A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals

Discussion Paper

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December 2009

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1 Executive Summary

The Council of Australian Governments (COAG) is seeking regulatory reform in a number of areas, including chemicals regulation. The aim of these reforms is to reduce the regulatory burden on businesses and increase government efficiency.

Following the release of a Productivity Commission (2008) Research Report on chemicals and plastics regulation, COAG has directed that a proposal be prepared and submitted in the first half of 2010 for a single national framework to improve the efficiency and effectiveness of the regulation of agricultural and veterinary (agvet) chemicals. In doing so, COAG (2008b) noted that:

- the integration of regulatory activities up to the point of retail sale with a national control of use regime would encourage a nationally consistent approach to risk management and improve the consistency of risk management outcomes; underpinning the assessment and authorisation process (registration and permit); and
- this recommendation may have significant resource implications which will be considered during the Commonwealth budget process.

This discussion paper provides information on:

- the rationale for the current National Registration Scheme;
- stakeholder feedback to date on the current;
    - assessment and registration process; and
    - control of use regulation;
- issues for consideration in the development of a new regulatory framework;
- possible structures for a single, national framework; and
- funding issues.

Feedback is specifically sought on:

- alternative structures and governance frameworks for integrating agvet chemical assessment, authorisation and control of use.
- advantages and disadvantages in the ways in which control of use is carried out.
- improvements to priority setting and efficiency of agvet assessment and authorisation;
- the case for and against cost recovery of control of use regulation; and
- where possible, evidence to support positions/submissions.

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3 About This Discussion Paper

This discussion paper on a single national integrated framework for the effective and efficient regulation of agvet chemicals describes:

- the rationale for the current National Registration Scheme;
- initial stakeholder feedback on the current:
    - assessment and registration process; and
    - control of use regulation;
- issues for consideration in the development of a new regulatory framework;
- possible structures for a single, national integrated framework; and
- funding issues.

The paper has been prepared by two independent consultants engaged by the Department of Agriculture, Fisheries and Forestry. Views expressed in the paper do not necessarily represent those of the Product Safety and Integrity Committee or of individual jurisdictions represented on the Committee.

Feedback on the discussion paper is welcome from all stakeholders.

HOW TO PROVIDE A RESPONSE TO THE DISCUSSION PAPER

The paper includes questions and provides opportunities for comment. The Product Safety and Integrity Committee is inviting written submissions on the issues raised in the discussion paper, using the questions set out in section 2 as a guide. All submissions will be treated as public unless the submitter specifically requests that the submission, or part of it, be treated as confidential.

Readers can respond in writing to:

Product Safety and Integrity Committee Secretariat
Innovation, Productivity and Food Security Branch
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Or email to psic@daff.gov.au

For further information, you can contact the PSIC secretariat on 02 6272 3330. The latest date for submissions is close of business on 10 February 2010.

4 Consultation Phases

There will be three phases of consultation:

- phase one has already taken place, soliciting initial views from stakeholders;
- phase two will relate to this discussion paper, and
- phase three will be undertaken during implementation – following COAG's endorsement of the proposed regulatory model.

Phase One - Initial Round of Consultations

Following the request for written submissions by PSIC, a preliminary round of consultations were held in August and September 2009 to seek initial input from key stakeholders on the current system together with issues that need to be considered in the development of a single national regulatory framework. Since then follow up discussions have been held and further written submissions have been received.

Phase Two – Follow Up Consultations Following Release of this Discussion Paper

Prior to release of this Discussion Paper a second round of face to face stakeholder consultations was undertaken in each capital city in early December 2009 to discuss the essence of the paper, including the cost recovery principles.

In addition stakeholders will be able to submit further written presentations to PSIC as outlined in section 3.

Following the closing date for submissions, a draft report will be prepared for consideration by the the Primary Industries Ministerial Council (PIMC) at its April 2010 meeting. The Council of Australian Governments (COAG) has directed PIMC to bring forward a proposal for a new national regulatory framework in the first half of 2010. The draft report to PIMC will incorporate the feedback from the consultations and will include options for a single national regulatory framework, addressing operational and funding issues.

Phase Three – Implementation of Recommendations

Following the report's endorsement by COAG, a period of implementation will commence. Consultation regarding the specifics of the legislative framework and funding will be undertaken at this time.

Full implementation of the framework is expected to take a number of years.

5 Introduction

Agricultural and veterinary chemicals play a key role in Australian agriculture and in many domestic, sporting and other urban activities. The term 'agvet chemicals' and the regulatory coverage of such chemicals in Australia includes a diversity of products used to protect crops, livestock, buildings and other urban infrastructure and domestic animals. In agriculture herbicides used to reduce weed competition and insecticides and fungicides for crop protection are vital to the profitable and sustainable process of producing high quality products for the Australian domestic market and export markets. In parallel with those products is a range of veterinary chemicals which have an important influence on the health and welfare of livestock and on the quality of final livestock products. Chemical use has become an integral and growing part of modern Australian agriculture and is important for agriculture's ongoing productivity growth (ABARE 2006). Additionally, agricultural and veterinary chemicals have an important role in forestry and aquaculture, sports such as golf, horse racing and greyhound racing and in urban service and household sectors.

5.1 Background

While the growing positive contribution of chemicals is vital to the productivity of Australian agriculture, the quality of agricultural output and the productivity of other sectors, there could be negative consequences of chemical use in the absence of effective policy control. Many pesticides are hazardous and there may be substantial risks to human health if those products are not used correctly. As well, there are potential dangers to the environment from pesticide use.

Assessment, registration and control of use of agricultural and veterinary chemicals are managed through the National Registration Scheme. The regulatory coverage of the scheme includes a range of products including some surface disinfectants, pool and spa sanitisers, anti fouling paints and timber preservatives as well as agricultural and veterinary products. The Scheme is a two tiered partnership between the Commonwealth and state and territory governments. Assessment, registration and all other activities up to the point of retail sale are controlled nationally, by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Control of use — activities beyond the point of retail sale — is managed by state and territory governments. Overlapping the regulatory controls is a collection of quality assurance systems, some purely private, others with public-private partnerships. There are also generic controls, such as those over hazardous substances and dangerous goods, that include agvet chemicals.

Over recent years there has been a number of reviews of all or part of the suite of regulatory policies for agvet chemicals. The most recent of those was carried out by the Productivity Commission as part of its review of regulation of chemicals and plastics as a whole. With respect to agricultural and veterinary chemicals, the Commission recommended that a national system of control of use be developed and that changes be made in the way the APVMA sets its priorities and directs its efforts. This paper arises from a COAG decision to consider those recommendations (COAG 2008b) and explore alternative options.

5.2 Rationale for Regulating Agricultural and Veterinary Chemicals

The underlying rationale for regulating agvet chemicals rests on two things. First is the likelihood that their uncontrolled use could have negative consequences for public health, occupational health and safety, crop/animal safety, the environment and trade. In economic terms some of those consequences take the form of external costs. Second is the existence of information failures or asymmetries. For example, while the producer knows what chemicals have been applied to a food crop consumers are unlikely to be able to tell.

The combination of the hazardous nature of many agvet chemicals and the ways in which they can be used means that users can potentially impose external costs in a number of ways. For example, spray drift from farm applications of herbicide may damage crops on other farms, pollute waterways or have adverse health effects on neighbours or passers by. Inappropriate use of agvet chemicals on agricultural products may leave residues at a level that disrupts domestic and export trade. The sensitivity of Australia's trading partners to chemical residues in agricultural produce means that violation of an internationally accepted residue limit by one Australian producer can have a wide ranging negative effect on returns to Australian exporters of a product.

In an unregulated market chemical users may have little incentive to consider the full social costs of their actions, basing decisions on their own costs only and ignoring the additional external costs of those decisions. The result may be excessive use of chemicals and use in ways that are economically inefficient and socially inappropriate. The existence of external costs may provide a rationale for policy intervention, provided a policy can be found that produces net benefits. There is a variety of potential policy instruments for addressing problems of social cost. In many instances a tax on the output or activity that gives rise to the cost, or an equivalent quota, may offer the best solution. Tax or quota solutions, though, generally work well only when there are fairly simple and known relationships between production activities and external cost.

The choice of regulation, rather than taxing polluting or other risky chemical use activities, reflects the nature of agvet chemicals and their use. The sheer size and complexity of potential chemical use in agriculture means that there is no practical way of using simple tax, subsidy or quota approaches to resolve issues of spillover effects from chemical use effectively. Rather, it is more practical and simple to use an assessment and registration process backed up by monitoring and enforcement of use provisions.

The regulatory approach chosen for agvet chemicals involves a two tiered system. Assessment and registration of chemicals is the first stage. A second set of activities is designed to regulate particular uses of agvet chemicals. Underlying the two tiered policy is a presumption that some of the external costs saved by regulating would have been high enough to justify regulation. That seems reasonable enough, given the possibility of extremely adverse health or trade outcomes from inappropriate use of some of the chemicals concerned. However, the information available on the potential extent of those costs is neither complete nor consistent across jurisdictions.

The choice of regulation as the primary policy solution does not preclude the use of other policy instruments as well, provided that any such instruments can be well designed and integrated.

5.3 Purpose

The impetus for attempting to develop an integrated national system of assessment, registration and control of use of agvet chemicals arises in part from recommendations made by the Productivity Commission (2008, p.XLVII) and a consequent COAG (2008b) response. The Commission made the following recommendations.

Recommendation 8.1

The Australian Government, in consultation with the states and territories, should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority to ensure that:

- ***the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned***
- ***its assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals.***

Recommendation 8.2

The Australian Pesticides and Veterinary Medicines Authority (APVMA) should regulate the use of agricultural and veterinary chemical products after the point of retail sale through amendments to the Agvet Code:

- ***The scope of the new control-of-use regime should be negotiated through the Primary Industries Ministerial Council, and should include, at a minimum, uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.***
- ***The Commonwealth, state and territory governments should renegotiate the intergovernmental agreement to confer the necessary powers on the Commonwealth, and develop service level agreements for the regime to be delivered by the states and territories.***
- ***The APVMA should recover additional costs through a mix of charges and levies.***

The Commission also made a number of observations about the fragmented and inconsistent nature of state and territory controls and about the effectiveness, or otherwise, of the APVMA's operations. An interpretation of Recommendation 8.1 which seems consistent with the logic of the rest of the Commission's report is that the APVMA should direct its greatest assessment effort to those chemicals which appear to have relatively high risk and avoid imposing excessive cost in the cases of chemicals with relatively low risk.

It needs to be kept in mind that the degree of risk apparent at the assessment stage is one, only, of a number of issues that may legitimately influence the amount of effort put into assessment. The risk from use of a product depends not only on those factors which the APVMA assesses, but crucially on the amount of the product used and how and where it is used. Thus, by extension, the Commission's Recommendation 8.1 should be taken to mean that the effort put into training, monitoring and enforcement activities should be commensurate with the total risk posed by the product.

COAG, in its response to the Commission's recommendations essentially adopted recommendation 8.1 and gave the following response to recommendation 8.2 (the full text is in Appendix 1):

> ***COAG directs the Primary Industries Ministerial Council (PIMC) to bring forward to COAG for consideration in the first half of 2010 a proposal for a single national framework to improve the efficiency and effectiveness of the regulation of agricultural and veterinary chemicals.***
>
> ***COAG notes that the integration of regulatory activities up to the point of retail sale with a national control-of-use regime would encourage a nationally consistent approach to risk management and improve the consistency of risk-management outcomes, underpinning the assessment and authorisation process (registration and permit).***
>
> ***COAG also notes that this recommendation may have significant resource implications which will be considered during the Commonwealth's budget processes.***

In essence COAG adopted the thread of the Commission's recommendation, but with some room for movement. Rather than necessarily accepting the Commission's nomination of an expanded APVMA as the repository for control of use powers, COAG left open the possibility of alternative regulatory models and structures.

5.3.1 Purpose of the Paper

The purpose of this paper is to facilitate public discussion of the main issues involved in ensuring effectiveness and efficiency of agvet chemical regulation and in developing a national framework for control of use. To that end the paper contains an outline of the current scheme and an indication of major findings from a number of past reports. That includes discussion of recommendations from recent reviews. Some observations are made here on the basis of feedback received at preliminary meetings with regulators and stakeholders.

This paper contains the results of a broad review of the issues in agvet chemical regulation. The emphasis is on drawing out key points relevant to the likelihood of producing gains in effectiveness and efficiency in the assessment, authorisation and control of use. Where possible the potential benefits and costs of regulatory alternatives are identified. However, no full evaluation is attempted.

Section 11 contains a discussion of alternative regulatory models that might be used to achieve control of use at a national level that is coordinated with effective and efficient assessment and authorisation. The list of alternative models is not exhaustive, but it includes both national models, in which control of use is provided by a single national regulator (in one case integrated with assessment and registration), and harmonised models, in which control of use continues to be supplied by the states, but within a consistent national framework. Possible models for constructing such a framework range from template legislation to agreement on National Operating Principles. Some observations are made about the likely benefits and costs of the models, but without an attempt to judge which might be the most efficient solution.

Feedback on the discussion of issues and on the policy options outlined in the paper will be used to inform the process of development of a final regulatory proposal by the Product Safety and Integrity Committee (PSIC).

5.3.2 Scope

There are three important dimensions of scope in this discussion paper. The first concerns the chemical and product coverage. The second concerns the boundaries between agvet chemical control and other regulatory activities that impinge on agvet chemical use. The third concerns the policy coverage of the review, of this paper and of the final policy proposal.

With regard to product and chemical coverage, anything that is currently within the APVMA's responsibilities is within scope. That may include things which people believe should be removed from the APVMA's responsibilities. It is clear from early discussions with chemical users and producers that some believe that there is room for improvements to be made at the margin of the APVMA's current range of chemical and product responsibilities.

It is no simple task to define the most appropriate boundaries of control of use of agvet chemicals. Agvet chemicals are a distinct, but mostly small, subset of a number of broad categories of chemicals. The following list indicates the main categories into which they may fall, along with the policy areas/portfolios which generally have primary carriage for each of those areas.

- Poisons – food, public health.
- Hazardous substances – occupational health and safety.
- Dangerous goods – transport and storage.
- Pollutants – water, environment protection.
- Chemicals of security concern – national security.
- Biologicals e.g. vaccines – biosecurity.
- Trade relevant contaminants – agriculture (primary industries).
- Genetically modified organisms when they leave the research phase and are commercially available – agvet chemicals regulators.

Some aspects of handling or use of a particular agvet chemical may be regulated under one or more of the above categories. Additionally, the Commonwealth, all states and both territories have legislation specific to regulation of agvet chemicals. It is this latter regulatory set which is the focus of this review.

The policy coverage of this review is inclusive of all of the activities currently undertaken by the APVMA and all of the activities undertaken by states and territories specifically concerned with control of use of agvet chemicals except where those activities are primarily contained within other government programs. Control of use activities are within scope if they concern issues about the impact of agvet chemical use on trade or questions about good agricultural practice. However, issues about contaminants other than agvet chemicals and food standards are not within scope of the review. Similarly, whilst questions about inclusion of occupational health and safety warnings on APVMA approved labels are within scope, all other issues covered by occupational health and safety legislation are outside the scope of the review. In this context occupational health and safety should be seen as an important example of overlap, only.

Where people have concerns that they believe are related to agvet chemicals they should feel free to raise those concerns in responding to this discussion paper. Even in the final policy proposal there may be overlaps between agvet chemical regulation and other regulation. In some instances the cost of regulatory overlaps may be less than the costs that could arise as a result of there being significant gaps.

Key Questions for Stakeholders

Q1 In either the current state and territory control of use or APVMA responsibilities for agvet chemicals are there any gaps, overlaps or unnecessary inclusions and, if so, what are they?

6 The National Registration Scheme

There are two essential components of National Registration Scheme as it currently stands. The first is the product assessment and authorisation activities of the APVMA and its associated product quality and sales controls. The second is the control of use activities carried out by the states and territories. The makeup of the latter set of activities varies from state to state in its composition and intensity. Those activities also overlap with a number of other government roles in agriculture, industry and protection of householders and the environment.

6.1 Rationale for the Current National Registration Scheme

The National Registration Scheme was created in 1995 to replace an arrangement where products were registered independently at a state level with the Australian Agricultural and Veterinary Chemicals Council (serviced by the Commonwealth Department of Primary Industries and Energy) acting as national clearance house for agvet chemical registration from 1988 to 1992. The National Registration Authority (NRA) was established in 1992 and performed the clearance function from its establishment until the commencement of the Agvet Code on 15 March 1995. Behind the creation of the NRA was the recognition of the excessive cost of operating several assessment and registration bodies in parallel. The NRA was later to become the APVMA.

Although efforts have been made since 1995 to harmonise approaches to control of use, differences remain. At one level some states (and both territories) take a prescriptive approach to control, with use according to label as the baseline for their regulations, and some specific exceptions. Others are less prescriptive. The Victorian Government (2008, p.9) describes its approach as 'performance outcome based', with off label use allowed for chemicals not on the restricted list and providing the user complies with specific requirements and prohibitions on the label.

