relation to the budgets of state regulatory agencies. For example, only 2% of the California control of use budget comes from the EPA. In Europe there is a specialist agency based in Ireland that reports on control of use performance of member states. Furthermore, there are proposals to tie subsidies from the Common Agricultural Policy (CAP) to the control of use, thus redirecting the CAP away from agricultural intensification towards encouraging agricultural quality, perhaps even organic farming.[50]

The implication is that risk management and control of use will increasingly be a focus of concern in the EU and perhaps in the US.

3.7 International Harmonisation

There are a number of forums in which regulatory agencies discuss issues relating to harmonisation of processes and regulatory requirements.

For veterinary chemicals, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) has aimed at harmonising technical requirements for veterinary product registration since its establishment in 1996. The VICH, a trilateral programme between the US, Japan and the EU, provides a forum for a constructive dialogue between regulatory authorities and the veterinary medicinal products industry on the differences in the technical requirements for product registration in the EU, Japan and the USA. While Australia only has observer status in this forum, most of the VICH initiatives have been adopted by the NRA.

For pesticides, the OECD has been the main driver of international harmonisation since 1992. Steady progress has been made in harmonising data requirements, testing guidelines, risk assessment methods and in promoting measures to facilitate the sharing of work of pesticide reviews. A recent

[50] UK Consumers' Association Policy Report (2001), Setting aside the CAP- The Future for Food Production.

important milestone has been agreement on common formats for the submission of dossiers by industry and for the writing of evaluations (monographs) by government regulatory authorities. Work has now started on a project to map the world in zones in which residue behaviour would be comparable.

In terms of international standards, the Codex Alimentarius Commission, a subsidiary body of the Food And Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations, develops international food standards to promote food quality and safety. The scientific evaluations undertaken by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Joint Expert Committee on Food Additives (JECFA) have been significant inputs into the setting of over three thousand MRLs for pesticide and veterinary chemical residues.

Despite these forums, an all-embracing harmonised global system that includes single global risk assessments and single global regulatory decisions is neither feasible nor desirable. An OECD workshop in February 2001 accepted that some differences were unavoidable and, in some cases, necessary. It saw a situation in which one common dossier containing the core data would be reviewed once to an agreed timetable and then become available to be used by others. However, responsibility for conducting risk assessments and making regulatory decisions would be retained at the national level.

By 2010 it is probable that work sharing between the principle OECD regions and countries will be well established and that other bodies participating in international reviews, such as the FAO/WHO Joint Meeting on Pesticide Residues, CODEX and the Rotterdam Convention on Prior Informed Consent, will also have become involved.

Conclusion

The last decade has seen a trend in both North America and Western Europe toward increasing regulation of agvet chemicals, which has generally been undertaken in the name of ensuring that public health, environment, and occupational health and safety side effects of particular agvet chemicals are identified and dealt with in the registration and control of use process.

The re-registration process for legacy agvet chemicals registered prior to present day regulatory processes is now well advanced in both the US and Western Europe. The NRA itself is currently going through a re-registration process for its legacy agvet chemicals.

The US *Food Quality Protection Act 1996*, resulted in significant changes being made in the way the EPA registers agricultural chemicals. This was particularly so in respect of cumulative effects. A driving philosophy of the EPA is to give priority in terms of new chemical registration to those products which are seen to result in lower risk to the community. It has also provided a special track for the registration of bio-pesticides.

Nevertheless, in both North America and Western Europe non-government organisations representing consumers and environmentalists are pursuing agendas that are likely to lead to more intense scrutiny of agvet chemicals.

Looking ahead for the next 10 to 15 years, it is likely that the approaches being followed by regulatory agencies in North America and Western Europe will be in the direction of increased and more sophisticated regulation.

Chapter Four

The Future Management of Agvet Chemicals

4.1 A Challenging Environment for Agvet Chemicals

We have examined, both in Australia and in major overseas centres in North America and Western Europe, the major drivers of the regulatory environment for agvet chemicals over the next 10-15 years. While it is difficult to read the future, such a foresighting exercise has the merit of identifying broad trends which are likely to be important and which will influence community attitudes and the political process, and hence the development of public policy.

Important developments identified that are shaping the future agvet chemicals environment are:

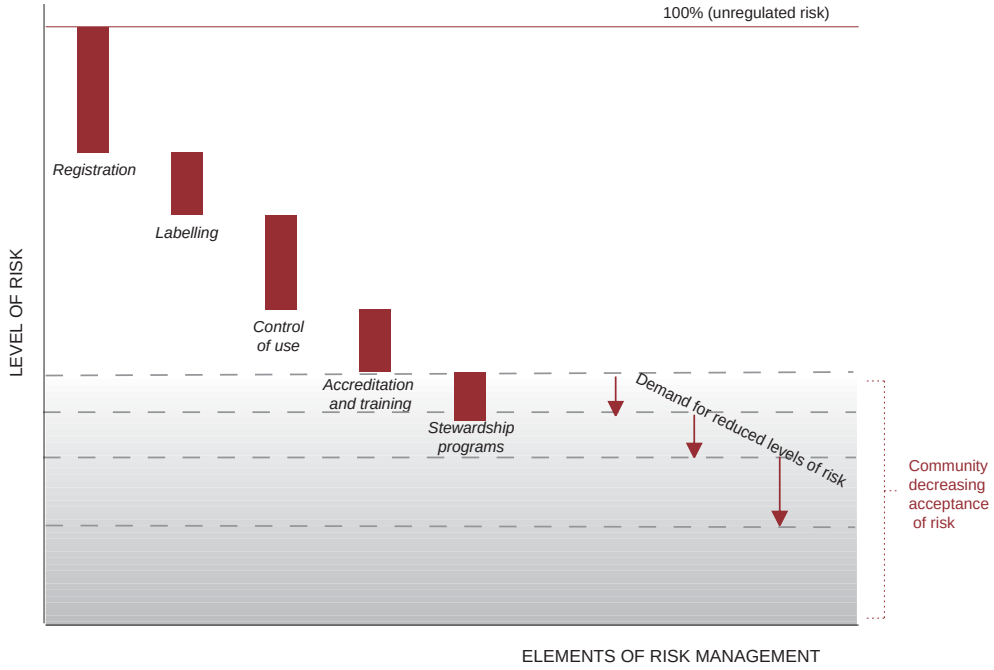
- Changing community attitudes towards risk, with the amount of risk societies are prepared to tolerate falling (see Figure 4.1). Individuals are prepared to tolerate risk where they feel they are in control, but their tolerance for risk is severely reduced where they feel it is beyond their control and action by society is required.
- A desire for greater information and transparency about risk factors and how they are being managed. Consumers are no longer willing to regard the food supply system as a black box — they want to look inside it.
- Concerns by the community for reassurance about the integrity of the food chain not only relates to food safety and health, but also to the effect of food production, transport and distribution on the environment.
- Australia as a major exporter of agricultural products is inevitably affected by changing regulatory requirements for food products in its major export markets. Regulatory changes in these countries will have important implications not just for local food producers, but also for foreign suppliers.
- On the supply side the biotechnology revolution will eventually have a very substantial impact on agriculture. However, the best judgement at the moment is that biotechnology will not replace the need for agvet chemicals in the next 10–15 years.
- There is a clear trend in the advanced countries, especially in Western Europe but reflected to some extent in Australia, towards organic agriculture. Nevertheless, it is generally accepted that over the time period we are interested in, organic agriculture is unlikely to significantly replace traditional agriculture.

The upshot of these drivers and trends is that agvet chemicals will remain important for agricultural production in the next 10–15 years, but that the environment influencing the regulation and management of agvet chemicals will become more challenging with important implications for governments and other stakeholders.

Figure 4.1 shows a schematic representation of the main elements of the agvet chemicals risk management system: registration, labelling, control of use, accreditation and training, and stewardship programs, and the way they contribute to reducing risk. It also shows the community's increasing demand for reduced levels of risk, and hence the pressure to lift the performance of the whole system, of which major elements are the direct responsibility of the regulators with other elements the responsibility of the agvet chemical industry and the users of agvet products.

Figure 4.1

THE CURRENT SYSTEM RELATIVE TO THE COMMUNITY'S RISK TOLERANCE



Source: The Allen Consulting Group

While our focus is on the regulatory environment, the good management of agricultural chemicals also depends on the producers of such products, the people that apply them and farmers. It is notable that the agvet chemical companies are responding to regulatory and economic pressures by developing "softer" and more targeted products and implementing stewardship programs. Farmers are adopting much more precise and controlled agricultural management methods and some are obtaining the training needed to properly apply agvet chemicals, however, further progress is needed in this area.

Box 4.1

SELF-REGULATION: RESPONSIBILITIES OF NON-GOVERNMENT PARTICIPANTS

Australia's performance in the management of agvet chemicals depends not only on the actions of regulators but also the direct participants. A number of voluntary initiatives have been taken by industry, farmers, and supermarket retailers, which serve to address issues of risk and community concern.

Agvet Chemical Companies

Australia agvet producers – in conjunction with farmers and government – have implemented a number of stewardship programs, including Agsafe (a co-regulatory stewardship program which provides training and accreditation to retailers), Industry Waste Reduction Agreement (which aims improve the use and reuse of containers for agvet chemicals), drumMuster (which is a container management program) and ChemClear (which is an industry-funded program for on-going collection and disposal of unwanted registered chemicals to commence in 2003-4)

Farmers

There are several voluntary quality assurance programs initiated by Australian farmers including ChemCert (a national training program), FlockCare (for sheep producers), CattleCare (for Cattle producers) and FreshCare (for horticultural producers). These quality assurance programs have become increasingly popular with producers and have extended to chemical usage, with schemes requiring producers to record details on chemical application and storage and contribute to increased chemical awareness and record keeping.

Supermarkets

Supermarkets and other purchasers of agricultural produce are requiring assurances from producers on the type and degree of chemical usage on products – eg wheat delivered to reception sites around Australia must be accompanied by an assurance that the grain has not been treated with certain chemicals. This trend is reflected in practices in Europe where in the UK leading supermarket chains such as Tesco, Marks & Spencers, Sainsbury's and Safeway all impose requirements on their suppliers consistent with EUREPGAP (an agreement on agricultural production standards and verification framework for fruit and vegetables).

Future Role for Self-Regulation

Voluntary initiatives from industry, farmers, retailers, or others involved in the production and/or use of agvet chemicals should be facilitated and encouraged under any agvet chemicals management regime. At the same time though, the limitations of such schemes should be recognised, with compliance often voluntary and their scope limited to the specific groups, eg farmers or agvet chemical producers. Governments, policy makers, and regulators should, as part of their regulatory and planning roles, work closely with the associations and organisations promoting these voluntary stewardship schemes, so as to maximise the benefit to the community and reduce the limitations of self-regulation.

Looking forward, future voluntary stewardship programs could be quite effective in addressing outstanding issues, such as agvet chemical producers committing to a 'whole-of-life' responsibility for agvet chemicals that they sell.

Source: The Allen Consulting Group

4.2 What Would an 'Ideal System' for the Management of Agvet Chemicals Look Like?

To provide a perspective on the adequacy of the existing Australian system for the management of agvet chemicals, it is instructive to spell out the elements of an ideal system which would be developed if we were starting with a clean sheet of paper.

4.2.1 The Objective

The starting point for the ideal system is the overall objective for it. Taking as a basis the legislative requirements for the NRA, one statement of the objective is that it is:

To protect public health, the environment and occupational health and safety, while ensuring that trade implications are taken into account and that agricultural producers have access to agvet chemical tools needed for competitiveness and sustainable agricultural production.