Leaving aside differences in treatment of use according to label, there are other reasons that states have maintained separate control of use regimes. For example, the Tasmanian government is currently in the process of developing a chemical policy set intended to include exclusion zones and enforceable water quality standards quite different to those that apply in other states. With regard to flexibility to respond to local conditions the New South Wales Department of Premier and Cabinet (2007, p.13) argues that each state or territory may need to impose '...jurisdiction-specific requirements for some agvet products to accommodate unique environments, community needs, climatic regions or a particular mix of physical, biophysical and social factors.'

6.2 Assessment, Authorisation and Management of Chemicals

Assessment of applications for registration of new agvet chemicals and new products based on existing chemicals is performed by the APVMA. The APVMA has a number of responsibilities related to management of the portfolio of registered products and assurance of the quality of products supplied by chemical manufacturers.

The functions of the APVMA's assessment and registration activities are to facilitate access to and use of agricultural and veterinary chemicals whilst limiting risks to:

- human health;
- the environment;
- target crops/animals, and;
- trade.

And satisfying itself that the product will be effective.

Ultimate responsibility for assessment of a new chemical or product rests with the APVMA. However, other agencies have responsibilities for important parts of an assessment and for making decisions about some aspects of risk management. Some of those agencies also set standards that play a major role in the APVMA 's risk assessment. The Office of Chemical Safety (OCS) assesses toxicology. It also assesses occupational health and safety aspects and sets dietary limits for the active chemicals. Assessment of risk to the environment is carried out by the Commonwealth Department of the Environment, Water, Heritage and the Arts (DEWHA) based on the proposed use of the product. For some chemicals or products either OCS or DEWHA may also recommend strategies for risk management. Additionally, other Commonwealth agencies set standards which have a direct impact on the APVMA – including the acute reference dose and acceptable dietary intake. Changes in those standards can have implications for existing registrations, as well as assessments of new chemicals and products.

In addition to those elements of assessment which are wholly performed by OCS and DEWHA a significant proportion of overall assessment effort is outsourced – often to assessors within state agencies. A number of registrants[1] suggested that one of the effects of this outsourcing and of the involvement of OCS and DEWHA may be that different parts of an APVMA assessment are informed by agencies with different appetites for risk. Over time there may be changes in the understanding of or appetites for risk in some or all of the agencies involved. Such changes may have implications for the consistency of assessments underlying the APMA's portfolio of registered chemicals and products.

In effect, the APVMA serves as the Australian market's gateway for agricultural and veterinary chemicals. The bulk of applications considered are for variation to existing registered products including generic products based on older chemistry. Also important are products similar or identical to products already registered overseas by multinational chemical producers. The APVMA also has responsibility for the oversight of products already registered. Beyond managing the authorisation of chemical products, the APVMA also is responsible for the quality of products actually marketed and for managing the market up to the point of sale to users. In this context an active compliance program is an important part of the APVMA's activities, although some stakeholders and government agencies have expressed concern about the authority's ability to perform this role effectively.

Two key outputs of successful chemical or product applications to the APVMA are approved product labels and approved MRLs (maximum residue limits). An approved label provides the basis on which users can apply the product in a manner that is consistent with the applicant's product design and the findings of the assessment process. In this context, some stakeholders and regulators in some

[1] See Animal Health Alliance 2009, for example.

jurisdictions have suggested that an effective approval process would be one in which the full set of possible crops/animals was included on the label. An approved label provides an explicit set of instructions that are valid at the time of assessment. For many products there may not be a need for change over the commercial life of the product. For others, things may change. Changes in application equipment or in knowledge about application techniques or changes in knowledge about the impacts of the chemical may mean that a label change is desirable, or even clearly necessary. In some cases the registrant will have a clear commercial incentive to seek change. Where there is no such incentive neither users nor, in most circumstances, the APVMA can initiate change – as is discussed further in section 7.4.

An APVMA MRL is a standard set for a maximum residue under Good Agricultural Practice for the approved use of the product. By virtue of the decision points built into the assessment process an MRL for a food product will always be at a level well below that which would be a health risk. So while a breach of an MRL is clearly an indication of a failure to use a product appropriately, it may not have any direct health implications. Nevertheless, it is important that users apply agvet chemicals only in ways that keep residues below MRLs. Regardless of size of the additional health risk from a particular MRL breach, the regulatory approach under the National Registration Scheme is explicitly risk based. Agvet chemical use even within regulatory limits can carry with it some risk. The possibility that the total chemical load from multiple products involves additional risk suggests that a conservative approach to residues could be justified.

The choice of whether to apply for registration of a product is a commercial one made by the potential registrant. Similarly, the choice of target and host species to include in an application for a new product, or an application to expand the approved coverage of an already registered product is made by the registrant. Those choices may be influenced by a number of factors including prospective sales of the product (or the extended coverage), the impact on the registrant's other products (if any) and the costs and timing of the registration process. For large scale uses of a product there may be a reasonable coincidence between the product's potential value to users and the incentive for registration. For some smaller scale uses the coincidence may not be that great – a particular use of a product may be important to a small group of potential users but of limited commercial interest to the registrant. The registration process thus does not provide any guarantee of access even for uses which are potentially valuable and would meet the APVMA's assessment criteria if evaluated. Consequently, producers seeking access to chemicals for a variety of minor uses can have that access blocked.

In addition to the assessment and registration process for new chemicals and products, the APVMA is responsible for a portfolio of registered chemicals. That responsibility underlies the APVMA's program of selective reassessment of chemicals under Chemical Review. The APVMA has a number of other subsidiary functions including exchanging information with international agencies and reporting to government.

Under its enabling legislation, the APVMA also has a designated role in cooperating with state and other Commonwealth agencies to '…encourage and facilitate the introduction of uniform national procedures for control of the use of chemical products' (Agricultural and Veterinary Chemicals (Administration) Act 1992, 7(1A),(k),p.5).

6.3 Control of Use

Control of use of agvet chemicals is a state and territory government responsibility. The particular set of tasks and the way in which they are performed varies between jurisdictions. There are four broad areas of focus of these sets of control of use activities: agricultural chemicals in agriculture and forestry; veterinary chemicals; agricultural chemicals in urban and industrial settings and household uses. Much control of use effort is directed to agriculture where a large part of the total chemical use occurs and where the risks of contamination of food products and trade risks are of concern. However, another important set of controls is aimed at limiting exposure to agvet chemicals used by pest controllers in urban settings. Use of agvet chemicals on golf courses, on other sports grounds and by roads and council staff also represent important potential largely urban contact points. Some jurisdictions indicate that neighbour complaints about inappropriate use of household or garden chemicals generate more complaints than in most other sectors.

Control of use policies can usefully be considered in two dimensions – activities and enabling legislative instruments.

6.3.1 Control of Use Activities

Control of use involves a wide range of activities, the combinations of which vary between jurisdictions. However, most of those activities fall into four broad groupings:

- training and accreditation of users;
- licensing of professional operators;
- monitoring, and;
- surveillance and enforcement.

Training of users is aimed at ensuring that those users understand their responsibilities and understand how to use agvet chemicals. Trainers indicate that training of mostly farmers has its origins in voluntary industry programs that were largely driven by a desire to avoid serious MRL breaches that would damage trade. User training requirements as control of use devices vary greatly between jurisdictions. For example: NSW requires all agricultural users to be trained; Victoria requires agricultural users to be trained to possess an Agricultural Chemical User's Permit (ACUP) in order to use restricted products and requires training for all professional users; NT requires training for higher risk products (S7 and restricted chemical products); Western Australia requires a high level of training for pest controllers, but no training for farmers or other direct users.

There is a varying degree of public involvement in oversight of training, although training is privately funded and delivered for the most part. Competencies for chemical user training are established under the National Training Framework.

In some states a requirement for users to demonstrate accreditation in order to purchase restricted chemicals is used as a way to link training and access. More generally a requirement for accreditation is restricted to licensing of professional users. Licensing of professional users is used widely across states and territories as a control of use device, but inconsistently. Across all jurisdictions licensing requirements exist for aerial operators although, as the Productivity

Commission pointed out, the conditions vary across jurisdictions. Pest controllers are licensed in all jurisdictions. Only some states require agricultural ground sprayers to be licensed.[2]

Licensing provides a means of ensuring that at least minimal levels of competence are reached by professional applicators. As well, a licensing requirement can facilitate auditing and trace back in cases of adverse events and provide a contact database for communicating changes in regulation or other important information.

Primary control of use activities are monitoring and surveillance. Core parts of these activities concern monitoring of residues in agricultural products and some other traded goods, monitoring of environmental impacts of agvet chemical use and, in some states, auditing of users and their chemical use practices. With regard to chemical residues, state and territory government monitoring efforts operate side by side with monitoring through such devices as the National Residue Survey, the Australian Total Diet Study, Freshtest and a variety of industry and supply chain operated quality assurance programs. There are varying degrees of interaction or coordination between private, private-public partnership and public control of use. Monitoring of the environmental impacts of agvet chemical is an almost purely government activity.

Enforcement activities may take a number of forms – from warnings, through industry action plans to legal action. Ultimately regulators may have to resort to fines or court action against individuals or firms for some breaches. Other cases may be resolved by actions within quality assurance programs – such as rejection of produce or disqualification from the scheme.

Control of use legislation for agvet chemicals has close ties, and sometimes overlaps, with legislation such as that covering dangerous goods, chemicals of security concern, therapeutic goods, occupational health and workplace safety, licensing and regulation of veterinary surgeons and trade practices.

6.3.2 Control of Use Instruments

Underlying control of use activities there is a complex set of legal instruments. Those instruments can be considered in several separate, but sometimes overlapping categories. First are those instruments which serve to directly underpin the control activities outlined above. Such things as powers of search, investigation, seizure and the ability to establish orders or notices to provide necessary backing for monitoring and enforcement activities. Aligned with that set of powers is legislation which establishes a variety of offences for misuse of chemicals. Part and parcel of the current set of instruments is legislation backing the establishment of area controls and other devices to allow responses to regionally significant problems. These instruments are discussed further in section 9.

Key Questions for Stakeholders

Q2 How effective are the current registration arrangements for facilitating adequate chemical access for minor uses?

[2] All licensing related to pest and weed controllers can be found at www.licencerecognition.gov.au

7 Issues for Consideration in Developing a National Framework

There are several factors to be considered in designing an integrated national framework of agvet chemical control. Clearly it would be desirable to retain the strengths of the current two part system whilst removing some of its weakness. Evident strengths are the rigour of the assessment and registration system on the one hand and aspects of effectiveness and local responsiveness in control of use. Evident weaknesses are an apparent lack of consistent focus on net benefit to the Australian community in the system as a whole, reduced access to chemicals, inconsistencies in control of use and less than optimal feedback mechanisms.

7.1 An Integrated System

The Allen Group (2002) developed seven 'principles' for operation of an integrated system. Those seven conditions are reordered here to provide a useful starting point.

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

The list is made up of a mix of desirable outcomes (1-3) and necessary instruments (4-7). International and local confidence in the system will be outcomes only as long as all the other five conditions are met. With regard to the necessary instruments (4-7), the development of strong feedback loops will have a key role in the success of a national regulatory system.

In developing their 'principles' the Allen Group may have missed two key points. First, they did not insist that their regulator have a strong state or regional presence and focus. Control of use may not be effective without the regulator having a local presence, knowledge and the ability to respond to regional concerns in a timely manner. Second, it is not clear that their model was based on a full consideration of the ultimate collection of risks faced by the community. In the following discussion, that ultimate collection of risks that result from the actions of regulators, chemical registrants, manufacturers and users in practice is referred to as 'total risk'.

7.2 Efficiency and Effectiveness in Authorisation

The Productivity Commission (2008, Box 4.2) suggested that the primary conditions necessary to ensure an efficient and effective chemical registration scheme were as follows (the full text of Box 4.2 is given in Appendix 2).

- The requirements of the scheme should be set to reduce overall chemical risks to levels acceptable to the community, taking into account the associated costs and benefits.
- Assessment effort associated with particular chemicals should be commensurate with their relative risk.

- The assessment scheme should be operated cost effectively.

The specific application of these conditions to the National Registration Scheme underlies the Commission's recommendation 8.1 with respect to the APVMA. The intent behind that recommendation was twofold. The first part was to ensure that the costs of assessment of any chemical or product were commensurate with the prospective benefits of the process – the benefits being the value of risks reduced or avoided. The second was to ensure that the same logic was applied to assessment and management effort across new products and those in the existing portfolio of registered chemicals.

The assessment process as it is currently structured has some tendency to impose greater assessment costs on higher risk chemicals or products and lesser costs on those with lower risk. To take that further would require a clear measure of the sum of risks assessed. In the assessment process work towards such an end would have limits, since final measures of the assessed risks are outcomes of the process. That would not be a problem for the existing portfolio of registered chemicals. What could be a problem is the development of a single measure of the sum of very different risks, including those to human health, environmental and trade. Nevertheless, just those types of aggregations of monetary, human and environmental factors are made in many other areas of public policy on an ongoing basis.

It appears that there may be some inherently perverse incentives in the current system for assessment, registration and charging for authorisation. The Productivity Commission's recommendation 8.1 represents an attempt to have the costs of registration aligned with product risk, and therefore likely external costs. ACIL Tasman (2008, p.52) take that logic a step further in pointing out that there may be a strong case for varying all APVMA charges according to risk. In this context, one reason that some older chemicals persist in the market may be that they are out of patent and can be supplied generically. This may provide such chemicals with a cost advantage over new, sometimes less risky, products. To the extent that there is such an advantage, a risk based charging system for all charges might modify the advantage held by older chemicals. As is indicated in section 12, though, developing a risk base for all charges may not be easy.

In addition to risk based charging, there is an option for the development of a program specifically targeted at easing the path for chemicals that can reduce the aggregate risk from the portfolio of registered chemicals. For example, the United States Environmental Protection Authority (2009) runs a program to expedite the registration of chemicals and products that can be shown to substitute for existing products but at less risk[3]. The European Commission (2009) has gone a step further in targeting some chemicals for substitution.

7.3 Product Risk, Total Risk and Precaution

In the National Registration Scheme risk assessment is carried out by the APVMA at an individual product level. Products are risk assessed at the point of application for registration. Some products may be subject to reassessment at some later date and there are aspects of aggregate risk from the portfolio of registered chemicals that are taken into account in dietary risk assessments. However,

[3] The applicant must submit a dossier requesting low risk status for EPA assessment.

there are aspects of the actual risk of use of a particular product and of aggregate risk that may not be covered effectively in the current combination of assessment and control of use.

7.3.1 Total risk

The total risk from registration and use of a chemical product has a number of components and may be a complex function of many factors. In one dimension risk may be viewed in terms of the categories established as the APVMA's assessment responsibilities:

- human health;
- trade;
- the environment;
- target crops/animals, and;
- efficacy.

All of these categories of risk are considered in the assessment process. In another dimension, risk may be viewed in terms of its size and nature. In this respect the main features are: the hazard of the product (toxicity to humans and other organisms); the extent of use; the locations of use and the ways in which it is actually used. Some key aspects of this latter dimension of risk are also considered in the assessment process. Estimates of the extent of use are taken into account in the environmental assessment. As well, in establishing an MRL, consideration is given to likely total exposure to the chemical (calculation of the national estimated daily Intake and comparison with the acceptable daily intake).

While the assessment process involves consideration of key elements of risk, not all parts are considered fully. Not unreasonably, assessments are done on the basis of a particular use pattern, which is embodied in the label instructions. The regulatory intent is for use according to label to be safe from the perspective of human health, target crops/animals, the environment and trade and to represent effective and appropriate practice (or good practice in pest control or companion animal management, as the case may be).

The actual use of an agvet chemical may deviate from the above standard for any one or more of several reasons. Among those possibilities are:

- permissible off label use, including;
    - veterinary prescriptions for minor use;
    - rates and frequency of application less than label (in most jurisdictions for at least some cases);
    - use in a state or territory not approved on the label;
    - use for a different crop under the conditions of Victorian or South Australian regulations or specific exemptions in some other jurisdictions;
- prohibited off label use, for example where;
    - the user deliberately chose to apply a restricted chemical off label because;
        - no legal solution to the pest problem was evident;
        - the pest was not on the label, but 'pest' instructions were unenforceable;
    - use at a higher rate or a higher frequency than on the label;

- the label was confusing or incomprehensible so the user made errors in application;
- more effective application technology or, ways of using existing technology, have been discovered since registration (particularly for spray technology and methods)[4] and the user chooses the more effective, but off label, method (where the off label choice is not allowed in the user's jurisdiction).

The list is not exhaustive. Some of the above actions may be risk reducing – for example, using at a lower rate or using with more effective spray technology. More from the above list are likely to be risk increasing than risk reducing. Where any of the latter group apply, the total risk will be greater than that reflected in the assessment. At least some of the additional risks are considered by control of use authorities, albeit generally at an informal level and not in a manner that is necessarily consistent with the assessment for registration. There is no clear focus on total risk in the current system.