This approach is consistent with overseas regulatory agencies such as the Canadian PMRA whose mission is:

To protect human health and the environment by minimising the risks associated with pest control products, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

4.2.2 Design Principles

We have identified seven principles which we believe should be the basis for designing an ideal agvet chemicals regulation and management system. These are:

- *Principle One — A Seamless System*

  In order for the system to operate effectively, common purpose and integration needs to be achieved across the different elements of registration, labelling and control of use. The absence of such integration will create gaps in the system and the potential for systemic failure and make the identification of clear lines of responsibility and accountability much more difficult.

- *Principle Two — Strong Feedback Loops*

  It is highly desirable that there are strong feedback loops between the different elements of the system. For example, between the registration process and decisions on labelling on the one hand, and consequences that emerge in the field on the other, so that necessary adjustments to reflect learning in practice can be applied quickly.

- *Principle Three — Flexibility to Respond to Emerging Issue*s

  The system should be constituted in such a way that it can respond quickly to new and emerging issues. This is desirable both in terms of ensuring risk is properly identified and managed and that new, softer products can be quickly introduced.

- *Principle Four —Provision for Continuous Improvement*

  In an area which ought to employ the latest scientific knowledge available, both in terms of the agvet chemicals themselves and good agricultural practice, it is desirable that the system is such that it fosters, rather than hinders, an ongoing search for improved practice.

- *Principle Five — Confidence in the Regulatory and Management Process*

  Confidence can only be built by adequate provision for transparency in decision making, putting the necessary information for making judgements into the public domain, and making adequate provision for consultation by stakeholders.

- *Principle Six — Effectiveness and Efficiency*

  As with other areas of regulation, agvet chemicals regulation should be in accordance with the COAG principles which require that regulation should be the minimum necessary in order to achieve effectively the public interest objectives being pursued.

- *Principle Seven — International Confidence*

  Because of Australia's position as a significant exporter of agricultural products, the agvet chemicals registration and management system needs to be at international best practice levels.

4.2.3 Capabilities and Resourcing

An essential part of an ideal system for the management of agvet chemicals is that the agency (agencies) charged with carrying out the function have access to people with the right skills and capabilities to perform their functions. The essentially science–based nature of the regulatory system means that the regulatory agency should ensure that its skill base is kept up–to–date and that it is able to access the best available scientific advice.

The resourcing of the regulatory agency is also important and must be proportionate to the agency's responsibilities. A clear imbalance between responsibilities and resourcing will quickly lead to a breakdown in community confidence.

4.3 How Does the Present System Compare to the Ideal?

The present system of agvet chemicals management in Australia represents something of a halfway house, with neither the Commonwealth nor the States having clear responsibility for the total system. Up until the establishment of the NRA in the mid 1990s, responsibility for the complete agvet chemicals management system lay with the individual States. A consequence was that there was no national system with all that entailed in terms of duplication of effort, inability to build critical mass of specialist resources and complexity and cost of process.

The establishment of the NRA meant movement to a single national system as far as the registration and labelling of agvet chemicals is concerned. This is generally regarded as having improved the operation of the overall system of agvet chemicals management. However, control of use of agvet chemicals remains the responsibility of the States.

Box 4.2

THE CURRENT SYSTEM FOR THE MANAGEMENT OF AGVET CHEMICALS: KEY ELEMENTS

1. Responsibility is divided between the Commonwealth and the States/Territories
2. The National Registration Authority for Agvet Chemicals has responsibility for the registration and labelling of agvet chemicals. These responsibilities extend to the point of sale of agvet chemicals.
3. The States/Territories have responsibility for the control of use of agvet chemicals beyond the point of sale. Responsibility for control of use is exercised by Departments of Agriculture, Environment Protection Agencies, or Departments of Health. In some States responsibilities are divided between agencies. Control of use can involve elements such as licensing of applicators, training and accreditation of applicators (including farmers) and field officers (including testing for residues).

Source: The Allen Consulting Group

The present system clearly fails the first design principle for an ideal system in that it does not provide for a seamless and fully integrated system, with the Commonwealth responsible for registration and labelling and State Governments responsible for post-registration activities, such as control of use, training and accreditation.

Partly for structural reasons associated with the separation of responsibilities for certain aspects of the overall agvet chemicals management system and partly for process reasons, there is inadequate provision within the current system for feedback loops in some important respects.

The complexities of the legislation establishing the NRA as a Commonwealth/State endeavour has in some respects meant that the ability of the NRA to respond quickly and flexibly to emerging issues has been constrained.

The lack of a seamless system, the weakness of feedback loops and the difficulties of responding flexibly to new circumstances places limits on the ability of the overall agvet chemical system to demonstrate continuous improvement. This is not to say that no improvements have been made, but rather that constraints exist on the ability to engage in continuous improvement.

The experience in Western Europe and North America has shown the absolute importance of maintaining confidence in the integrity of the regulatory system. While we believe there are a number of things which the NRA can do to improve its performance in this direction, the current fragmented nature of responsibility for the overall management of agvet chemicals limits the extent to which confidence in its overall effectiveness can be developed.

There are clear pressures at both the Commonwealth and State levels on regulators to achieve their objectives in the most efficient and effective ways possible. It is likely however that the separation of responsibilities inherent in the existing system of managing agvet chemicals means that opportunities for greater effectiveness and efficiency are being missed.

Australia's major export markets are looking for assurance about the integrity of food products coming from Australia. The lack of a seamless national system of agvet chemicals management makes the task of convincing our major export markets in this respect more difficult.

The upshot is that the current Australian arrangements for managing agvet chemicals, as indicated in our assessment in Table 4.1, fall short in important respects of what would be expected in an ideal system. The issue for the community is whether the gains from moving toward the ideal warrant the effort that would be involved.

Table 4.1

HOW DOES THE CURRENT SYSTEM STAND UP AGAINST THE IDEAL?

Design principles	Rating of curren system relative to ideal	Need for reform
A Seamless system	1	Requires structural reform
Feedback loops	1	Requires process reform
Flexibility	1	Requires process reform
Continuous improvement	1	Requires structure/process reform
Confidence	3	Requires process reform
Effectiveness and Efficiency	3	Review periodically
International confidence	3	Requires structural reform

Scored out of 5. The higher the score the greater the alignment with the ideal.

Source: The Allen Consulting Group

4.4 Why Business–As–Usual Plus Incremental Change is Unacceptable as a Way Forward

In an environment where access to export markets is critical to Australian agricultural producers, it is not good enough for Australia to be an average performer in terms of agvet chemicals risk management — it needs to be able to demonstrate that it is one of the leaders in this important field.

The community (both local and international) are becoming less tolerant of risk and are looking for high levels of integrity in regulatory systems for ensuring food safety and good agricultural practice.

Because Australia's agriculture is highly export oriented, with future growth in that sector coming overwhelmingly from export markets rather than supplying the local market, and the fact that Australia is not a member of NAFTA or the European Union, Australia is particularly exposed if serious adverse events were to occur which impacted on agricultural exports to major markets. In the event that Australia's regulatory system were seen to be less effective than it might be, significant detriment could be suffered by important parts of Australian agriculture, taking years to rectify.

It has to be of major concern that the present arrangement for management of agvet chemicals falls short of the ideal system. The current system is fragmented across Commonwealth and State responsibilities resulting in a lack of a uniform national approach that has the potential to undermine community and international confidence in Australia's system. Significant differences in State approaches and resourcing of the control of use function detract from a seamless system and contains the seed for a significant adverse event in the future. Box 4.4 illustrates some of these State differences.

Box 4.4

STATE/ TERRITORY RESOURCING OF CONTROL OF USE FUNCTION

In order to understand the approach of the States/Territories to the control of use function and their resourcing of it, we looked more closely into what is being done in three States: New South Wales, Queensland, and Western Australia.

New South Wales

The EPA has main responsibility for control of use of agvet chemicals. Over the last 5 years funding has increased somewhat with 18 full time staff engaged in the pesticides management program at a cost of $2.1 million per annum.

The NSW Department of Agriculture is only responsible for veterinary chemicals, and in NSW most ectoparasiticides are classed as pesticides for the purpose of control of use.

Queensland

The Department of Primary Industries has responsibility for the control of use of agvet chemicals. Regulation and extension work are carried out under two programs: (1) Responsible Use of Agvet Chemicals and (2) Chemical Residue Management. Control of use is not a separate program hence it is difficult to assess the level of resources devoted to it. Advice from the Department is that resources devoted to control of use has been reduced in the last decade. However, chemical control of use programs are being reviewed and it is anticipated that resources will be increased in 2002/03.

Western Australia

The Department of Health is the main agency responsible for control of use of agvet chemicals. It has 6 fulltime staff with a budget of $320,000 per annum. The Department licenses everyone who is employed for gain or reward in the application of agvet chemicals. The Department uses Local Government environmental health officers for local work.

The Department of Agriculture, which has responsibility for the licensing of aerial applicators of agvet chemicals, has 3 fulltime staff. It is expected that responsibility for this function will be shifted to the Department of Health in the near future.

There appears to have been some reduction in resourcing for control of use over the last decade.

Conclusion

Resourcing of control of use by the States/Territories appears to have been slightly down or at best constant over the last decade. Prima facie this seems inadequate in the face of changing community attitudes towards risk relating to food safety and environmental issues and the international trade exposures.

Differing control of use regimes does have resource implications for the NRA, having to deal with 8 different regimes.

Source: The Allen Consulting Group

It is against this background that we have reached the judgement that the time has come to embrace the need for taking the existing system of agvet chemicals to a new and much more effective level. Our judgement is that while business–as–usual plus incremental change can move the current system forward, improvements will not be general enough or happen sufficiently quickly to eliminate the risk of Australia facing a major adverse event in the next 5–10 years.

The stakes are high. It is not unreasonable to envisage a situation arising in which in response to a major adverse event associated with agvet chemicals use in Australia one, or all, of Australia's biggest trading partners - Japan, Korea, the EU and the US who between them account for around $13 billion in Australia's agricultural exports – could impose bans on the importation of Australian produce.[51] Such bans would entail high costs in terms of lost jobs, incomes and regional dislocation. Reforming the current system for the management of agvet chemicals to move to a truly national system would be a relatively small investment to make to avoid paying a high price for systemic failure in the future.

[51] As noted by FSANZ in their July 2002 submission to the national research priorities process being conducted by the Chief Scientist : "Although chemical hazards in the food supply have been addressed

Chapter Five

A National Risk Management System for Agvet Chemicals

5.1 Australia Needs a World Best Agvet Chemicals Risk Management System

Australia's predominantly export oriented agricultural sector, which exported goods worth A$30 billion in 2000/2001, will continue to be important for Australia in terms of GDP, exports, and its contribution to the economic wellbeing of rural and regional Australia.

Agvet chemicals are a critically important input to Australia's agricultural sector. Despite prospective developments in biotechnology and genetic engineering, increasing demand by consumers in developed countries for organically grown food, and the move in some Northern European countries to directly reduce the use of agvet chemicals, we conclude that over the next 10 to 15 years the use of agvet chemicals will remain an important part of the tool box of instruments available to agricultural producers.

At the same time, agvet chemicals use must be seen in the context of an environment of decreased community tolerance for risk and increasing expectations about environment protection and good agricultural practice. In such a situation the onus is on agvet chemical producers to demonstrate to the regulator that their products are safe when used according to the instructions and on the users (and applicators) of agvet chemicals to demonstrate they have the necessary training and knowledge to use agvet chemicals appropriately. In reality the use of agvet chemicals is a privilege accorded by the community on the basis that certain conditions are met rather than an unlimited right.

To meet the community's concerns about the potential risks associated with agvet chemicals use, while ensuring agricultural producers continue to have access to agvet chemicals needed for internationally competitive production, it is imperative that Australia has in place not just an effective but a world best agvet chemicals risk management system.