Within a single national regulatory system control of use, as well as assessment, registration and management of a portfolio of products would need to be integrated. To be economically and socially useful, such a regulatory system would need to have a clear focus on total risk, not just on a subset of its components. That would mean a somewhat different focus from that of the APVMA under its current legislation. That is not to suggest a weakening of rigour or change in orientation in the assessment and registration process. To attempt to forecast aspects of risk associated with off label use, for example, and use those in the assessment process would most likely not be productive. Rather, it is to suggest an additional emphasis on facilitating the use of information gained in both the assessment process and practical application with a view to enhancing efficiency and safety of chemical use. Thus, knowledge acquired about both permitted and illegal off label use may be important in chemical review. Adopting a total risk approach would also most likely require some change in focus for some, if not all, state control of use agencies.

In the context of seeking efficiency it is worth noting that there is a wide degree of latitude in the instructions on many labels. This can be particularly notable for spray application instructions. As well, equipment, knowledge and techniques may change rapidly. In practice there may be limited incentive for registrants to respond to such changes and little capacity for the APVMA to initiate change. It might be that finding ways to enhance the effectiveness of labels would offer the most effective and efficient way to reduce total risk. Making additional material available electronically might provide an advantage for some users, although the majority of farmers could not access such material directly.

There are at least two additional issues that may influence total risk across the portfolio of agvet chemicals. The first, identified by the Productivity Commission and underlying the second part of its recommendation 8.1, concerns the necessity for a focus on the aggregate risk from the chemical portfolio as a whole. Additional to that may be questions about the effect of total chemical load on human health and the environment.

[4] Only some labels specify application technology.

7.3.2 A Precautionary Approach

The APVMA's assessment and registration activities are explicitly risk based. Consistent with that approach, the monitoring and enforcement activities of state governments are risk based, although the various state interpretations of label instructions mean that the levels of risk chosen may differ from state to state. Some community groups argue for the application of a precautionary approach, rather than a risk based approach. The precautionary principle enshrined at the 1992 Rio Conference on the Environment and Development is:

- *Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

The boundaries when applying a precautionary approach are not entirely clear, although a level of precaution is not uncommonly applied to matters of human health. For example, adoption of the ALARA (As Low As Reasonably Achievable) policy to very low levels of radiation exposure is a form of precaution (Radiation Health and Safety Advisory Council 2002).

The precautionary principle was discussed at length by the Commission for the European Communities (2000) and codified in EC regulation. The Commission (p.4) argued that measures taken under the precautionary principle should be:

- *'proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review,* in the light of new scientific data, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.'

The European Commission's requirements for proportionality, consistency with similar measures and examination of potential benefits and costs suggests an interpretation of precaution that is not out of line with the Productivity Commission's requirement (stated above) that the '...value imputed to accepted risk should be broadly consistent with other regulations...'

In a practical sense, a requirement to take a precautionary approach might be interpreted as a need for caution in cases where there was uncertainty about the science, or for always taking the conservative estimate of risk when risks are not fully known.

In application, the meaning of precaution may not always be clear. For example, Sunstein (2005, p.23) illustrates how the European Court has made a series of conflicting decisions involving varying degrees of risk, in each of which the Court claimed to have taken a precautionary approach. Thus there is a risk that inclusion of a precautionary approach could introduce a degree of subjectivity into an otherwise objective assessment and registration process. Currently the APVMA applies the principle that caution should be exercised where scientific opinion is divided or scientific information is incomplete.

Before requiring any broader precautionary approach to agvet chemical assessment it would seem necessary to:

- provide an unambiguous statement of its meaning and application, and;
- demonstrate that its use would produce a cost beneficial outcome.

7.4 Communication and Feedback in the National Registration Scheme

The National Registration Scheme is based on management of risk. At the assessment and registration level, estimates are made of the likely human health, animal health and welfare, production, trade and environmental effects of using a chemical in a particular way – according to the label developed as part of the assessment and registration process**.** At the time of assessment and registration of a product it cannot be known how well users will comprehend the label instructions and how closely they will stick to those instructions. Effective feedback on actual uses and their consequences would be essential to an efficient risk management system.

The current system could not be described as one with fully effective feedback. In the first place, the two part regulatory process appears to have led to a fracture in communication between the APVMA and state and territory control of use regulators. There are formal policy level channels through PSIC, AWPIT and PIMC. As well, the APVMA's Registration Liaison Committee is meant to '…provide a forum for the ongoing development and operational coordination of the NRS and for consultation on the development of operational policies, guidelines and protocols within both the APVMA and the signatory organisations to allow effective alignment of the agvet chemical control objectives of the APVMA and States and Territories' (APVMA 2009a). Yet it is not clear that there is a good flow of information about control of use issues to the APVMA at the operational level. From another view, the very different approaches to control of use in different jurisdictions have implications for the overall validity of the APVMA's risk assessments which are based on the presumption that all use is according to label (as is required in the APVMA's legislation). It is not evident that the importance of those implications is clearly known to users or to regulators in some of those jurisdictions. Nor, it seems, does the APVMA have access to good information on actual use.

At another level is the effectiveness of feedback to the APVMA from various user, industry and community sectors. The Industry Liaison and Industry Committee provides a line of communication between the regulator and registrants, with support from the Industry Technical Committee. The Community Consultative Committee serves to provide a link with broader elements of the community. Early discussions with stakeholders suggest less than fully effective links with chemical user groups including pest controllers, aerial sprayers or ground sprayers or with the broader farming community. In one sense such a gap is predictable, given that control of use is a state and territory responsibility. However, there may be significant costs arising from this gap.

The APVMA also operates an adverse experiences reporting system. Reports related to use of agricultural chemicals appear to be underrepresented, relative to those to do with use of veterinary chemicals. Also, the system is limited to reports on registered or other legitimate uses – reports of misuse incidents are excluded. One problem with the adverse experiences system may be that it is not the obvious place for people to go when they have something to report. There may be a case for integration with other reporting systems including those run by poisons information centres state environment protection centres.

Reporting the findings of a 2003 ABARE Outlook workshop, the APVMA (2003) observed that neither feedback nor monitoring in agvet regulation and use was either complete or coordinated. Since that

time the APVMA has developed the adverse experiences reporting system. No other significant improvements are evident.

Key Questions for Stakeholders

Q3 What particular costs or benefits would arise from greater integration of assessment, authorisation and control of use of agvet chemicals?

Q4 What do you take the precautionary principle to mean? What are the potential costs or benefits that could arise from adoption of a more precautionary approach in circumstances where lack of full scientific certainty exists in agvet chemical assessment, registration or control of use?

Q5 How responsively and effectively does the APVMA appear to take up information provided by industry or signatories to the National Registration Scheme?

Q6 How could information be more effectively provided by industry or signatories to the National Registration Scheme and how could it be better integrated into the APVMA's regulatory activities?

8 Assessment Registration and Access to Chemicals

Since the National Registration Scheme was established in 1995 it has been reviewed frequently, either in its entirety or by elements. The observations made here are drawn from some of those reviews and from recent written or oral statements by stakeholders.

8.1 Review, Recommendations and Feedback from Stakeholders

Price Waterhouse Coopers et al. (1999) reviewed the operation of the National Registration Authority and of the control of use regimes of Victoria, Queensland, Western Australia and Tasmania from the point of view of National Competition Policy. The report was supportive of both the economic rationale for the single assessment authority and the rigour of its operation. It contained recommendations with respect: to low risk chemicals; competition in provision of assessment services; licensing of manufacturers; veterinary prescription rights; the coverage of efficacy review and data protection. Most of those recommendations were acted upon, at least in part. Radcliffe (2002) reported the results of a detailed study of the regulation and use of agricultural chemicals. The report provided a generally positive assessment of the standards of food safety in Australia and of the APVMA's risk assessment process. In 2002 the APVMA commissioned the Allen Group to consider the best regulatory structure to meet likely future changes in the social, economic and technological environment. The Group recommended the integration of assessment, registration and control of use in a single national agency.

More recently, the ANAO (2006) audited the APVMA's performance. The ANAO made six recommendations which the APVMA agreed to implement. Of particular relevance here are recommendations to the effect that the APVMA should:

- improve the monitoring of statutory timeframes;
- improve its registration processes by analysing errors and omissions in applications;
- assess whether there is a more contestable approach to sourcing scientific advice from Australian government agencies, and;
- assess whether the approach taken to chemical review adequately accounts for the risk of chemicals not yet under review.

A brief report on the progress toward meeting the ANAO's recommendations is contained in APVMA (2009b, p.61).

Since then the Productivity Commission has reviewed the APVMA's activities in the broader context of chemicals and plastics regulation. The Commission's recommendation 8.1 is for a change in the APVMA's enabling legislation to require that assessment costs be commensurate with the risks of the chemicals being assessed and that the organisation's priorities be focused on managing the total risk of chemicals registered.

To some extent the APVMA's modular assessment framework seems likely to lead to assessments of higher risk chemicals or products having greater assessment costs than lower risk chemicals or products. However, there is no currently available measure of the extent of this effect.

8.1.1 Issues in the Assessment Process

Most stakeholders who made explicit reference to the APVMA's assessment and registration activities gave strong support for the scientific rigour of the process. Some, however, questioned either the process itself or its current rigour. The Animal Health Alliance (2009, p.28) questioned whether the APVMA was managing to maintain previously high professional standards in its work. Some community groups questioned the risk based approach or the science underlying the APVMA's process, or both. Whilst there was only limited questioning of the relevance or the rigour of the assessment process, there were more pervasive claims of underperformance in a number of other areas. The criticisms covered a mix of issues arising from the legislative constraints faced by the APVMA, the APVMA's performance and the interaction between the two.

With regard to assessment and registration, the main areas of dissatisfaction concerned:

- the time taken for assessment;
- cost impositions, particularly in terms of additional data requirements;
- unpredictability in time taken to complete assessments;
- apparently different appetites for risk and other inconsistencies between reviewers and between the APVMA and other government agencies involved in assessments;
- the continuing absence of data protection with respect to minor use permits;
- difficulty in having the registration of apparently low risk products facilitated[5].

Timeliness of completion of assessments clearly remains a significant problem. While it would not necessarily resolve broader timing problems, one thing that might result in an improvement would be a move to assessment on the basis of agreed data packages. That is, to base assessment on a package which the applicant agrees contains all the data that it plans to submit. Currently, under s11(3) of the Agvet Code an applicant is entitled to submit additional data at any time during the assessment process. That can lead to a degree of uncertainty for both parties.

Both the Animal Health Alliance (2009) and ACIL Tasman (2008) have argued that it should not be the regulator's responsibility to ensure efficacy or assess trade risk. They argue that there are either market mechanisms or existing regulatory devices outside the APVMA's remit that will ensure an efficient result. If that is true, then the additional effort required by the APVMA is waste. For trade data, it is argued that chemical producers and users have a strong market incentive to avoid risk. That is true up to a point. On the other hand, the impacts of a trade incident can have implications well beyond those borne by one agricultural producer, well beyond those borne by one agricultural industry and probably well beyond those borne by one chemical producer.

The arguments advanced against the regulator having a requirement for specific Australian efficacy data are twofold. First, the chemical producer has a strong market incentive not to misrepresent the

[5] Some countries such as the United States do have low risk schemes as an incentive for manufacturers to invest in newer products. However, close inspection of the US scheme shows that it is not a low risk scheme *per se* but gives preferential assessment timeframes for products that meet some predefined hazard criteria. Such a scheme may have applicability to the Australian context.

product. Second, the user has additional protection from misrepresentation under Australian consumer law. An alternative view is that the absence of efficacy data in the registration process may lead to a significant asymmetry of information, to the disadvantage of users. Efficacy testing may reveal significant complexities or even deficiencies in performance of a product that would affect the long term performance of the product. It might not be in the product owner's interest to reveal these to the market. Additionally, in the absence of label instructions guided by efficacy testing, users might be more likely to carry out their own experimental investigations, possibly with significant risk increasing consequences. A related concern is the likelihood of biosecurity risks arising from treatment of livestock with a chemical that is registered but does not work effectively. Some stakeholders have expressed strong support for continued efficacy testing in APVMA assessments.

Feedback from a number of industry stakeholders and from some jurisdictions questioned the ability of the APVMA to take on additional responsibilities at least until there was a demonstrated improvement in performance in meeting its existing set of responsibilities. In this context, the Productivity Commission's preferred model of incorporation of control of use activities into an expanded APVMA was thought to be questionable.

8.1.2 Feedback on Other Issues

Users who had applied for minor use permits made a similar set of claims about timelines and unpredictability to those listed above. Almost by definition of minor use, applicants for permits are users who have access to a limited range of chemicals. Timing can therefore be critical, as the applicants may have no interim coverage for their particular chemical demand. Without evidence of timeliness of both applications and APVMA responses it is not possible to judge the merits of these claims.

On the other hand, some community groups saw the APVMA as having been captured by the chemical industry and being unresponsive to concerns about contamination of food and the broader environment by pesticides. Some in that group were amongst those who expressed a desire to have decisions about registration and use of agricultural and veterinary chemicals based on a precautionary approach. There appear to be two distinct issues here. At one level there is an argument about the institutional structure and its effect on the APVMA's incentives and behaviour. At another level is a rejection of the risk management model on which the National Registration Scheme is predicated.

A number of industry and community stakeholders have questioned the APVMA's effectiveness in achieving compliance. The APVMA's current compliance powers appear limited compared to those of other regulators, such as the TGA. In particular, it does not have the mix of administrative civil and criminal enforcement powers common to a number of regulators with quite diverse legislative responsibilities.

A related matter concerns the question of whether the regulatory framework should contain a mechanism for providing direction to the APVMA on broader policy issues. For example, broader public policy consideration might suggest that the use of an antibiotic in food-producing animals that is a 'last line' product in human medicine is inappropriate, particularly where an effective alternative exists for treatment of the animals. Under current legislation the APVMA must consider each

compound and use pattern independently. Similarly there is a question whether the community should be exposed to pesticides that are bioaccumulative but which on existing science appear not to cause harm to humans. Currently the APVMA must assess any such products purely on the known science. There are broader public policy questions in such cases as these which cannot be appropriately addressed by the APVMA.

With regard to chemical review the APVMA appears constrained in at least two ways by its existing legislation. First, it can require that the scientific underpinning for a registration be brought up to contemporary standards only if there is evidence of likely undue harm from the product. Second, there is no cutoff date for data provision to a review. In effect, a review can be interminable. In this context it is worth noting that the APVMA legislation does not have provision for a chemical reregistration program, such as that which operates in the EC.

An issue that is common to the use of minor use and emergency permits in food producing industries is the lag between issue of a permit and MRL by the APVMA and its uptake into the Food Standards Code by FSANZ. This lag can result in producers using a chemical legally and responsibly, under the Agvet Code but not being able to market the produce because the chemical has a default MRL of zero. Resolving this issue is a COAG Early Harvest reform. COAG (2008a), at its meeting of 3 July 2008, agreed to implement recognition by FSANZ of MRLs set by APVMA for domestically grown produce. The agreement is yet to be implemented.

8.2 Labels

Amongst users, trainers and some state regulators who had ongoing contact with users there was a litany of complaints about labels and observations about circumstances in which the impact of instructions on labels can be perverse. Concerns included:

- vagueness about what information on a label is mandated and what is voluntary;
- archaic labels with instructions in outdated occupational health and safety terms and for use with outdated technology;
- inconsistencies in instructions between the label and MSDS of the same product;
- conflicting or nonsensical statements (to the extent that some users and trainers maintain ‘stupid label’ lists);
- different apparent meanings for the same term on different labels, and;
- difficult or vague language.

The APVMA’s risk assessment is valid as long as the product is used according to label. It is evident from discussions with stakeholders that some users struggle to understand some label instructions and that others do not bother to do so. The APVMA has been working to rewrite labels to align with a set of principles agreed by a Registration Liaison Committee Working Group. The Working Group’s principles are as follows.

- Information relating to the key risks to be grouped and arranged in a set order.
- Important use restriction statements be prominently shown and be based on information presented to the APVMA which demonstrates that the aspect of use that is to be restricted is either known to, or can be reasonably be expected to, cause an adverse effect to third parties, ie with respect to trade, public health, animal health or the environment.

- Instructions on labels must be clearly worded so that statements that are warnings to users of possible adverse outcomes, or advice to achieve best results, are not restricted by directive "do not" statements.

The APVMA appears to be constrained in its ability to respond to the need for label change. In the first place reviewing and replacing labels on the large inventory of 'grandfathered' products would be a costly process. Additionally, there are legislative constraints on the APVMA's ability to require changes to labels or to respond to new technology. Where there is evidence that an instruction on a label is insufficient the APVMA can require changes. But, it cannot require that an additional instruction be placed on the label even if there is evidence that its absence reduces the effectiveness of the instructions. The constraint that the APVMA must approve a hard copy label to be fixed on the product container seriously limits the possibility of the regulator encouraging computer based instructions.

8.3 Minor Use and Permits and Permitted Off Label Use

Australian agriculture includes only a few industries that approach a size that provides a substantial market for chemical products. At the tail end of the size distribution of Australian industries is an extremely diverse group of small industries with demands for a large and ever changing portfolio of chemical products. These include many horticultural food crops and a variety of amenity horticultural uses. Hence, an ongoing issue is the problem of provision of access to chemical products for 'specialty crops' or 'minor uses' in larger industries.

Consequently, there was much discussion amongst stakeholders in early consultations of what occurs under the APVMA's minor use permits, permitted off label use in Victoria and South Australia and NT and use within tolerances in Queensland. Some Victorian and South Australian users were particularly concerned about the possibility and consequences of losing off label use.

Minor uses are generally accepted as being those which provide for a market too small to induce chemical producers to include the particular crop and pest combination on a product label. In other words a minor use is one for which the expected net sales revenue is not sufficient to compensate for the cost of additional testing or if the use is not supported by the company for other reasons, e.g. corporate policy, marketing strategies.

Accessing a sufficient selection of chemicals for minor use can also be a problem in some livestock industries and in aquaculture. Generally producers of minor livestock species and aquaculturists can seek to use products off label under veterinary supervision, making the minor use problem less pressing in these industries than in small cropping industries. In major trade species only one individual animal can be treated[6].

There are no reliable figures for chemical use in minor uses. Individually, specialty crop and livestock products are small scale and may not involve substantial chemical usage. So, in one sense, the issue could be regarded as a diversion from the broader issues of large scale chemical use. Yet many of the minor uses are for horticultural products which are significant dietary components and have high

[6] Except in NT, where single animal off label treatment is not permitted.

market value. Therefore both the food safety and economic stakes may be much higher than the value that is apparent from the total chemical use. As well, the number of minor and specialty products is expanding to cater for an increasingly multicultural society and changing food preferences. Further, growing of specialty crops in intensive horticultural areas at the rural-urban interface increases the possibility of negative externalities from unapproved minor uses of chemicals.

Provided that it can be assured of the safety and efficacy of an existing chemical product for a particular off label use, the APVMA can issue a permit for a minor use, or for experimental use or emergency use. In assessing an application for a permit the APVMA may draw on data from one or more of several sources including: existing data held by the APVMA, international residue data accessible through fora such as the Joint FAO/WHO Meeting on Pesticide Residues and the Codex Committee on Pesticide Residues, new data provided by manufacturers from international sources or new data provided by the applicant. Around 85 per cent of applications are assessed without a requirement for applicants to provide new test data. Even so, accounting for the time and effort involved in organising and making an application, the total cost to a small industry applicant may be significant.

Intuitively, though, the first port of call for somebody seeking clearance to use a product for a minor use would be the registrant of the product. If a user, or users, can convince the registrant to apply for inclusion of the crop in question on the label, the problem is solved from the user point of view. There can be two difficulties here. First, it may be difficult for a small group of users to attract the interest of the registrant. The market extension from adding the crop may not be of sufficient size to be worthwhile for the registrant. The process of seeking the extra registration will most likely require provision of extra test data, at least for residue and for efficacy under Australian conditions (under the current APVMA requirements). Test results do not come cheaply. The margin on the prospective extra sales to treat a small crop may be small relative to those additional costs or negative.

It may be possible to provide improved incentives for registrants to apply for more minor uses on labels. Extending protection for data submitted in support of a permit application would be a straightforward improvement in incentive although it is not clear how strong an effect such an extension would have. As well, there may be ways that the APVMA could expedite applications for new products on the basis that the registrant included in the application crops from:

- a listing of top ‘100-200’ minor use gaps, or;
- an allocation to grower industry groups of ‘fast passes’ for minor use.

It might also be desirable to allow registrants to update labels with crops for which grower organisation seeks permits for an administration fee only. Where such a charge is cost reflective it would represent an efficiency improvement. Further work on processes for minimum data requirements for crop groups might also be worthwhile.

8.3.1 International Approaches to Minor Use

The minor use issue is not unique to Australia or to relatively small markets. Both the US and Canada run large government funded minor crop programs. The US IR-4 program is a cooperative arrangement between the US government, chemical companies and Land Grant universities. The

Canadian Minor Use Pesticide Program (Agriculture and Agri-Food Canada 2009) runs on similar lines. The direct relevance of these programs for Australian agriculture is questionable. Total budget funds for the US IR-4 program were $US18m in 2006-07 (CSREES 2009). On top of that were substantial payments in kind by the Land Grant universities which carried out much of the program's research. The definition of a minor crop under the US I-R4 program as one grown on less than 300,000 acres (121,410ha.) an area far greater than the Australian area of most horticultural crops.

Minor users in the UK have at least three possible avenues to access chemical products (Chemicals Regulation Directorate 2009). First, there is general off label access to a range of products, on the understanding that the user accepts all liability. Such an approach might be possible in Australia given a specific exemption to standard consumer law provisions. Second, the user can apply for a Specific Off-Label Approval. Third, a collection of chemicals which are no longer in general use, for various reasons, is maintained for 'essential uses' – minor uses recognised as being constrained in their access to chemicals. This latter category of chemicals and uses results from a cooperative EC program designed to assist producers of specialty crops in recognition of the relatively low risk from very low volumes of chemical use.

8.3.2 Government Assisted Minor Use Access

Several groups made submissions to the Productivity Commission arguing for adoption of a publicly funded scheme for alleviating minor use problems (for example, MULO 2007). The Commission (2008, p.215) argued that a case had not been made for public funding of a program to facilitate access to appropriate chemicals for minor uses. The Commission did not address the question of what alternatives there are to a program with at least some degree of public funding. In essence the options faced by regulators are appear to fall into five broad sets.

1. Do little to facilitate access directly, with the attendant risk that there will be inappropriate use of chemicals on an ongoing basis and consequent damage to human health, trade and the environment should any of those risks be realised.
2. Provide lawful but limited off label use access to low risk chemical uses.
3. Expand monitoring and enforcement activities to reduce non-compliances and improved outcome focus.
4. Fund a system designed to provide timely access to appropriate chemicals for minor use,
5. Find alternative regulatory solutions.

It is worth noting two things about the broader set of responses that would be necessary to meet the Commission's recommendations as a whole. First, the existing minor use permit scheme is substantially funded by cross subsidies from the APVMA's general revenue. That revenue comes mainly from assessment charges, annual fees and the sales levy on more widely used chemicals. Importantly, since Australian farmers are mostly price takers on the world market, the bulk of the cost is ultimately borne by farmers in the broadacre cropping and livestock industries. Cross subsidies of that nature reduce efficiency. Removing the cross subsidy would be consistent with the Commission's approach to efficiency. But it would significantly raise the cost of minor use permits and thus reduce minor use access to approved chemicals. As well, it seems that any nationally consistent approach to enforcement of label conditions, as recommended by the Commission, would involve a reduction in access through systems such as the off label access allowed under Victorian legislation. That too would reduce access for minor use although it is unclear how great the

reduction would be. To the extent that off label use is in horticulture, many of the uses may be covered by APVMA permits valid in other states. In such cases an end to off label use in Victoria would have no effect on chemical access for Victorian producers, however, where a permit does not exit there will be an increase in costs and a reduction in the timely access to chemicals. Nevertheless any off label uses outside this group potentially involve some additional risk. So, in order to meet the Commission's broader conditions, a nationally consistent approach would either produce more human health and environmental cost or require greater enforcement effort, unless an alternative scheme for funding minor use access was adopted.

How much the act of reducing the degree of cross subsidisation of the minor use permit system would affect the total costs of permit applications is unclear. The APVMA currently charges $320 for a permit application. Resource costs of servicing permits average around $2,000. So there is a cross subsidy of around $1,680 per application. (In its draft cost recovery impact statement the APVMA (2008) proposed a fee increase to $700.) The total cost of a permit application includes the cost to the applicant of all tests required and of making and following up the application. Data requirements for an application may vary from minimal, when assessment can be done on the basis of extrapolation, to residue testing only, to full residue and efficacy testing. Estimates of the cost of providing a full set of efficacy and residue tests for a permit application run between $20,000 and $60,000. However only around 5 per cent of applications require submission of such data. The majority of applications have data requirements towards the lower end of the cost range, with around 85 per cent requiring no new test data. So cross subsidisation within the APVMA may be significant compared to the total costs for many applications. In a smaller percent of applications it will be a very small part of an applicant's total cost.

In concluding that the case for public funding of minor use access had not been made, the Commission did not appear to be aware of the cross subsidisation of minor use permits. So it did not consider the consequences of removal of the cross subsidy.

It is unlikely that greater risks to human health and the environment would be acceptable under (1). So either greater monitoring and enforcement effort or an alternative funding model would appear to be necessary in any nationally consistent system without cross subsidies within the APVMA's activities. In this context it may well be that the cost of greater monitoring and enforcement (3) would be greater than the cost of facilitating access through direct government funding (4). Whether or not there is a role for legitimate off label use (2) or alternative regulatory options (5) is additional questions.

8.3.3 Permissable Use for Species not Included on the Label

In some circumstances use of agvet chemicals may be permitted for host species not included on the label. There are two primary sets of such circumstances. The first set relates to veterinary prescription rights that apply to use of unregistered products and compounded products. Outside Victoria and NT veterinary surgeons can legitimately make off label prescriptions in two primary cases – for a single animal of a major trade species, or generally and for multiple animals of minor

species[7]. The second set relates to permitted off label uses of agricultural chemicals the most extensive of which applies in Victoria and South Australia. In each of these cases, a primary purpose of the off label policy is to overcome chemical access for minor uses.

It has been strongly argued by some stakeholders that the veterinary prescription rights are particularly beneficial and relatively low risk. These rights were built into veterinary control of use on a national basis in 1999, in response to recommendations by to the Price Waterhouse et al. National Competition Review. It has been argued that minor use prescriptions fall well within the professional expertise of vets. And the general record keeping requirements for vets means that traceability is high. On the other hand, this method of solving a user's minor use problem effectively places the burden of risk assessment on the vet. For low levels of use and in conditions where the main risks are to the animal being treated there is no obvious problem with such an approach. This use could also be considered essential for animal welfare. Decisions of that type are likely to be well within the professional competence of the vets who make them. However, in recent consultations some stakeholders have questioned the extent of those rights, pointing out instances where prescription reaches a large enough scale or represents a significant enough food safety or environmental risk to be of concern. In cage aquaculture, for example, prescriptions may involve environmental risk. Even in Australia's largest aquaculture industries agvet chemical use is ranked as minor use. That can potentially lead to substantial use of veterinary products or their derivates flowing directly into the marine environment without full risk assessment.

In most Australian states in most circumstances the sole potential legal solution to an agricultural chemical minor use problem is through the APVMA's minor use permit scheme. There are notable exceptions. In South Australia off label use is permitted for specifically exempt horticultural crops grown under PIRSA approved quality assurance schemes. The quality assurance schemes provide built in monitoring. In Victoria off label use is allowed for all but restricted agricultural chemicals provided that maximum rates and frequencies are not breached and that users abide by all restraints (Do Not, Not For, etc.).

Use of chemicals for crops that have not been included either in the assessment process for registration or for some other formal assessment process (such as that for permits) inevitably involves some elements of unassessed risk. Without access to appropriate instructions on a label or through a permit process users might add to the dietary load of a chemical that is already used extensively on food crops, for example. Alternatively, use of a chemical on feed grain or a fodder crop for which there is no established withholding period may raise a potential trade issue in livestock industries in the crop might be used as feed. The importance of such issues will depend on a number of factors, including extent of use. In this context it is important to consider the total risk. From the extent of use alone, off label uses that go beyond a very small scale will involve greater total risk. For example, with regard to food crops, there is more likely to be an issue if the chemical is used for a fruit crop that is an important dietary component than for a herb that is a tiny dietary component. On the other hand, where an off label system allows use on major crops there may the

[7] As noted above no off label prescriptions are allowed in NT for unregistered products. There is nothing in the Victorian legislation to prevent a vet making off label recommendations for more than one animal of a major trade species.

potential for quite significant risks. As well, even in relatively small crops, it may be possible to push consumption of a chemical that is widely used on other crops are towards or beyond the acceptable daily intake inadvertently.

Despite the apparent risks of off label use, there is no evident pattern of residue violations in Victoria, where off label use is most extensively permitted. Of tests carried out in the Victorian Produce Monitoring Program in 2007-08 97.0 per cent contained no measurable residue and only 0.1 per cent contained residues above FSANZ MRLs. All cases where MRLs were exceeded were referred to the Department of Human Services and found to be well below levels that would be a health risk (Department of Primary Industries Victoria 2009). The results for 2007-08 are consistent with those from the monitoring program over a number of years.

A key question is whether, in a national framework of integrated assessment, registration and control of use, there would be any role for uses on different crops to those on the label. Intuitively, an integrated system would involve conditions which made it possible to handle reasonable demand for access to chemicals through either label instructions or permits. On the other hand there could be cases where the extent of additional risk is outweighed by the cost of assessment, even for a minor use permit. It may be worthwhile examining the possibility of finding ways to ease access for very small uses, particularly for uses on non food crops.

Key Questions for Stakeholders

Q7 What would be the advantages/disadvantages of adopting an assessment process for new chemicals or products based on an agreed time for an agreed data set?

Q8 What are the most important ways in which the efficiency of the APVMA's assessment process could be enhanced?

Q9 How close is the alignment between chemical/product risk and effort in the assessment process and how best could it be enhanced?

Q10 What is the benchmark against which the performance of the APVMA should be assessed?

Q11 What is the evidence that assessment would be more efficiently performed without the APVMA being required to carry out either efficacy or trade assessment? How would the risks that are currently managed through APVMA assessment of efficacy or trade risk be adequately managed in the absence of that responsibility?

Q12 What would be the advantages and disadvantages of introducing a requirement for reregistration of agvet chemicals after a set time?

Q13 Is there a case to be made for revision of the APVMA's compliance powers and, if so, what improvements are needed?

Q14 Is there evidence to suggest that there would be net benefits from government budgetary support of applications for minor use permits?

Q15 What role, if any, could off label access to chemicals for minor use play in an integrated national system?

Q16 What are alternative systems for minor use and specialty crops/animals?

9 Control of Use

Control of use is handled in quite different ways in different jurisdictions. Differences exist at three broad levels: resource intensity of control, philosophy underlying control and departmental and institutional responsibility.

There are quite divergent philosophies underlying control of use. At one end of the spectrum is the approach taken in NSW and Tasmania, in which there is a requirement for users to stick to label instructions in most circumstances. At the other end is the approach described by the Victorian Government (2008, p.8) which has '…flexibility provided and the onus placed on primary industries to manage agvet chemical risks.' Regulatory oversight is intended to involve close ties with industry quality assurance and governance schemes and sufficient resources devoted to monitoring and compliance activities focused to '...address identified/substantiated 'public' risk' (Victorian Government 2008, p.9).

Questions about the relative resource intensity of control of use are difficult to answer with any certainty. In the first place there are very different institutional models in different jurisdictions. Disentangling control of use activities from overlapping activities will be an important task for development of a final policy proposal, which will be part of PSIC's consideration. However that task is work in progress. More importantly, differences in the size of the agricultural sector and in both the size and structure of non agricultural uses between jurisdictions makes comparison difficult. It can be said with reasonable confidence, though, that the outer bounds of relative effort are described by the regimes in Victoria at the most intense and Western Australia at the least intense.

Aside from the relative effort put into monitoring and enforcement, there are also significant differences in the approach taken in different jurisdictions. Some jurisdictions and some industry stakeholders have argued that there is an important distinction to be made between prescriptive and performance based controls. In this context, a requirement for all uses to be strictly according to label would be seen as a prescriptive approach. On the other hand, the coordination between PIRSA and approved quality assurance schemes for permitted off label uses in South Australia is performance based – with residue testing and other activities within the quality assurance scheme playing a key role. Similarly, the relationships between DPI Victoria and industry quality assurance schemes are performance based, as are Victorian industry action plans. The Victorian approach centres on improving outcomes (in terms of residue measures and user practices) through a strong focus on monitoring and resolution of problems through action plans and other industry level changes.

9.1 Rationale for Local Controls

States and territories may be keen to maintain at least some flexibility in control of use for a number of reasons. The Productivity Commission argued that there seemed little legitimate basis for maintaining flexibility on a state and territory basis. Its reasoning followed an argument made by CropLife Australia (2007) to the effect that agricultural regions are poorly aligned with jurisdictional boundaries.

The Commission's conclusion seems reasonable in terms of chemical issues that apply across particular crops or agricultural sectors. For non agricultural uses of agvet chemicals, however, it is

the structure of urban areas and their surrounds that is most important. In addition, there are sometimes issues that require responses confined to quite tightly defined regions. In this context the Victorian Government (2008,p.8) argued that '…approaches such as agricultural chemical control areas have been successful and Victoria would be keen to maintain such 'options' in our 'regulatory toolbox'.' A relevant question in this context is whether such requirements are specific to jurisdictional controls or whether they could be met by other means.