The components of a modern agvet chemicals management system are shown in Figure 5.1 below. This underlines the reality that more is involved than Government regulation of assessment, registration and labelling, and control of use – access to technology, the skills of users, good communications, and participation in international policy development are also important.

over a period of decades, there are nonetheless new chemical hazards emerging constantly.….the ongoing emergence of chemical hazards continues to challenge the safety of the food supply". (p7).

Figure 5.1

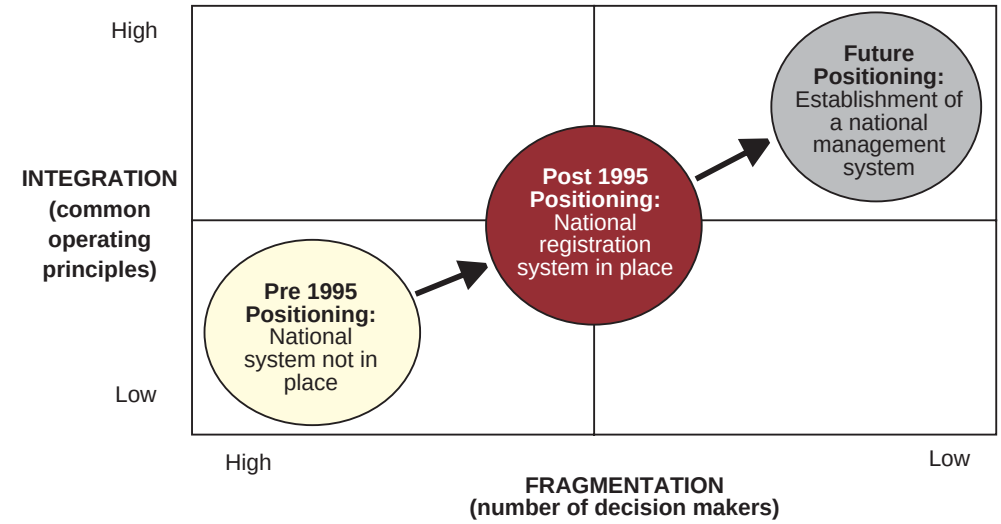
COMPONENTS OF A MODERN AGVET CHEMICALS MANAGEMENT SYSTEM

Source: The Allen Consulting Group

Progress was made in the early 1990s with the adoption of the National Registration System for agvet chemicals and the establishment of the NRA, but those reforms focused on registration and labelling of agvet chemicals and as such can only be seen as a step, albeit an important one, towards the establishment of a truly national risk management system for agvet chemicals. The issue is how to move from the present situation to the future positioning shown in Figure 5.2, with a high degree of integration (adoption of common operating principles) and low fragmentation (a small number of decision makers).

Figure 5.2

POSITIONING OF THE AGVET CHEMICALS MANAGEMENT SYSTEM



Source: The Allen Consulting Group

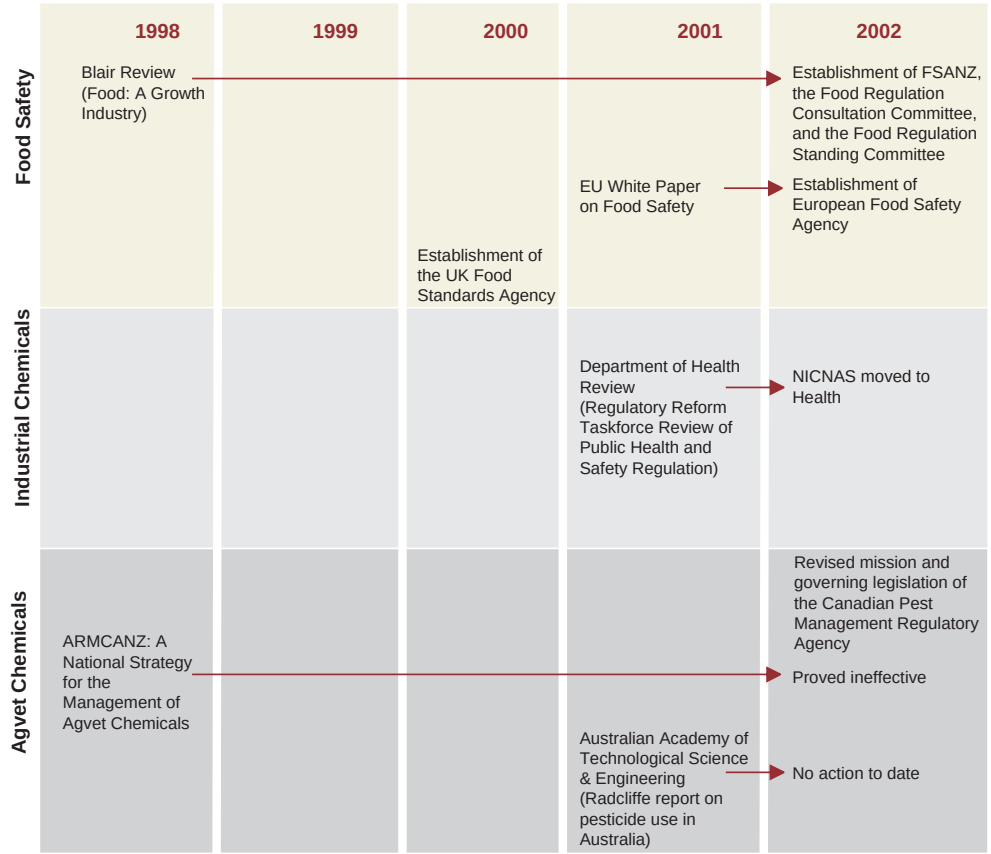
The analysis presented in Chapter Four concluded that business-as-usual coupled with incremental change is not sufficient to meet future needs. Accordingly, it is essential to identify what must be done to establish a world best national agvet chemicals risk management system. The experience in Western Europe, including the UK, in recent years with the response of the community and governments to a series of food safety issues shows that once a crisis point is reached far reaching changes are likely to be introduced overnight. The risk with such an approach is that change may go too far, thus imposing costs that may take many years to remove.