At another level, the NSW Cabinet Office stated that some degree of flexibility was needed '…to manage the community's real or perceived view of risk in that state' (p.20). The assessment and registration process for agvet chemicals is science based and objective. It is clear enough that there could be a case for local response to real local risk. A question here is whether an otherwise objectively based system should be flexible in response to a 'perceived view of risk' where that differs from real risk.

Queensland has introduced special control of use regulations for three catchments for the Great Barrier Reef to address specific herbicide chemicals found in the water in these areas of the reef. These catchments were felt to need special protection. Introduction of these controls in relation to diuron products was considered necessary as the APVMA has not finalised a review of diuron which was original scheduled for completion in 2005 as a commitment towards the original Reef Water Quality Protection Plan.

9.2 Effective and Efficient Control of Use

Basic control of use activities are: training, or oversight of training; licensing and accreditation; monitoring and surveillance and enforcement. From the earliest reviews of the National Registration Scheme inconsistencies between jurisdictions in control of use have been a core concern. Some changes have been made as a result of the review process, but significant recommendations of those reviews have not been implemented. While there is good consistency in the veterinary medicines area, there is much less with agricultural chemicals. In their National Legislation Review Price Waterhouse Coopers et al. (1999) commented that 'the time delay costs associated with permits … would be immensely impractical for veterinary purposes.' In March 1999 the Standing Committee on Agriculture and Resource Management endorsed national regulatory principles for controls over the use of veterinary chemicals and agreed that the principles should be incorporated into State and Territory legislation. Most jurisdictions have fully adopted these agreed principles into control of use legislation.

Enforcement may involve largely softer actions such as issuing warnings and advice. Also, proactive approaches seeking industry change may offer a more effective option to punitive approaches with a focus on individuals. Still, the regulator must have some substantial punitive power in reserve for other elements of enforcement to be effective. Overlapping with regulatory controls on use is a variety of industry and supply chain quality assurance systems. An efficient control of use system is one which integrates with, rather than conflicts with, those voluntary schemes where that is feasible.

It may be straightforward to assess a chemical product for safety and efficacy when applied according to best practice. It will seldom be as simple to ensure that the registered product is used

safely and efficiently. Many things may contribute to the appropriateness, efficiency and safety of use of an agricultural or veterinary chemical. A product is most likely to be used appropriately and effectively, though, when users:

- know how handle chemicals;
- can easily understand the label instructions;
- are competent in safety procedures and application technology, and;
- have minimal incentives, or inclinations, to apply the product inappropriately.

Knowledge of how to handle chemicals might come from one or more of several sources. Clearly training programs have a potential, if not essential role to play as is discussed further in section 10. Resellers may also have an important part to play in proving guidance on handling and transport, along with being able to offer advice on use.

User understanding of label instructions will be facilitated by having clear and consistent labels on the one hand and competent users, on the other. As is noted above, there is work to be done to lift the quality of all labels to a reasonable level. With regard to user competence, training may play an important role. For a small, but not insignificant, group of users improving labels will not help. That group is composed of people who have difficulty reading a label, or simply cannot read one. Many, but not all of the members of that group are from non English speaking backgrounds.

It is probably reasonable to suggest that most users of chemical products would prefer to use those products in a way that they could be confident was safe for themselves, for others and for the environment. However, their incentive to ensure that safety may be strongly influenced by environmental and business conditions and by the nature and intensity of monitoring and enforcement. As well, it is almost inevitable that a small proportion of users will choose to act in an irresponsible manner. That means that an effective system of monitoring needs to be in place and to be backed up by meaningful sanctions for recalcitrant cases.

With regard to environmental and business pressure, it is important that users have access to products appropriate to changing conditions. In other words, the regulatory system should be responsive to new demands, not unduly rigid and not slow.

9.2.1 Relationship with Assessment and Authorisation

Provided that there is a rigourous and efficient assessment, registration and labelling process, efficient control of use of chemicals should result in outcomes that are consistent with that process. Intuitively, that would seem to require a system that ensures that users stick to label instructions. In practice that may not always be true as there may be situations that were not considered during the assessment. For example, for insecticides in integrated pest management regimes, usage rates may need to be lower than label rates and application times may be more widely spaced than label times. As well, there may be issues with the currency and effectiveness of label instructions as outlined in section 8. Thus, to assure effective control of use, labels and any supplementary means of communicating the requirements for safe use and good practice must also be effective.

It seems evident that use consistent with the main elements of the initial risk assessment would be necessary to deliver an efficient result, as well as effective one. While all label instructions must be consistent with that assessment in order to be approved, some might be introduced by the

registrant for commercial reasons not to do with policy relevant risks. Although some deviations from label instruction may not involve additional risk it seems that in many cases either:

- additional risk assessment will be needed, specific to the deviation, or;
- there will be additional risk that is not assessed.

There are some off label uses that may not involve any significant increase in risk contributing factors from those built into the assessment process. The most obvious is the use of products at lower rates or less frequent applications than specified on the label. Such an approach is not currently legal in all jurisdictions. The freedom to operate in this way is often essential to successful operation of integrated pest management programs. However, chemical use at lower than label rates can carry with it the risk of building resistance in target species.

Use of agvet chemicals for a different pest to those on the label might be extensive, or it might not. Such use is essentially untraceable in most, if not all circumstances. There are at least two sets of circumstances in which such use may involve significant risk in major crops and animal species. The first involves trade risk as a result of the absence of appropriate information on withholding periods. The second is where use for an additional pest adds significantly the dietary load of a chemical already used on food product protection.

Another qualification to the apparent desirability of users to always following label instructions concerns the limitations of the incentives for registration of crop and chemical combinations discussed in section 7. There seems no guarantee that all combinations that would be economic and potentially meet the APVMA's assessment requirements will be registered. Some jurisdictions and industry stakeholders have argued that there are significant chemical access problems arising from the current system.

9.3 Reviews, Recommendations and Feedback from Stakeholders

The Radcliffe report contained several observations and recommendations which are still relevant. These included an observation that codes of practice for environmental management would become as important as food safety and quality assurance systems. Radcliffe recommended systematic monitoring and the establishment of a database that would allow a benefit/cost analysis of alternative state control of use systems. The intent behind that recommendation was to provide guidance in the establishment of a harmonised system of control of use across states. The system has not been harmonised – hence the current review. Nor was the database established.

As is noted above the Allen Group's preferred regulatory option of a vertically integrated provider of assessment, registration and control of use was not adopted by PISC. Instead, the Group's second choice of adoption of a set of National Operating Principles was taken up. The National Operating Principles adopted are more in the form of agreed goals than prescriptive directions.

The Productivity Commission's concern about the cost of inconsistencies between states arose from two observations. The first concerned the impact of different licensing requirements for professional operators on the costs to those operators who worked across state boundaries. The second concerned the potential impact of very different interpretations of chemical label instructions between jurisdictions. Underlying the Commission's findings here were a number of observations

that were consistent with those made by Radcliffe and by Price Waterhouse Coopers et al. The most important of those findings were:

- that inconsistencies in licensing imposed costs on licensed operators;
- that the further control of use diverged from the outcomes of the assessment and registration process, the less effective was risk management likely to be; and
- that differences in control of use regimes created competitive disadvantages between producers in different jurisdictions.

It is worth noting in this context that the conclusions about consistency in approach to control of use in each of the three studies were based on arguments of principle rather than on empirical evidence. As is noted in section 8.3.3 evidence from the Victorian Produce Monitoring Program does not suggest a significant pattern of residue problems associated with off label agvet chemical use. Additionally, it might be argued that the second point above was based on a presumption that the assessment, registration and labelling process represents best practice and results in registration of an optimal set of crop/animal and pest combinations on high quality labels. As is indicated in the above discussion, this is not always true.

It is plausible that there could be differences in regulation between jurisdictions due to regional difference in climate and industry even though state boundaries are poorly aligned to agro ecological regions. A look at the existing differences in regulation, though, suggests that other factors, such as the differences in philosophy mentioned in sections 9.1, dominate the variations in regulatory approach.

The tempo and content of initial stakeholder feedback on control of use issues varied greatly between jurisdictions. Not surprisingly, users responded very differently depending on the regime in their particular state. There were several primary areas of concern:

- licensing and accreditation of pest controllers and ground sprayers;
- training and accreditation of users;
- minor use permits and off label uses;
- off site effects of pesticide use, including
    - spray drift ;
    - residues in food;
    - environmental consequences;
- responsiveness to regional issues, and;
- user concerns with adoption of buffer zones.

Generally users in states without off label options did not raise the possibility or desirability of their own states adopting such approaches. Rather, they were more concerned with the operations and perceived deficiencies of the APVMA's minor use permit scheme. On the other hand, producers who have access to permitted off label uses expressed concern about potential impact of policy change – concerns about the likely increased cost involved in seeking permits and about the timing and difficulty of the permit process. Of particular concern were the possible loss of access to unrestricted chemicals without the necessity to obtain a permit, increased regulatory burden and implications for minor and speciality crop/livestock production.

While there was some attachment to particular state regulatory approaches, there was also a good deal of support for the ideas of a single, seamless, system. This was particularly true of users, trainers and professional operators who operated close to or across state borders.

9.4 Off Site Effects

A key reason for regulation of agvet chemicals in the first place is the potential for user actions to result in the imposition of external costs through such events as spray drift, pollution of waterways and residues in food crops. Assessment and registration provides a first line of defence against the imposition of such costs, excluding products that are too dangerous and setting instructions for use for those that are registered. Responsible use, backed by effective control, is meant to complete the circle.

Both community groups and some user groups expressed concern about spray drift and other off site effects of chemical use. The focus for user groups was mainly on spray drift. User groups expressing concern about spray drift emphasised the importance of training in limiting the off site effects of chemical applications. For example, cotton industry representatives indicated that a significant proportion of spray drift damage to crops was a consequence of spraying in unsuitable weather conditions. They argued that many of those spray drift incidents could have been avoided had users been more appropriately trained.

Spray drift was also a major concern for community groups. Those groups also expressed objections about a broader set of issues, with particular emphasis on:

- residues in food;
- pollution of waterways;
- liberal use of pesticides in urban and peri urban areas by local authorities;
- for those with chemical sensitivity, a difficulty in avoiding chemicals or communicating their problem to either users or regulatory authorities.

A key problem underlying concerns expressed by consumer and some other community groups is the absence of a publicly available database reporting residue testing relevant to food safety — with the exception of the Victorian Produce Monitoring Program[8]. The results of the Australian Total Diet Study are freely available. However, the survey is biennial, only, and covers a representative sample of products, rather than a comprehensive list. Results from private quality assurance schemes, such as those of the major supermarket chains are restricted to the contracting parties. Similarly, detailed results from surveys such as the Freshtest are either not available or are available at commercial rates which exclude the general public**.** Summary National Residue Survey results are available in the NRS annual reports (DAFF 2009). However, NRS contributors are mainly from meat and grain industries.

The sparsity of residue data in the public arena emphasises results such as those reported by Choice (2008) for strawberries. Choice tested strawberries from 31 growers and reported 3 cases where an MRL was exceeded or there was a residue of a chemical not approved for use on strawberries. Choice correctly observed that MRLs were set very conservatively and that it was unlikely that any of

[8] Department of Primary Industries Victoria 2009.

the 3 cases would involve a serious health risk. The APVMA analysed the information used by Choice and found that there were actually no breaches of MRLs.

Spray drift events are major features of industry and broader community concern about agricultural chemical use. Depending on the circumstances and the product being used, spray drift has the potential to damage other producers' crops, to damage native vegetation or aquatic life or to pose a direct threat to the health of people, livestock or domestic animals in its path. Drift events underlie the development of a number of policies involving exclusion or buffer zones or chemical control areas.

Another facet of this set of issues concerned user industry fears of state government responses to pesticide concerns. The Tasmanian Poppy Growers Association Inc. (2008) response to the Tasmanian government's exclusion zone and related 2008 policy proposals typifies those fears. Similar concerns were expressed by other Tasmanian industries and by users in New South Wales with respect to buffer zone proposals.

9.5 Compliance and Legislative Tools

Monitoring, follow up and enforcement activities are key parts of control. In the following discussion some particular examples of control of use activities are outlined.

9.5.1 Approaches to Monitoring and enforcement

Broadly there are three ways to identify problem, or potential problem areas in chemical use. First is to wait for adverse reports. Second is to use broad monitoring devices, such as the residue testing in the National Residue Survey, state surveys or Freshtest or either formal or informal contacts with the managers of quality assurance and stewardship programs. Third is to design specific targeted programs of monitoring and investigation. All jurisdictions have access to the first approach and have some capacity to respond to problems identified by public or industry reports of spray drift or other reports of environmental damage. Similarly, all have, or potentially have, access to a range of data sources on residue tests. Access to information on user performance in non agricultural uses is not so clearly available without specific targeted programs.

In most jurisdictions there are no formal relationships between quality assurance schemes and regulators.[9] South Australia and Victoria are exceptions. In South Australia approval may be given, for off label use of an agvet chemical, conditional on the user being part of an approved horticulture quality assurance scheme. In Victoria industry schemes are explicitly recognised in the control of use legislation. In these cases enforcement powers operate as a benchmark (minimum requirement) for private schemes. From a public point of view, the reliability of quality assurance schemes may depend on whether or not they are subject to independent audit. The government benchmark exists to protect the entire community, not just one sector.

[9] Testing laboratories in Queensland have an obligation to report any case in which an MRL is exceeded. However, given that there is no such requirement in other jurisdictions, there is an incentive to have tests done outside Queensland. See also s56A of the Victorian Agricultural and Veterinary Chemicals (Control of Use) Act 1992 – 'Notification by commercial laboratories'.

To the extent that governments rely on quality assurance and stewardship programs, they have a duty of care to ensure that those programs offer effective market and community protection. There is a also a broader regulatory role to the extent to which there are gaps in coverage of those programs. The National Residue Survey covers mainly meat and grain products. Freshcare covers fruit and vegetables channelled through capital city central markets. A variety of industry specific programs cover other specific industries. The major supermarket programs have broad coverage but are not generally accessible. Rather, they simply provide some background assurance. A number of mostly smaller industries, particularly in horticulture, are not well covered by these systems. In this context it is not surprising that both in both Victoria and NSW regulators have had recent programs to improve performance in the strawberry industry.

A good deal of the monitoring and enforcement in all jurisdictions is reactive, in the sense that ameliorative or enforcement activity follows some form of adverse report. In some jurisdictions the total resources devoted to control of use are insufficient to allow much other than reactive enforcement. This is largely true of WA efforts in the agricultural sector, for example. On the other hand, there is substantial planned monitoring and follow up in some states. For example, NSW DECCW take a strategic approach to identification of a limited number of chemicals and other priority issues. In 2009 those priorities covered – pesticide use: around waterways; in the bee industry; at bowling greens and golf courses, on turf grass and sporting turf facilities – plus 2,4-D and 1080 products. As indicated above, Victoria also has a targeted monitoring program, carries out user audits and establishes industry work programs. Similarly, NT has a limited program with follow up with growers. A requirement that all chemical users keep records of use is an important part of both the NSW and Victorian programs (and the NT program for commercial producers). Other targeted monitoring programs include Tasmania's water quality monitoring measures measures and Queensland's targeted monitoring of those products not well represented in the National Residue Survey and those producers that local intelligence identifies.

Aside from the monitoring and enforcement activities outlined here and training, accreditation and licensing activities, control of use may involve a range of other actions. Of particular importance in this respect are various forms of area control, such as buffer or exclusion zones and chemical control areas.

9.5.2 Effectiveness and Efficiency in Monitoring and Enforcement

There is an extensive list of potential monitoring and enforcement tools. What is the most effective and efficient combination of those tools depends on a number of things. A key consideration in the selection of monitoring and enforcement tools is the order of priority in risk avoidance or reduction.

Whilst monitoring and enforcement by regulators is important, it needs to be developed in the broader context of the growth of private quality assurance efforts. A great deal of care would be needed to avoid duplication of regulatory effort, and the imposition of double costs on users. Avoidance of duplication of private efforts is important to the achievement of efficiency for two reasons. First, limiting regulatory effort on duplicate activities will have the effect of – either limiting total regulatory spending or allowing part of the total to be devoted to risk reduction in other areas. Second, avoiding duplicate regulatory effort will mostly also avoid duplication in user compliance effort.

Defining the details of monitoring and enforcement is a task for the implementation phase of setting up a national regulatory framework. The broad coverage and level of monitoring and enforcement will need to be estimated in order to give a reasonable indication of the total cost of regulatory effort.

9.5.3 Legislative instruments

Underpinning control of use activities is a set of legislative instruments designed to provide regulators with the monitoring, investigative and enforcement powers with which to implement control. Some key instruments are as follows.

Offences for inappropriate use Fundamental to control of use is a regulator's ability to enforce the particular interpretation of label instructions adopted in the jurisdiction. For example, in NSW it is an offence to apply an agricultural chemical other than according to label. In Victoria it an offence to apply an agricultural chemical at a higher rate than according to label.

Offences for off target damage Limiting the risks off site to people, property, crops, livestock and the environment is an important part of control of chemical use. A regulator's ability to do so may depend on the availability of powers to apply punitive sanctions to users who cause off target damage.

Offences for possessing or using unregistered chemicals The necessity for regulatory power to prevent/stop use of unregistered products seems clearcut.

Civil penalties The ability to apply a range of civil penalties may be important to effective enforcement. Those penalties may include; infringement notices, enforceable undertakings and injunctions. The regulator may also have the ability to publicise offenses.

Inspection and enforcement officer powers Effective monitoring and enforcement may depend critically on such basic powers.

Powers of seizure The ability to confiscate material may be important in an number of instances including: unregistered chemicals; contaminated food products, other contaminated agricultural products and equipment.

Ability to make orders The ability to instruct users to take specified actions with regard to chemical use, sale and possession in order to manage risks may be important. In particular it may be important to have the capacity to respond at short notice, rather than to have to go through a full parliamentary approval process.

Requirement to keep records A requirement that users keep records is not a control instrument in itself. However, records may become important if used in the context of periodic or targeted audits or in attempts to trace back from reported damage to the source.

Area controls All jurisdictions have the power to declare and enforce some form of area defined restrictions on chemical use. For example, Victoria uses declaration of agricultural chemical control areas to limit the risks of damage to horticulture from 2-4D spray drift. Tasmania is in the process of developing regulations that will involve exclusion zones around some sensitive sites.

Penalty levels Penalties are a backstop for control of use. The effectiveness of any control of use system depends in part on having penalties that are strong enough to act as a deterrent but not unduly onerous or capricious.

Quality assurance and stewardship Instruments to provide incentives for producers to comply, through quality assurance and stewardship programs, for example, may form an important part of a proactive approach.

Key Questions for Stakeholders

Q17 What is the evidence that a particular approach to control of use is/is not effective and efficient:

- in agricultural use, or;
- in urban amenity horticulture or sectors such as management of golf courses and other sporting venues, or;
- in pest and weed control?

Q18 Is there a need for flexibility of control of use to respond to State or regional issues, and how could such flexible arrangements be delivered by a single national regulator, if at all?

Q19 What is the evidence that government penalties are more effective than industry incentives in achieving compliance with chemical use rules?

Q20 To what extent is there a need for a balance to be determined between government compliance action and industry mechanisms?

10 Competencies, training, accreditation and licensing

Within the National Training Framework there is an existing set of competencies for training of agvet chemical users. Training requirements for various classes of users vary considerably between jurisdictions. The existence and extent of this variation, for professional classes of users, was a major issue raised by the Productivity Commission.

In early discussions with stakeholders, there were two distinct areas in which training and accreditation was raised as an important issue. The first was in the area of professional operators; aerial sprayers, pest controllers and ground sprayers. Issues raised by the three groups revealed an increasing level of concern from aerial sprayers to pest exterminators to ground sprayers, reflecting a descending level of training and consistency between states. In each state or territory pest controllers operate under some form of license or accreditation. The primary concerns raised by the group were about a need to standardise the level of training required across states. There were similar concerns amongst ground sprayers, expressed more strongly as the rules are particularly inconsistent for this group.

There was strong support from a diversity of groups, including farm representatives, for training of farmers and other general users. A number of stakeholders suggested that proof of accreditation should be a requirement for purchase of chemicals, as it currently is in Victoria and NT for APVMA restricted chemicals. While there was broad support for training of users, concern was expressed about variation in the quality of training courses.

10.1.1 Issues about Competencies, Training and Accreditation

There is a diversity of requirements for training, licensing and other forms of accreditation across the jurisdictions. Differences between jurisdictions can be confusing and potentially costly to businesses which operate across state borders. As well, differences have the potential to have anticompetitive effects. There are issues at two levels here. The first concerns training and licensing requirements for individuals or businesses that apply chemicals for profit. The second concerns training and possibly accreditation requirements for farmers and other direct users.

10.1.2 Licensing

Resolving the national training and accreditation issue for professional chemical users would seem to be relatively straightforward. There is an existing set of competencies under the Australian Training Framework and there are courses developed to deliver those competencies. What is at issue is the precise set of competencies the will give the best result nationally. As it stands, pest controllers and aerial operators require some form of training and licensing, or other accreditation, in every state and territory. There is not a universal requirement for ground sprayers.

A PSIC working party has made considerable progress towards eliminating the conflicts between jurisdictions in training requirements for aerial sprayers. With regard to pest controllers, there are substantial differences in licensing or accreditation requirements. For example, in Western Australia the training requirement included 13 competencies. In some other states as few as 3 of those competencies are needed to meet licensing requirements. Work is currently under way to develop and improved model for licensing in NSW. A discussion paper summarising the outcomes of the Pest

Management Industry Sector Committee pest management licensing workshop held in Sydney on 30 July 2009 will be released in late November 2009. The policy review and development process of which the workshop and discussion paper are part has broad national participation.

There are no data available on the areas covered by ground sprayers, either private or commercial. It seems likely, though, that commercial operators cover more ground and come into contact with more people than do private users of ground spray units. On that basis alone, there appears to a strong rationale for requiring that a person offering ground spraying services commercially should be required to have training appropriate to the task. That extent of coverage is additional to the primary reason for licensing which is that they operate on other peoples' land in a professional capacity.

10.1.3 Training of Other Users

The issues with training and accreditation of users are somewhat more complex. Intuitively, it seems reasonable to expect that a user should be able to demonstrate the necessary competencies in order to gain access to chemicals. The Centre for Health Promotion Research (1995) reported strong gains in Western Australian farm user understanding and behaviour as a result of training. The effectiveness of user training has been little studied, though, so there is limited direct evidence of its impact on user behaviour. Also, beyond a basic level of competency in handling chemicals, the skills needed to do a job safely and effectively can vary greatly with the chemical and the application concerned. That would suggest that requiring a standard level of training across the board could be counterproductive. In this context it is worth bearing in mind that the national competencies were originally designed to meet industry needs. It may be worthwhile to revisit the design of competencies specifically to suit regulatory needs if there are to be general requirements for training.

A structured training requirement, with skills required geared to the user's activities and the level of risk, might be effective and would be likely to meet less resistance than a 'one size fits all' approach. If there is a requirement for training, it may need to be backed up by an accreditation requirement. In this context specific requirements for the use of fumigants and vertebrate pest products stand out.

10.1.4 Accreditation and Access Controls

A further question about user training is whether some form of accreditation should be needed for a user to gain access to a particular class of chemicals, or even to any agvet chemical. At present every state or territory except NSW has the power to impose accreditation requirements at the point of sale. Under the current two part structure of the National Registration Scheme there is some potential conflict between the imposition of any such requirements and APVMA responsibility control to the point of sale (the reason that NSW does not have such a requirement). The accreditation requirement for access to products on the Victorian restricted chemicals list (which includes all APVMA restricted chemicals) and a similar requirement in NT appears to demonstrate that such an approach can be effective.

A requirement for proof of accreditation at the point of sale would appear to have a lot to offer in terms of effectiveness. For example, presentation of an Agricultural Chemical User's Permit (ACUP) is

required for a user to purchase APVMA S7 and restricted chemicals in Victoria. Proof of training to Level 3 is required for issue of an ACUP.

Key Questions for Stakeholders

Q21 What evidence is there that training is effective in improving agvet chemical use?

Q22 Should there be a required level of training for access to agvet chemicals and, if so, what should be the basis for establishing that requirement (eg level of training and scope of operation, such as commercial operator or private landholder)?

11 Possible Structures for a National Regulatory Scheme

The current National Registration Scheme is a partnership between the states, territories and the Commonwealth. In its response to the Productivity Commission's report on Chemicals and Plastics COAG recognised that partnership by instructing that PIMC propose a '... single national framework to improve the efficiency and effectiveness of the regulation...' without prescribing the form of that framework. It did emphasise the importance of integration and of '...consistency of risk-management outcomes...'

11.1 Design and Governance of Alternative Models

There are many possible national frameworks in which it might be possible to manage control of use of agvet chemicals. These range from inclusion of control of use in the package of regulatory services provided by a single national body to continued separate provision by state agencies with some greater coordination or harmonisation than currently exists. Subsequent to its Research paper on chemical regulation the Productivity Commission (2009) commented on 'lessons' about national level regulation learned from its work on chemicals and plastics regulation. The Commission made observations about a broad spectrum of possible models for ensuring some degree of consistency in regulation across jurisdictions. While there are many possible ways to provide some greater consistency of control than currently exists, it may be that only a few of them offer practical solutions that are effective and efficient.

At its most basic the choice breaks down to:

- incorporating control of use into the activities of a single national regulator, either;
    - integrated with assessment and registration, or;
    - as a separate control of use body, or;
- choosing one from the many options available for greater harmonisation of control of use by state agencies, including those discussed below;
    - template legislation;
    - model legislation;
    - harmonisation of subordinate law;
    - adoption of agreed principles, or;
    - mutual recognition .

11.1.1 Approaches with a Single National Regulator of Control of Use

In its recommendation 8.2, the Productivity Commission suggested that the development of an integrated national regulatory system for agricultural and veterinary chemicals should be achieved through an expansion of the APVMA's responsibilities with control of use outsourced to the states and territories through service level agreements.

11.1.2 A Single National Provider of Assessment, Registration and Control of Use

The Productivity Commission recommended that in taking over all control of use activities the APVMA take and fund its responsibilities through additional fees and charges. The most obvious way to facilitate such a change would be a conferral of powers by the states to the functions of the

APVMA, in addition to the arrangements in the Agvet Code which underpin the APVMA's current activities. As well, the Commission argued that, given a conferral of powers by the states, the APVMA would have the ability to raise funds for control of use activities through levies and charges.

It is apparent, though, that two further assumptions underlie the Commission's recommendation: that state governments would easily cede power over control of use and that the degree of flexibility in controls sometimes needed at a State or regional level could effectively be delivered through service level agreements. The Commission argued that any need for flexibility occurred at a regional level and that state boundaries lined up poorly with agricultural regions. As is noted in section 9.2.1, though, the latter argument may not be as strong for non agricultural uses of agvet chemicals.

There might be a number of ways in which control of use could be delivered by a single national regulator, amongst which are:

1. a national regulator which controls use through its own regional branches;
2. a national regulator which outsources control of use on the basis of open tender, or;
3. a national regulator which outsources control of use to state governments, with those governments choosing which agencies will deliver the services.

Of the three options, presumably option (1) would allow achievement of the greatest level of consistency in control of use across regions and with assessment and authorisation. It is likely, though, that the setting up and management of regional offices would involve greater cost that would options (2) or (3), at least in the initial phase. A national regulator of this form would need to develop ties with a range of state and territory authorities – such as primary industries, health and environment.

Since option (3) relies on existing state and territory institutional structures, it may be possible to implement it with less transition cost than would be involved in setting up either options (1) or (2). On the other hand, it may be more difficult to ensure consistency of control of use delivered through the currently very different structures between states and territories.

Option (2) represents an attempt to combine the consistency that can be a feature of delivery by a single regulator with the potential efficiency gains from competitive tendering. Success could depend critically on the quality of specification and oversight of the contract. Whether or not the providers had effective regional contacts might depend on who the successful tenderers were and, therefore, on the quality of the tendering process, amongst other things.

For individual states which agency handles agvet control of use is likely to matter for broader reasons. Changes that involve loss of agvet control of use responsibilities may also impinge on critical mass of pesticide expertise or scientific expertise that currently covers integrated work across agvet chemical and related work. Essentially the same issue may arise under models if state and territory government provision under harmonised legislation or regulation requires control of use to be handled by the same portfolio across all jurisdictions.

As is outlined in section 7, a national regulator of an integrated assessment, authorisation and control of use would have a quite different set of responsibilities to either the APVMA in its current form or any of the state or territory control of use agencies. It seems that it would also need to have a clear focus on total risk in its broader operations.

That highlights the issues set out in section 8 with respect to the legislative constraints on and performance of the APVMA as it stands. The results of recent reviews, along with feedback from a range of stakeholders suggest that there is still significant room for improvement in the efficiency of the APVMA's performance of its current functions. As well, some jurisdictions have questioned the APVMA's current effectiveness in facilitating user access to appropriate chemicals. Governments would need to be confident that those issues could be resolved before creating a regulator with expanded responsibilities.

In considering the prospect of a single national regulator, there might also be some greater organisational risks than would be the case with a more diversified structure. Avoiding industry capture and maintaining transparency may be more difficult for a single organisation than for a collective group. In a related context, the Productivity Commission (2009, p.4) notes that competition between jurisdictions may provide benefits as a result of enhanced incentives to seek more efficient solutions.

11.1.3 Separate National Regulators of Assessment and Registration and Control of Use

Rather than adding a new set of responsibilities to the APVMA's existing set, control of use might be handled by the creation of a separate national body to control use. Potentially, the creation of such a body could allow the development of a more consistent control of use regime without loading additional responsibilities onto the APVMA. In this context it might be worth reflecting on the stakeholder reluctance to support expansion of the APVMA mentioned above.

Ultimately, what could be achieved through a dedicated control of use authority would depend critically on the scope of its responsibilities. Some stakeholders have suggested that a national body could take responsibility for facilitating registration of or permits for minor use, in addition to core control of use activities. On the one hand it may be possible for a control of use authority to focus more effectively on key areas of monitoring of use and effects of use than it would for an organisation still dominantly concerned with assessment and registration. A dedicated control of use body might better be able to maintain effective feedback loops with users. On the other hand, having two organisations might add some administrative cost and set up potential difficulties maintaining effective feedback from use to the assessment and registration process. However, such difficulties appear to exist already, as is mentioned above.

In this context, the Productivity Commission (2008, p.206) expressed a general preference for separation of chemical and assessment and other chemical regulatory activities. With respect to the APVMA, however, it suggested that there was no urgent need for change. Further, it noted that any change would need to be well thought out so as to avoid any jeopardy to the gains in efficiency and effectiveness in assessment and registration that have already been realised in adopting the National Registration Scheme.

Nevertheless, one possible model would involve splitting off the broader functions now performed by the APVMA and forming a national authority solely with responsibility for assessment registration. Management of chemicals along with control activities from production or importation to use could then be included in the responsibilities of the national control of use authority.

11.2 Harmonised Control of Use by State Regulators

Effective and consistent control of use may be possible through harmonised provision through state agencies, rather than through a single national authority. The Productivity Commission (2009, p.4) noted that there may be a number of potential advantages of state level delivery of services that are coordinated nationally. In this context the ability to '...respond more rapidly and effectively to the needs and circumstances of their constituents than could a national government' is particularly notable. As noted in sections 7 and 9, such an ability is important in management of agvet chemical use. There is a wide range of possible arrangements which might be used to deliver consistency in control across jurisdictions. At one end of that spectrum is the adoption of template legislation, where essentially the same legislative framework is adopted by all jurisdictions. At the other end is the agreement on a common operating framework, such as the current National Operating Principles.

Only some of the possible options for state based control of use are discussed here. More detailed discussion of these and other alternatives is provided in Productivity Commission (2009 and 2008, chapter 3). In effect, though there appear to be two quite different approaches. First is the use of template or model legislation which is described in more detail below. Second is a variety of instruments such as mutual recognition and adoption of national principles.

11.2.1 Template Legislation

The template legislation approach involves the adoption by all jurisdictions of a mutually agreed text. That text may be from the existing legislation of one state or from a new act developed specifically for the purpose. An act specifically drafted for the purpose seems most likely if template legislation were to be adopted for agvet chemical control. The primary advantage of using template legislation is that the initial legislative base would be the same in all jurisdictions.

That would not necessarily guarantee consistency of control of use over time, though. In the first place, there may be latitude for regulations developed under the same legislative umbrella to vary between jurisdictions. As well, consistency of the initial template may not be maintained in future amendments to the legislation. Nonetheless, template legislation could provide a significant move toward consistency.

From a state or territory government point of view the relatively inflexible features of template legislation and the limited ability of the parliaments of individual jurisdictions to direct and review the content of the legislation may be an important limitation. In other words, the same feature that makes template legislation attractive from the point of view of achieving national consistency may be a drawback at the individual jurisdiction level (Productivity Commission 2009, p.20).

11.2.2 Model Legislation

Perhaps the nearest alternative to the template approach is the use of model legislation. The approach involves the development of a base document which contains the core agreed elements of legislation. Each state or territory develops its own legislation from that base. Each jurisdiction has a degree of flexibility in fitting the legislation into its broader legislative package. Thus model legislation can be used to provide a great deal of consistency between jurisdictions, whilst leaving some important degree of flexibility. A possible downside of that flexibility is that inconsistencies between jurisdictions can be built in to the legislation or operating rules within that legislation from

the start. In other words, while the task of setting up similar rules across jurisdictions may be easier and less costly for model legislation than for template legislation, the degree of consistency achieved may be less.