For Australia, in the absence of an immediate crisis, there is a choice: either undertake reform now that is appropriately considered and openly discussed before implementation or face the possibility of a 'knee-jerk' reaction in response to community outrage at a perceived risk to public health or the loss of important export markets. Clearly the first option is to be preferred.

The need for progress in this area is further highlighted by the fact that progress on the risk management of agvet chemicals has not kept pace with developments in related regulatory areas. As illustrated in Figure 5.3 a good deal of attention has been given to the food safety regulatory system both in Australia and elsewhere.

Figure 5.3

STRATEGIC REVIEWS AND RESULTING REFORMS



Source: The Allen Consulting Group

To remedy this, and to put in place the components of a modern agvet chemicals management system shown in Figure 5.1, action is required in a number of areas relating to structures, content and processes. Reform of this kind will only be possible with the co-operation of the Commonwealth and State Governments. Furthermore, to build confidence in the new system, this process must be undertaken in concert with industry, consumers, and other stakeholders.

5.2 Reform Options

The current agvet chemicals risk management system is fragmented and not well integrated. To address this, two broad structural approaches suggest themselves to reposition the agvet chemicals risk management system in the way shown in Figure 5.2. These involve either vertical integration or horizontal integration. Each are discussed in turn with two options being identified under both.

Horizontal Integration

Reform Option One: Horizontal Integration under a New Agency

This option involves establishing a new agency, the Australian Pesticide Safety Authority, and ensuring that all elements of the Commonwealth Government's responsibilities for agvet chemicals risk management reside within that agency. This would mean transferring to the new agency all elements of the Commonwealth Government's responsibilities from a range of agencies (including specific functions, staff, and resources) related to agvet chemicals and consolidating those functions in the Australian Pesticide Safety Authority. Agencies would continue to be responsible for roles other than those that relate to agvet chemicals. The agencies this reform option would potentially impact on include:

- NRA all current functions;
- Office of Gene Technology Regulator functions that relate to the registration and approval of genetic or biotechnology agvet products;
- FSANZ functions that relate to the setting of MRL's for agvet chemicals;
- National Occupational Health and Safety Commission (NOHSC) functions that relate to occupational health and safety and agvet chemicals;
- Environment Australia functions related to environmental impact of agvet chemicals production and use;
- Department of Health functions relating to agvet chemical use, incidents, or related areas;
- Australian Quarantine and Investigation Service (AQIS) functions relating to monitoring of agvet chemical imports and any other trade related matter.

While the NRA already carries out some of these functions to some extent, this reform option envisages all activities being performed within the one agency without reference to or input from other agencies. That is, the Australian Pesticide Safety Authority would act as, and be seen to be, the only agency responsible for the management of agvet chemicals.

This reform option would see the States retain responsibility for control of use. Ensuring a coordinated national approach to control of use would require negotiation between the Australian Pesticide Safety Authority and the States.

The advantages of this option are that it consolidates into a single agency all regulatory functions relating to agvet chemicals that are currently undertaken by the Commonwealth.[52] This would allow for seamless coordination of those regulatory issues. Furthermore, it would allow for the Australian Pesticide Safety Authority to use its single agency status to raise the profile of the management of agvet chemicals and therefore to build community confidence that the risks of agvet chemicals are being appropriately managed.

The main disadvantage of this option is that it would not adequately address the key design principle of establishing a seamless national system. The Australian Pesticide Safety Authority and/or the Department responsible for policy matters would still need to negotiate with States on issues relating to control of use, accreditation, training, record keeping etc. Furthermore, this option would be administratively difficult, as separating out sub-components, resources, and staff of regulatory agencies or departments may not be possible and could certainly be quite costly.

Reform Option Two: Horizontal Integration under a Commonwealth Department

Under this option responsibility for all agencies and departmental functions at the Commonwealth level relating to agvet chemicals would be consolidated in one Department. This would involve placing administration and policy responsibility for all bodies responsible for agvet chemicals, including the NRA, to either the Minister for Agriculture (under AFFA) to the Minister for Health (under the Department of Health), the Minister for the Environment (under Department of Environment and Heritage), or the Minister for Workplace Relations (under NOSHC)

This would mean that all policy issues relating to therapeutic goods, food safety, occupational health and safety, gene technology, and chemical safety could be coordinated within one Department.

As with *Reform Option One*, the State's would retain responsibility for control of use, with a national approach to control of use requiring coordination between the States and a single Commonwealth Department.

The advantage of this option is that it ensures that a related set of policy issues fall under the responsibility of one Department and hence it would result in coordinated policy decisions subject to the legislative requirements of the agencies concerned. It could alleviate a perception of some stakeholders that the current agvet chemicals system is captured by agriculture and/or the agvet chemicals industry.

[52] In line with good regulatory practice it would be inappropriate to pass policy functions to Australian Pesticide Safety Authority. Therefore it is envisaged under this option that policy matters relating to the Authority would reside within a single Commonwealth Department.

In addition to not adequately addressing the key design principle of establishing a seamless national system, the disadvantage of this option is that it could lead to a disconnect between agriculture departments in States responsible for control of use. Furthermore, it may result in a narrower focus for agvet chemicals to the detriment of broader policy objectives, eg public health concerns could dominate over considerations relating to agriculture and trade and the environment.

While administratively this option is less complex to put into practice, it would not address the central issue of national coordination of control of use, training, etc.

Vertical Integration

Reform Option Three: Vertical Integration under a New Agency

This option would see the establishment of a new agency, the Australian Pesticide Safety Authority, which would be responsible for management of all issues related to the registration and use of agvet chemicals in Australia. The vertically integrated Australian Pesticide Safety Authority would be responsible for the functions currently undertaken by the NRA as well as functions currently undertaken by the States, such as control of use, training, record keeping, etc.