For either the template or model legislation approaches there is a possibility of drift away from the core legislation over time. Under either model each state or territory has its own legislation and can potentially make changes over time. Unless there is an effective process for coordination of changes between jurisdictions, there is potential for inconsistencies to develop over time. Oceania Health Consulting (2005) provides an example of such drift in the Therapeutic Goods Act.

Adoption of either template or model legislative approaches has the potential to provide a great deal of consistency between jurisdictions, although possibly at significant start up cost. There are alternative approaches which would provide a greater degree of consistency than currently exists between control of use regimes. Three of those alternatives are discussed here: adoption of codes of practice; mutual recognition and adoption of agreed principles. All three are already used to some extent in chemical regulation.

11.2.3 Harmonisation of subordinate law

What the Productivity Commission refers to as 'harmonisation of subordinate law' appears to cover a range of alternatives under which adoption by all jurisdiction of consistent legislation or regulation covering details of control, without necessarily involving large scale changes to the primary acts under which control of use is managed. Concentrating on harmonising aspects of detail has the potential to allow significant movement toward a common system without requiring the more costly reworking of whole control of use systems.

A particular application of harmonisation could be the adoption of a 'National Pesticides Code', with control of use elements under state law. Examples of applications of national codes under harmonised subordinate law include the Building Code of Australia, the Food Standards Code and the Dangerous Goods Code. The approach has the potential advantage that the Code may be recognised in state law in a way that allows changes to the Code to be effective in state law without frequent reworking of state legislation. Good coordination at the outset would be important, though. In this context the Productivity Commission pointed out problems with the Dangerous Goods Code due to differences in state legislation from the outset.

11.2.4 Adoption of agreed principles

Agreement by all states and territories to act according to a set of agreed principles can potentially provide at least a partial solution to policy differences between jurisdictions. In 2004, the Primary Industries Ministerial Council accepted a set of National Operating Principles for control of use for agvet chemicals. The development and acceptance of the Principles was the culmination of a response to the recommendations made by the Allen Group (2002). Adoption of agreed principles appears to have the potential to drag control of use in various jurisdictions closer together. As yet there seems no evidence that the particular set of National Operating Principles adopted for agvet chemicals has removed any significant inconsistency in control of use between jurisdictions or resulted in any efficiency gain, though. A relevant question here may be whether it is the concept of National Operating Principles that is the limitation, or whether adoption of a stronger set of principles could offer greater gains. The existing National Operating Principles for agvet chemicals or

more of the nature of broad goals than enforceable controls. It may well be that adoption of a stronger set of principles could provide effective coordination.

11.2.5 Mutual recognition

A policy of mutual recognition is frequently used by states and territories as a way of smoothing differences in business regulation. Mutual recognition offers a way to achieve some greater level of consistency between jurisdictions with major legislative change. With regard to agvet chemicals there is mutual recognition of pest controller licenses, so that practitioners licensed in one state can operate in other states. In this particular case there are significant differences in the levels and composition of competencies required for licensing between jurisdictions. Thus, resolving policy differences first might be a necessary condition for mutual recognition to contribute to effectiveness and efficiency. More generally, mutual recognition appears to be more suitable for facilitating cross border business activities. Control of use of agvet chemicals is not primarily concerned with cross border activity.

Key Questions for Stakeholders

Q23 Under what conditions could a single national regulator be expected to deliver assessment, authorisation and control of use services effectively and efficiently and, if so would there be a need for flexibility at a regional level?

Q24 Is there a harmonised model of governance that would provide control of use by state agencies that was effective, efficient , integrated with assessment and authorisation and consistent across jurisdictions:

- from the models considered in section 11, or;
- alternatives not mentioned here?

Q25 With respect to permit applications, regional knowledge and access to local advice what would be some of the disadvantages and advantages of control of use by either:

- a single national authority, or;
- harmonised provision by state agencies?

12 Funding Issues

The cost of control of use regulation is currently funded by state and territories governments. As part of the development of a single national framework, the funding of those activities requires consideration.

In the research report on chemicals and plastics regulation, the Productivity Commission (2008, recommendation 8.2) recommended that the additional costs be recovered by the APVMA through a mix of charges and levies.

In its response COAG noted that "this recommendation may have significant resource implications which will be considered during the Commonwealth's budget processes".

Options for cost recovery or government funding of control of use regulation, are canvassed in this section, using the principles set out in Australian Government's Cost Recovery Guidelines and other guidance material.

The assessment is limited to assessing the case for and against cost recovery of control of use activities.

Options for fees and charges (including integration with the existing APVMA fees as well as charges and consideration of the existing APVMA fees and charges, such as the setting of registration and assessment fees below cost), will be considered when the regulatory framework has been confirmed and an estimate of resourcing and associated costs developed.

12.1 Why Recover the Cost of Regulatory Activities?

Cost recovery is the recovery of some or all of the costs of a particular activity. In the public sector it is different from general taxation, where there is no link between the revenue raised and the funding of a specific activity.

Where used appropriately the Australian Cost Recovery Guidelines note that the imposition of cost recovery can improve economic efficiency and generate other positive benefits. However where cost recovery arrangements are either inappropriate or poorly designed they may provide no net economic benefit to the community over general taxpayer funding and could negatively impact on the regulated industry.

12.2 Key Principles Underpinning Cost Recovery Arrangements

In assessing the case for cost recovery or government funding there are a set of principles, set out in the Commonwealth Cost Recovery Guidelines which have been used as a key point of reference.

Efficiency

Cost recovery should be economically efficient. Specifically the imposition of cost recovery should:

- be consistent with the government's policy objectives;
- send important pricing messages to users or customers about the cost of resources used;
- reduce the impost on general taxation revenue; and

- improve horizontal equity by ensuring that those who use or create the need for regulation, or are the beneficiaries of the services, pay for the costs.

When introducing cost recovery arrangements it may also be appropriate to adopt a phasing in approach over an appropriate period of time.

Operating Principles

- cost recovery should relate to specific activities, not the agency as a whole;
- targets should not be set for the level of costs to be recovered;
- activities and services that have public good characteristics may be taxpayer funded;
- cost recovery should exclude services to government which are not integral to the regulatory activity; and cost recovery should be based on efficient costs; and
- cost recovery arrangements should have clear legal authority for the imposition of charges.

Overarching Principles

Irrespective of the above, cost recovery should not be applied where:

- it is not cost effective;
- it would be inconsistent with government policy objectives; or
- it would unduly stifle competition and industry innovation.

OECD Guidelines[10]

In developing cost recovery arrangements consideration should be given to reduced charges for users where full cost recovery would represent an excessive burden on individual users. This may be especially relevant to lower income individuals, smaller entities, users located in remote areas, and heavy volume users of services. The criteria for applying reduced charges should be clear and explicit.

Key Questions for Stakeholders

Q26 What other key principles need to be considered in assessing the case for or against cost recovery?

[10] OECD 1998

13 Is Cost Recovery of Control of Use Appropriate?

The objective of this section is to set out the arguments for and against cost recovery of control of use regulation, using the Cost Recovery Guidelines and other relevant guidance.

There are considered to be two broad options for funding the cost of control of use regulation:

- cost recovery, by way of a mix of fees and charges: or
- Government funding.

It is also noted that partial cost recovery is an option, although the Cost Recovery Guidelines support partial cost recovery only where new arrangements are phased in.

In its review of chemicals and plastics regulation, the Productivity Commission (2008) recommended that the additional costs be cost recovered through a mix of charges and levies. It noted that:

- if a national regime were established, a conferral of regulatory responsibility for control of use on the national regulator would be required and this would give it legal authority to raise the requisite funds;
- a potential increase in the cost of agvet chemicals would not of itself constitute an economic inefficiency. An increase in the cost may be efficient, if it creates an improved signal of the true cost to the community of using a particular product; and
- from an equity perspective, the outcomes of control of use regulation should not be perceived as a public benefit. Control of use regimes are more appropriately described as a reduction in the negative externalities of pesticides. Further it could be argued that the control of use regulations might create some benefit to agvet product manufacturers.

The Productivity Commission also noted that it supports a phased introduction of cost recovery arrangements.

13.1 Policy Objectives of Agricultural and Veterinary Chemical Regulation

The precise objectives of control of use regulation vary across states and territories, based on their respective legislation. However there are considered to be common objectives for control of use regulation which comprise the identification and management of risks arising from the use of agvet chemicals to:

- food safety;
- domestic and international trade, including access to markets;
- public health; and
- the environment.

13.2 The Role of Government

Generally governments do not seek to recover the cost of their core activities because it is neither feasible nor appropriate to charge groups directly for these activities. These cover areas such as

defence, social security and transfers to state governments to fund hospitals, schools and infrastructure and include activities such as the development and maintenance of policy, standards and supporting legislation, as well as parliamentary serving functions. It is generally accepted that these activities are provided to the community as a whole (ie they are public good services) and should be taxpayer funded.

The Productivity Commission noted in its original review of cost recovery by Government agencies that there are circumstances where governments need to regulate the way in which the private sector supplies products. In such cases government involvement is considered to be a form of market intervention to address market failures where the private sector is unlikely to allocate sufficient resources to manage the potential risks, resulting in a net social and economic loss to the community. This is considered to be applicable to agvet chemicals where, despite the existence of forms of self regulation, government intervention has been deemed necessary.

Control of use regulatory activities include:

1. monitoring compliance, investigation and enforcement, including the testing of produce for residues;
2. licensing of Users of Agvet chemicals;
3. maintenance of competency and training frameworks;
4. provision of information to the community and users of agvet chemicals;
5. services to government; and
6. investment in assessing the presence of agvet chemicals in the natural environment.

Although some would disagree, these regulatory activities could be regarded as being outside the scope of core government activities, in full or part, in which case consideration of cost recovery of these activities is appropriate.

13.3 The Role of Industry

13.3.1 Agvet Chemical Industry

The agvet chemical industry includes manufacturers and suppliers of agvet chemicals. Prior to supply, sale or distribution they are required to register their products and obtain approval for product labels from the APVMA, which is responsible for the assessment, registration and regulation of agvet chemicals upto the point of retail sale.

From a control of use perspective the major dependency on the agvet chemical industry is through the provision of effective control of use information on product labels. They provide critical information about how to handle, use and dispose of agvet chemicals and critically address information failures (they also provide legal protection for the registrant of the product). However it has been suggested that labels are not user friendly due in part to the lower levels of education, particularly in primary production, restricting the user's ability to correctly interpret the information.

Ideally manufacturers also take some responsibility for the downstream impact from the use and disposal of agvet products, encouraging them to design products which seek to minimise those impacts.

13.3.2 Users of Agvet Chemicals

Users of agvet chemicals include:

- the primary production industry. This includes farming and agriculture businesses, together with commercial crops sprayers (ground and aerial). For veterinary chemicals this also includes veterinary surgeons;
- pest controllers (commercial buildings and residential premises);
- non commercial users, including lifestyle landholders and householders; and
- environmental weed and pest controllers (government, private and commercial).

The chemicals are used across agriculture and forestry, urban and industrial settings and household uses.

The responsibility on the users is to use agvet chemicals in a responsible manner to minimise the risks to public health, the environment and trade.

Self regulation occurs where users:

- keep themselves informed regarding the use of agvet chemicals through appropriate levels of competency training;
- obtain appropriate licences and permits;
- develop appropriate risk management plans for the use of agvet chemicals;
- use chemicals in accordance with product container labels; and better practice principles;
- maintain appropriate records regarding use;
- notify third parties where use of chemicals may impact on them; and
- comply with withholding periods after use.

13.4 The Case for Government Funding or Cost Recovery

13.4.1 Monitoring Compliance, Investigation and Enforcement

The key regulatory activities undertaken on a recurring basis include:

- monitoring of compliance with relevant legislation and better practice use of agvet chemicals (planned and unplanned);
- agvet chemical user audits and surveys (planned and unplanned);
- agriculture and veterinary chemical use investigations, including unacceptably high levels of residues, complaints of misuses of agvet chemicals and contamination (including spray drift) of plants, animals, humans and the environment;

- provision of advice, information and assistance to regulated industry; and
- enforcement of breaches (warning letters, infringement notices and court appearances).

It is also envisaged that the national regulator could be required to respond to major incidents and may be required to undertake specific work at the instigation of government (see section 12.5).

13.4.1.1 Arguments for Government Funding

The community is the main beneficiary of the regulation

Stakeholders have previously made the case that control of use regulation is primarily for the benefit of the Australian community rather than a narrow group of beneficiaries and the community should pay for the regulation through tax payer funding.

Cost recovery is not efficient

The Productivity Commission noted in its original review of cost recovery by government agencies that "cost recovery arrangements that are not justified on grounds of economic efficiency should not be undertaken solely to raise revenue for Government activities". If so there is little or no advantage over taxpayer funding.

Indicators that cost recovery of control of use regulation is not economically efficient include:

- it is not possible to target the firms creating the need for regulatory activity with some degree of accuracy; and
- the imposition of fees and charges does not clearly support the government's policy objectives through creating incentives for use of agvet chemicals in a responsible manner.

It is not considered to be feasible to directly charge the users of agvet chemicals for monitoring, investigation and enforcement activities, other than where penalties are imposed through fines or legal action. As noted by the Productivity Commission, the most likely mechanism for imposing fees and charges would be through adjustment of the existing APVMA fees and charges, which are collected from manufacturers and suppliers of agvet chemicals.

It may, however, be problematic to apply a set of fees and charges on manufacturers which would accurately target the individual users creating the need for regulation and the creation of incentives for compliant users.

It has been previously noted the total risk is considered to be a product of a number of individual risks, being product risk, deviation of actual use from better practice and extent and location of use.

The Productivity Commission suggested that a tiered level of fees and charges could be introduced, consistent with the product risk, most likely through different levels of annual charges (ie the products considered to be high risk pay a higher annual charge). A potential problem with this approach is that it may not necessarily reflect the total risk where it does not take account of the in use risks (ie the deviation from better practice and the extent and location of use). Potentially, products that have a low in use risk could be charged disproportionately high fees.

Alternatively the recovery of control of use activities through a sales levy would result in high volume products paying the bulk of the regulatory costs, irrespective of the actual in use risk. A levy

tends to spread the costs across the industry, assuming they can be passed onto the users, but cannot target those products or users who are creating higher levels of regulatory effort.

Accordingly, targeting the firms who create the need for regulation through the imposition of fees and charges on manufacturers may be difficult. Although it is possible to recover regulatory costs from the users of agvet chemicals as a whole this may not provide strong incentives for individual users to improve their practices, other than for their own benefit.

Cost recovery would represent an unfair financial burden on individual users

A potential outcome of additional cost recovery is an increase in the cost of agvet chemicals for users, where the additional cost of regulation is incorporated in the retail price. Although this would impact on non commercial users, a significant proportion of the cost would be borne by the primary industries sector, specifically the farming sector.

Although it could be argued that where those increased costs can be passed onto end consumers through higher produce prices and the financial impact on the farming community would be low, this may not be the case in the majority of circumstances.

ABARE statistics[11] indicates that upto 60% of agricultural produce is exported and therefore subject to exchange traded prices.

Additionally, for export industries, the domestically consumed portion of production is subject to export driven prices, such that, in practice, much more than 60% of agricultural produce is export price based.

Accordingly the majority of increases in input costs cannot be passed onto the ultimate consumers of the produce. This would place an additional financial burden on the farming community. It could also be viewed as a dilution of the efficiency principle as the costs are not passed onto the end consumer of farm produce.

The Productivity Commission noted that it would support a phasing in of cost recovery of control of use regulation, which could alleviate this issue.

The cost of enforcement should be Government funded

Stakeholders of regulatory agencies, generally, have argued that the compliant sections of the regulated industry should not fund the enforcement and prosecution of non compliant participants. Rather it is appropriate for this activity to be tax payer funded, particularly where fines and penalties are paid into consolidated revenue.

Cost recovery would result in unacceptable levels of industry capture

Certain stakeholders have noted that there is a risk of industry capture where regulators are funded by the regulated industry.

In essence the argument is that the independence of the regulator is compromised as a result of industry funding, either from the regulated industry as a whole, or specific industry sections.

[11] ABARE 2008 p26

Potential volatility in annual revenue would adversely impact on the regulator

Where activities are funded by cost recovery, year on year funding can vary significantly due to factors beyond the control of the regulator, eg the volatility in industry sales revenue. This can impact on the regulator's operating capability.

13.4.1.2 The Case for Cost Recovery

Cost recovery would not be inconsistent with the Government's policy objectives

If an increase in the cost of agvet chemicals were to result in higher levels of misuse of agvet chemicals there is an argument that it would be inconsistent with the Government's policy objectives. No evidence has been found to indicate that this would be the case.

The regulated industry is a beneficiary of control of use regulation

A number of stakeholders have noted that the Australian community is the primary beneficiary of control of use regulation. However an argument has also been made that the regulatory activities benefit industry as well.

For example the Productivity Commission noted in its report on plastics and chemicals regulation that it "does not consider that from an equity perspective the outcomes of control of use regimes should be perceived as a public benefit. Control of use regimes are in place to manage the adverse impacts of the use of pesticides and their outcomes are more appropriately described as a reduction in the negative externalities of pesticides. Further as observed by CropLife (sub 35) in the absence of effective control of use regulations, the APVMA may be required to set significantly more restrictive assessment and registration requirements and, potentially, withdraw some products from the market. Thus it could be argued that control of use regulations might create some benefit to agvet product manufacturers".

It could also be argued that the minimisation of risks to overseas trade and market access provides a specific benefit to the primary industry participants.

The identifiable group that creates the need for the regulation should pay for it

Control of use regulation is undertaken to reduce negative impacts or externalities caused by inappropriate use of chemicals by the users.

The Commonwealth Cost Recovery Guidelines note that cost recovery may "improve equity by ensuring that those who use Australian Government products and services or who create the need for regulation bear the cost".

The Productivity Commission also noted in its Inquiry into Cost Recovery by Government Agencies (2001) that "the case for recovering the costs of administering regulation is complex. Because some regulation is intended to reduce the likelihood of negative spillovers, the beneficiary pays principle does not universally apply. A more general principle that may apply is that where regulation is designed to minimise impacts on either consumers or third parties (that is, from spillover effects), the price of each regulated product should incorporate the efficient costs of its regulation. This approach has efficiency and equity advantages over the alternative of funding through general revenue."

Charging is cost effective

Cost recovery of control of use activities through the imposition of fees and charges on manufacturers is likely to be cost effective. The APVMA already collects fees from manufacturers of agvet chemicals such that the additional administration costs should be low.

Cost recovery by industry provides a sustainable source of funding

There is a risk that funding of regulatory activities by Government may be insufficient, by comparison with the risks being managed. Due to competing priorities Governments have reduced funding for control of use regulation, which has impacted on the level of regulatory activity. This is evident in the disparity of services and resources provided by the different states and territories as discussed in chapter 9 (page 38).

Funding outside the public sector financial framework could avoid this problem, by creating an independent income stream, free from Government funding pressures

13.4.2 Licensing of Users

Cost recovery of licensing of users already occurs across state and territory jurisdictions. Because the licensing arrangements themselves vary it is not surprising that cost recovery practices also vary. In some jurisdictions full cost recovery of the administrative cost of issuing licenses occurs, whilst in other jurisdictions, cost recovery appears to be partial or minimal.

Description of Regulatory Activities

Under a national regulatory framework a single licensing system or framework is envisaged, encompassing:

- commercial pest management technicians and businesses;
- commercial ground and aerial sprayers of agvet chemicals; and
- users of agvet chemicals for high risk use (accreditation).

The licensing of veterinary surgeons is covered through separate arrangements and is not considered in these arrangements.

Activities undertaken by the regulator include the establishment and ongoing maintenance of the licensing system, including monitoring of licence conditions, together with the collection of licence fees.

Licensing of Users

The argument for recovery of the cost of a national licensing system for commercial sprayers (ground and aerial) and pest managers and fumigators appears to already be well established. Arguments for cost recovery include:

- the imposition of cost recovery is not considered to be inconsistent with the Government's policy objectives, unless the fees are set too high and encourage avoidance;
- although there is a benefit to the community, through improved usage practices, the issuance of a licence can also provide a commercial benefit to the licence holder, where it maintains professional standards and provides a basis for excluding non compliant suppliers.

The establishment of a nationally consistent licensing system should also benefit the regulated industry by removing current mobility barriers;

- where a licence fee is imposed on fee for reward operators it does not necessarily represent an unfair burden on individual users;
- those who create the need for the regulation pay for it; and
- charging is considered to be cost effective, particularly under a single national system, with the administrative cost of collection of application and renewal fees well below the revenue collected.

Accreditation

Cost recovery of accreditation would be self funding as training organisation already charge for attendance at their courses.

13.4.3 Maintenance of Competency and Training Framework

Under a national regulatory framework there would be a need to ensure that the competency and training framework meets the government's regulatory objectives.

In practice, the cost of oversight is expected to be low because the framework would be largely self funding. As noted above attendance at training courses is already cost recovered and the National Training Framework is administered by the Australian Qualifications Framework (AQF).

Although there would be a need to ensure the framework continues to meet the Government's regulatory objectives this should be a limited function, which is considered to be a core role of government. There is therefore a case for government funding.

13.4.4 Provision of Information to Users of Agvet Chemicals

State and territory regulators currently provide information to users of agvet chemicals through a variety of mechanisms, increasingly using electronic mediums such as agency websites, but also proactively through seminars and the provision of information to specific industry groups on both a proactive and reactive basis.

This function is considered to be complementary with the other components of the regulation of agvet chemicals. There does not appear to be a basic product set as envisaged in the Cost Recovery Guidelines.

Accordingly the case for and against cost recovery would appear to be similar to that for monitoring compliance, investigation and enforcement and the recovery of the cost of this activity could either be government funded or recovered within the same set of fees and charges.

13.4.5 Services to Government

A range of services are provided to Government as part of a regulator's accountability requirements. Under a national regulatory framework this would continue. The Cost Recovery Guidelines state that, whilst some servicing functions integral to regulatory activities are appropriate for cost recovery, other services to Parliament should be taxpayer funded.

Examples include:

- advising Parliament on issues on which the agency has expertise;
- answering Parliamentary questions;
- briefing Ministers and responding to their correspondence;
- financial reporting; and
- complying with international treaties.

There is also considered to be a case for Government funding of committee activities which form part of the core functions of Government rather than a regulatory service. Although some activities may be classified as integral to regulatory activities stakeholders have advised that they believe they are funding an increasing level of activity that is, essentially part of the Government's core role of developing regulatory policy and standards, which should be taxpayer funded.

13.4.6 Public Interest Activities and Community Service Obligations

Where services are conducted at the direction of Government or as a community service obligation there is an argument for taxpayer funding.

There are instances where the regulator may be required to undertake reviews or assessments at the request of Government, which may be in response to a community request. In such cases it can be argued that the service is to the community rather than the regulated industry. An example cited is a review being undertaken by the APVMA into the use of simazine in swimming pools, which is understood to have been initiated by the Minister for Agriculture, Fisheries and Forestry.

13.4.7 Establishment Costs

The establishment of a single national regulatory framework will require initial funding, the quantum depending on the regulatory model chosen. Establishment activities would include:

- drafting of amendments to relevant Commonwealth legislation and supporting regulations;
- development of governance arrangements;
- development of agreements between Commonwealth and states and territories; and
- investment in IT systems and administrative processes for the new regulatory framework.

Options for funding include:

- Government funding. Some establishment costs, such as drafting legislation, are considered to be core government activities and Government funding would appear appropriate; or
- recovery from the regulated industry over a reasonable period of time. It would be feasible to recover all or part of the establishment costs over, say, a five year period, by imputing them on the other fees and charges.

13.5 Regulatory Models

In section 11 a number of options for the regulatory model have been identified. The Productivity Commission envisaged a national approach whereby the APVMA takes over all control of use activities and fund its responsibilities through additional fees and charges. Under this model the

extension of the current fees and charges is considered to be feasible from both a legal and operational perspective.

However, if a harmonised approach is adopted the application of cost recovery for control of use activities may be more difficult. As noted above, under a centralised approach fees and charges can be collected from the regulated industry through a single set of fees and charges. However under a harmonised approach, whereby the states and territories continue to undertake the control of use regulation, a mechanism will need to be established to provide funding for those activities, most likely through service agreements.

13.6 Cost Recovery Arrangements of Other Commonwealth Regulators

The approach to cost recovery of monitoring, compliance and investigation activities varies across Commonwealth regulatory agencies.

13.6.1 Therapeutic Goods Administration (TGA)

TGA regulates therapeutic products, including prescription medicines, medical devices, over the counter medicines and complementary medicines. As well as evaluating applications to register therapeutic products on the Australian Register of Therapeutic Goods (ARTG) it is also responsible for the full regulation of registered products, including:

- monitoring compliance with standards, including testing of products, auditing product data, analysing reportable incidents, investigating complaints and recalling non-compliant products from the market;
- surveillance, investigation and enforcement of the provisions of the relevant legislation (excluding control of use of human drugs regulation undertaken by states and territories);
- industry support activities, including the development of guidelines and promoting international harmonisation; and
- services to Government to support the objects of the legislation.

TGA recovers the full cost of its post market regulatory activities through fees and charges paid by product sponsors and manufacturers. Its fees and charges are subject to review and adjustment annually.

13.6.2 National Industrial Chemical (Notification and Assessment Scheme) NICNAS

NICNAS is the Australian government's regulatory scheme for industrial chemicals. Its activities include:

- assessing industrial chemicals that are new to Australia for their health and environment effects, before use or release in the environment;
- assessing industrial chemicals that are already in use in Australia in response to concerns about their safety;

- making risk assessment and safety information on chemicals and their potential OH&S and safety, public health and environmental risks widely available to workers, the public, industry and other government agencies; and
- enabling the public, organisations and key stakeholders to have effective input into decision making processes regarding the safe use of chemicals.

It is understood that its activities, including new chemicals and existing chemicals assessments programs and its education, awareness and compliance activities, are now fully cost recovered by registration charges and fees and administrative charges for new chemicals assessments. The Productivity Commission recommended in its Research Paper on plastics and chemicals regulation (2008) that the review program for existing chemicals be greatly accelerated and the cost of conducting initial screening be met from Australian Government budget funding.

13.6.3 Office of Gene Technology Regulator (OGTR)

The Office of the Gene Technology Regulator provides administrative support to the Gene Technology Regulator in the performance of his functions under the *Gene Technology Act 2000*. The *Gene Technology Act 2000*, which came into force on 21 June 2001, introduced a national scheme for the regulation of genetically modified organisms in Australia, in order to protect the health and safety of Australians and the Australian environment by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms.

Once an agricultural GMO product is commercially available and has progressed beyond the research stage, it is then the responsibility of the APVMA, with control of use the responsibility of the states and territories.

The OGTR is fully government funded. A review of cost recovery options in 2004 found that, given the lack of commercialisation of gene technology, the introduction of cost recovery could negatively impact on the development of the industry and would not be economically efficient.

13.6.4 Civil Aviation Safety Authority

CASA conducts the safety regulation of civil air operators in Australia and of the operation of Australian aircraft overseas. It also licenses agricultural pilots (crop-dusters), in connection with flying safety issues. Its 2006 CRIS noted the following funding model had been adopted.

Source of Funding	Activities Funded
Government appropriation	Standard setting, government services, prosecution and administration.
Fuel Excise *	Education and safety promotion, planned and unplanned surveillance.
Cost Recovery	Entry control (regulatory services) and other requested services.

* - The fuel excise is a duty on aviation fuel.

13.6.5 Australian Maritime and Safety Authority

AMSA is the national safety agency with a primary role in maritime safety, protection of the marine environment and maritime and aviation search and rescue.

Its expenditure is largely cost recovered from the maritime industry through three separate levies. A regulatory functions levy funds AMSA's ship regulatory and standards compliance monitoring functions including involvement in international regulatory forums.

Key Questions for Stakeholders

Q27 What other arguments are there in support of government funding of control of use regulation, particularly monitoring compliance, investigation and enforcement?

Q28 What is the view of stakeholders regarding the arguments made for cost recovery of monitoring compliance, investigation and enforcement, particularly:

- cost recovery would not be inconsistent with the Government's policy objectives;
- the regulated industry is a beneficiary of the regulatory activities; and
- the users of agvet chemicals create the need for the regulatory activity?

Q29 What is the potential impact of cost recovery of control of use regulation on:

- manufacturers, if it results in higher regulatory fees; and
- the users of agvet chemicals, if it results in higher prices for agvet chemicals?

Q30 What are the potential risks that an increase in the cost of agvet chemicals will result in higher levels of improper usage?

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Glossary of Terms

Term	Description
Agvet chemicals	Agricultural and veterinary chemicals
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARTG	Australian Register Of Therapeutic Goods
AWPIT	Animal Welfare and Product Integrity Taskforce
CASA	Civil Aviation Safety Authority
COAG	Council of Australian Governments
FSANZ	Foods Standards Australia and New Zealand
MRLs	Maximum Residue Level
MSDS	Material Data Safety Sheet
NRS	National Registration Scheme
OGTR	Office of the Gene Technology Regulator
PIMC	Primary Industries Ministerial Council
PIRSA	Department of Primary Industry and Resources South Australia
PSIC	Product Safety and Integrity Committee
SLAs	Service Level Agreements
TGA	Therapeutic Goods Administration

Appendix 1— COAG Response to the Productivity Commission's Recommendations for Chemicals and Plastics Regulatory Reform from its Report of July 2008.

Recommendation 8.1

The Australian Government, in consultation with the states and territories, should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority to ensure that:

- the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned
- its assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals.

Response

COAG agrees to a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure that:

- the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned
- its assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals.

COAG agrees that the regulation of agricultural and veterinary (agvet) chemicals must be effective and properly deal with the risks posed by the chemicals concerned and efficient in terms of maximising the benefits to the community, taking account of the cost. Consistent with these principles COAG supports the recommendation that assessment effort and priorities should be risk-based, noting that the quantification of risk is an assessment outcome.

APVMA assessment categories, prescribed by regulations, are established on a risk-based gradient and facilitate the alignment of assessment requirements with the risks posed. Modular assessment arrangements under that framework allow the specific tailoring of assessment costs to match product risks. Reforms being progressed through the chemicals and plastics early harvest agenda will further improve the efficiency with which low risk agvet chemical products are administered by the APVMA.

APVMA's reconsideration of existing agvet chemicals is underpinned by a rigorous and transparent scoping process to define the issues warranting reconsideration, and a risk-based prioritisation process. In response to the recommendations of an Australian National Audit Office performance audit the APVMA is currently re-evaluating its approach to ensure the ongoing effectiveness of its Chemical Review Program. That work will ensure that assessment priorities are directed at the most efficient management of the risks associated with agvet chemical products.

To assist in directing and clearly articulating the objective that assessment effort and priorities should be risk-based the Commonwealth will explore the potential for embedding additional guiding values in legislation, consistent with the principles underpinning the Commonwealth best practice regulation requirements.

Recommendation 8.2

The Australian Pesticides and Veterinary Medicines Authority (APVMA) should regulate the use of agricultural and veterinary chemical products after the point of retail sale through amendments to the Agvet Code:

- The scope of the new control-of-use regime should be negotiated through the Primary Industries Ministerial Council, and should include, at a minimum, uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.
- The Commonwealth, state and territory governments should renegotiate the intergovernmental agreement to confer the necessary powers on the Commonwealth, and develop service level agreements for the regime to be delivered by the states and territories.
- The APVMA should recover additional costs through a mix of charges and levies.

Response

COAG directs the Primary Industries Ministerial Council (PIMC) to bring forward to COAG for consideration in the first half of 2010 a proposal for a single national framework to improve the efficiency and effectiveness of the regulation of agricultural and veterinary chemicals.
COAG notes that the integration of regulatory activities up to the point of retail sale with a national control-of-use regime would encourage a nationally consistent approach to risk management and improve the consistency of risk-management outcomes, underpinning the assessment and authorisation process (registration and permit).

COAG also notes that this recommendation may have significant resource implications which will be considered during the Commonwealth's budge processes.

Appendix 2 — Productivity Commission Box 4.2 — Features of and effective and efficient chemical assessment scheme

- The requirements of the scheme should be set to reduce overall chemical risk to levels acceptable to the community, taking into account the associated costs and benefits.
    - At a minimum there should be recognition that zero risk is very costly to achieve and that there are tradeoffs (including between different risks) involved in reducing a particular risk.
    - The value imputed to accepted risk should be broadly consistent with other regulations that seek to address similar objectives. (This is because if a particular risk can be reduced at a lower cost to the community under a different scheme, resources should be shifted to that scheme.)
- Assessment effort associated with particular chemicals should be commensurate to the *relative* risk.
    - The assessment agency should have provisions for prioritising the allocation of its scarce resources on the basis of chemical risk. The administrative resources should be allocated in a way that minimises the aggregate risk of all chemicals irrespective of their status as new or grandfathered.
    - The assessment requirements should be calibrated in a way that minimises biases against the introduction of safer alternatives by manufacturers/importers.
- The assessment scheme should operate cost effectively.
    - The cost to the assessment agency of conducting the assessments should be minimised through choice of assessment methodology, as well as appropriate performance monitoring and review.
    - Unnecessary data requirements on introducers of chemicals should be eliminated.
    - Duplication with other national and international assessments should be minimised.
    - Licensing controls that complement or substitute the assessment should achieve their risk-management objectives at the lowest aggregate compliance and administrative cost.