The advantage of this option is that it would fully satisfy the design principles discussed in Chapter Four, namely, it would create a seamless system, with strong feedback loops, the potential for flexibility to respond to emerging issues, provision for continuous improvement, and it could engender domestic and international confidence in the management system.

The vertically integrated agency would still be required to manage interfaces with other organisations to ensure that relevant information is accessed. For example, care would need to be taken that the key linkages between State agencies and the farming community are not lost.

Notwithstanding the potential for significant improvements in the management of agvet chemicals in Australia, this option requires the co-operation and agreement of the State's to pass the responsibility for post-registration of agvet chemicals to the Commonwealth. Achieving such cooperation would require significant effort on the part of the Commonwealth to convince the States that it would be in the national interest for them to cede power to the Commonwealth to enable a vertically integrated national agency to be established.

Reform Option Four: Vertical Integration through the Adoption Of National Operating Principles

This option would see the Commonwealth and the States establish 'National Operating Principles' for the management of agvet chemicals, which are to be adopted by the States/Territories. These principles would focus on a standard methodology and approach to monitor and enforce use of agvet chemicals in accordance with registration and labelling requirements.

State and Territory Governments would retain responsibility for administration of control of use programmes and all other post-registration and labelling activities, such as training and accreditation.

States/Territories would be required to submit an annual report to a National Committee of Commonwealth/State Ministers on the management of agvet chemicals in their State, including reporting use patterns, incidents of health and/or environmental problems, trends and other initiatives.

An independent agency would audit the performance of the State/Territories administration and issue a report to the National Committee of Ministers, which would be made public.

This option could be facilitated through the Agricultural and Veterinary Chemicals Policy Committee (AVCPC) or through a yet-to-be-established inter-jurisdictional committee.

While enjoying a number of the advantages of *Reform Option Three*, this option would not need the State's to cede responsibility to the Commonwealth on control of use issues relating to agvet chemicals, hence this option may be easier to implement. This option could be modelled on the approach taken to establish FSANZ.

At the same time though, this option would require significant ongoing commitment to a national system by the States and the Commonwealth, which adds to the costs and potentially undermines the longevity of such as scheme. Furthermore, it does not ensure full integration of risk management activities, as multiple jurisdictions continue to be responsible for control of use and other post-registration activities, feedback loops are more complex involving multiple jurisdictions, and it raises complex resourcing and performance monitoring issues.

5.3 The Preferred Reform Option

Having regard to the design principles for a truly national agvet chemicals risk management system developed in Chapter Four, we have evaluated the horizontally integrated options (*Reform Options One* and *Two*) and the vertically integrated options (*Reform Options Three* and *Four*) in the way shown in Table 5.1. The outcome of this evaluation is that vertical *Reform Option Three* is strongly preferred.

Table 5.1

ASSESSMENT OF REFORM OPTIONS

Design Principles	Rating of Reform Options			
	Reform Option 1	Reform Option 2	Reform Option 3	Reform Option 4
A Seamless System	1	1	5	5
Feedback loops	3	2	5	5
Flexibility	3	1	5	4
Continuous Improvement	3	3	5	3
Confidence	3	3	5	3
Effectiveness and Efficiency	3	3	5	3
International confidence	2	2	5	4
Overall assessment	3	2	5	4

Scored out of 5. The higher the score the greater the alignment with the ideal discussed in Chapter 4

Source: The Allen Consulting Group

The establishment of an Australian Pesticides Safety Authority with responsibility for both registration and labelling of agvet chemicals and control of use is the approach most likely to provide the platform for the development of a world leading agvet chemicals risk management system that is sufficiently robust and flexible to address the emerging issues highlighted in this report.

Proposal

Establish a vertically integrated Australian Pesticides Safety Authority as outlined in *Reform Option Three.*

5.4 Additional Requirements for a National Agvet Chemicals Risk Management System

Adoption of the preferred reform option would put in place the structure needed to develop a world leading agvet chemicals risk management system. While structural change is a necessary condition, by itself it will not be sufficient. In order to take the agvet chemicals risk management system to a new and higher level it will be essential to complement structural change by a set of initiatives identified by reference to each of the design principles developed in Chapter Four.

Principle One – A Seamless System

A seamless system for the risk management of agvet chemicals is most likely to be fully achieved through structural reform that integrates agvet chemical registration, labelling, control of use, and training and accreditation, as highlighted in *Reform Option Three*.

However, this will not necessarily ensure that some of the benefits that are associated with horizontal integration will be captured. To address this, the risk management system needs to ensure adequate input on issues related to public health, the environment, occupational health and safety. One way of doing this is to provide direct representation for relevant agencies on the Board of the Australian Pesticide Safety Authority. Alternatively this could be achieved through a series of inter-agency agreements.

Proposal

Provide for representation on the Board of the Australian Pesticide Safety Authority by agencies with an interest in agvet chemicals, including the Department of Health, Environment Australia, and the National Occupational Health and Safety Commission.

Principle Two – Strong Feedback Loops

The presence of strong feedback loops is closely related to ensuring a seamless risk management system and in practice requires detailed knowledge and understanding of the consequences of agvet chemical use and application subsequent to registration. This requires the development of a national database on usage of agvet chemicals.

While vertical integration of the system provides a structure in which this knowledge and understanding can be obtained and used, there will still be relevant information collected and retained by other agencies. Provision will need to be made by way of inter-agency agreements for the Australian Pesticide Safety Authority to gain access to this information.

Proposal

Develop a national database and information system on usage of agvet chemicals.

Develop a series of inter-agency agreements on collecting, collating, and sharing relevant information, in relation to: food safety issues and MRLs with FSANZ; occupational health and safety incidents with the Department of Health and NOHSC; environmental impacts with Environment Australia.

Principle Three – Flexibility to Respond to Emerging Issues

The risk management system needs to be sufficiently robust to manage current and emerging issues. Getting early warning of emerging issues is an important element of risk management. The establishment of the vertically integrated Australian Pesticide Safety Authority will assist significantly in this respect. However, flexibility of response will also be influenced by the degree of prescription in the governing legislation for agvet chemicals risk management. Within the broad policy directions set by Parliament, flexibility is needed in determining the appropriate technical procedures for managing risks.

One area requiring a degree of flexibility is the issue of access to minor use agvet chemicals, which may require a streamlined approach to permits and registration. Another area is the issue of ensuring sufficient incentive for multi-nationals agvet chemical companies to seek registration for new chemicals at an early date in Australia, particularly if registration has already occurred in the US and/or Western Europe.

Proposal

As the policy functions related to agvet chemicals risk management will remain with Government departments, there will be a need to develop a strong interface between the vertically integrated risk manager (ie the regulator) and the responsible policy arm of Government.

Provide for a streamlined registration requirement, subject to an assessment of risks (such as toxicological, environmental, and health impacts), for minor use which was delineated by an appropriately determined threshold, for example, volume used (eg less that 0.5 tonnes usage). This approach may be more acceptable for minor use chemicals, that have already been approved (but only) by regulators in North America and/or Western Europe. Further, this may be more appropriate for veterinary chemicals than agricultural chemicals where Australia's unique geographical and climatic conditions are not so much a factor.

Reform data protection rules to allow for greater data protection for new products than would otherwise be the case under the current system, eg 12 to 15 years data protection. It could mean reducing renewal fees on application or annual registration fees for a period of time (in effect a subsidy to the company). Alternatively, taxation concessions, direct funding assistance, or rebates to encourage earlier registration could be used.

Principle Four – Provision for Continuous Improvement

Ensuring that the system allows for continuous improvement requires the ability to learn, a willingness to change, and an analysis of performance against objective benchmarks.

A key part to this is ensuring the competency and skill of those involved in risk management (eg registration, labelling, control of use, training, etc) are appropriate to satisfactorily consider all factors impacting on the risk management system. Continuous improvement should also be encouraged not only within the risk management system but also with participants and stakeholders. Furthermore, continuous improvement should involve an external review of the national risk management system for agvet chemicals.

Proposal

Ensure the science base and technical competency of the staff of the Australian Pesticide Safety Authority is appropriate to the task and that the Australian Pesticide Safety Authority is able to draw on a broad range of skills, in areas such as communication, stakeholder engagement, economics, health, agriculture, and industry.

Develop national accreditation and training programmes for users (and applicators) which promote better understanding of managing agvet chemicals. This could be driven through existing industry channels and be supported and facilitated through collaboration between industry and government.

Encourage stewardship initiatives by agricultural producers and agvet chemicals producers which improve the performance of the risk management system and contribute to Australian agriculture's clean and green reputation.

Conduct a review every 5 to 7 years to ensure emerging issues are appropriately considered and addressed.

Principle Five – Confidence in the Regulatory and Management Process

The composition of the Board of the Australian Pesticide Safety Authority is clearly important to maintaining confidence in the national risk management system. The Board should be seen to be balanced and not dominated by one set of interests.

Confidence in the regulatory risk management scheme also requires open and transparent processes for decision making. An essential part of this is ensuring full opportunity is provided for consultation and input by relevant stakeholders. Full disclosure of the basis of decisions made is also important.

Effective communication is essential not just with direct stakeholders but also with the wider community. This requires the Australian Pesticide Safety Authority to develop a well defined profile and recognised communication/information service to the public.

Proposal

Ensure independence of the Board of the Australian Pesticide Safety Authority.

Provide adequate representation on the Board of the Australian Pesticide Safety Authority for key stakeholders, including agvet chemicals companies, users, environmentalists, consumer representatives, etc.

Provide full consultation opportunities for all relevant stakeholders about regulatory decisions and processes, including consumers, environmentalists, industry, agriculture and government.

Consider holding Board meetings of the Australian Pesticide Safety Authority in public and answering questions from the public at those meetings, an approach used in the UK.

Publish regulatory decisions and the basis for those decisions and invite comment or feedback on those decisions.

Ensure a readily identifiable 'public face' for the risk management system and a capacity to engage with the wider community on issues relating to agvet chemical management.

Audit the performance of the risk management system against a set of objective criteria. Audit findings should be publicly released and include recommendations for improvements in risk management.

Principle Six – Effectiveness and Efficiency

An efficient and effective risk management system for agvet chemicals requires proportionality. That is, regulatory oversight needs to be in proportion to the risks involved and resourcing of the Australian Pesticide Safety Authority should be adequate to fully meet its responsibilities.

The wide ranging remit proposed for the new Authority will require decisions to be made about its financing. The principle should be that the costs of operating the Authority should be borne by those that stand to benefit most directly.

Proposal

Registration requirements should be structured to reflect lower requirements for low risk agvet chemicals and minor use chemicals (as discussed above in Principle Three).

Cost recovery charges for registration, labelling, control of use, training etc should be reviewed in line with the recommendations of the Productivity Commission's Review of Cost Recovery by Government Agencies.

Principle Seven – International Confidence

Given the importance to Australia of agricultural trade, a national agvet chemicals risk management scheme must ensure that major trading partners remain satisfied that Australia's risk management system is world best and more than meets accepted international norms of performance.

Australia should continue to participate in the work of the key international agencies such as Codex, VICH, and the OECD. Nevertheless there are considerable time delays associated with these organisations and in practice problems if they are to arise will most likely do so in relation to a trade issue with a particular country. Accordingly, as well as participating in multilateral bodies, a priority for the Australian Pesticide Safety Authority should be to build strong relationships with counterpart agencies in the US, Canada, and the EU – looking to the future it will also be necessary to build relationships with counterpart agencies in Asia.

Proposal

Recognising the considerable time delays that can be involved with the work of relevant international bodies, give priority to building strong bilateral relationships with the EPA/FDA in the US, the European Commission Health Directorate, the Pesticides Safety Directorate in the UK, and the Pest Management Regulatory Agency in Canada.