Consultation Regulation Impact Statement

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

Contents

1 INTRODUCTION

The Primary Industries Ministerial Council (PIMC) has charged the Product Safety and Integrity Committee (PSIC) with delivering a detailed regulatory model for a single national framework for agricultural and veterinary (agvet) chemicals. PIMC must present this regulatory model, any necessary intergovernmental agreements and a funding model to the Council of Australian Governments (COAG) by June 2011.

PSIC commenced its work in 2009, with preliminary discussions with stakeholders in August and September. In December of that year, PSIC published the discussion paper (Rose and Sheppard 2009) for comment. Four working groups have taken the comments on the discussion paper and reported to PSIC. In early 2010, PSIC developed a broad set of policy principles and desired outcomes which it incorporated in the National Policy Framework for the Assessment, Registration and Control of Use of Agvet Chemicals (hereafter referred to as the National Framework) — since endorsed by COAG in August 2010.

This consultation regulation impact statement (RIS) sets out broad options for the single national framework, consistent with the policy principles that COAG approved in August 2010. To assist the development and implementation of the national framework, PSIC is now seeking additional input and information from stakeholders on their preferred options. This consultation process includes accepting written comments and face-to-face meetings in all the states and territories. Details of consultation timing will be made available on the release of the paper.

In parallel with the development of this RIS, the Minster for Agriculture, Fisheries and Forestry released the Policy Discussion Paper Better Regulation of Agricultural and Veterinary Chemicals, seeking stakeholders' views on proposals for improvement of efficiency and effectiveness in assessment, registration, review and compliance in the agvet chemicals sector. The Policy Discussion Paper consultation is separate from, but complementary to, the broader COAG reform process. Proposals outlined in the Policy Discussion paper are, therefore, included as part of the broader set of options presented in this RIS so submissions made on the Policy Discussion Paper need not be repeated for those issues covered by both reform processes.

In recognising the importance of this round of stakeholder feedback and the complexity of the set of policy options raised, PSIC has not indicated preferred options for this RIS. Through this RIS, all stakeholders will have a further opportunity to provide their views to the committee before the final regulatory model is developed and presented to PIMC.

Throughout this RIS, specific requests are made for feedback from stakeholders on the policy options and are consolidated in table 1. These requests represent needs for information that are clearly known at this stage of the policy development process. Additional information may be needed to fully evaluate the options and develop a final policy package. Consequently consultation with stakeholders will need to be an ongoing process.

Submissions on this RIS should be forwarded to the PSIC Secretariat by 11 April 2011. PSIC will publish all submissions on its website, unless specifically marked not for publication.

The email address for comments is PSIC@daff.gov.au.
The address for hardcopy submissions is:
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2 BACKGROUND

Agricultural and veterinary (agvet) chemicals include a diversity of products used to protect crops, livestock, people, domestic animals, infrastructure and environmental assets from pests and disease. They play a key role in ensuring the productivity and competitiveness of Australian agriculture, forestry and aquaculture. In other contexts, agvet chemicals are important to protect buildings, sports grounds and other urban amenity infrastructure such as parks, street plantings and home gardens. Further, some agvet chemicals are important to protect human health and amenity in the household and other sectors, including domestic animals.

While there are important to industry productivity, health and amenity benefits from the use of agvet chemicals, there can be negative consequences if use is inappropriate. Many agvet chemicals are hazardous and there may be substantial risks to human health and the environment if those products are not used correctly. In order to ensure the legitimate use of agvet chemicals without undue risk, both access to, and use of, these products is regulated.

Access to, and use of, agvet chemicals is currently regulated through a two tiered system described in a Ministerial Agreement between the Commonwealth, states and Northern Territory concerning the administration of Australia's uniform agricultural and veterinary chemicals registration laws (signed 29 September 1995). Assessment, registration and control of supply to the point of retail sale are undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Control of use of agvet chemicals, once sold, is the responsibility of individual states and territories. In a number of recent studies and communications from both industry and community stakeholders, questions were raised about aspects of both the efficiency and effectiveness of the two tiered system (for example, ACIL Tasman 2008, Australian National Audit Office (ANAO) 2006, CropLife Australia 2007).

Following the release of a Productivity Commission (2008) Research Report on chemicals and plastics regulation, COAG (2008) directed that the Primary Industries Ministerial Council (PIMC) prepare and submit a proposal to COAG in the first half of 2010 for a single national framework to improve the efficiency and effectiveness of the regulation of agvet chemicals. COAG noted that the integration of the regulatory activities underpinning the assessment and authorisation process (registration and permit) with a national control of use regime would encourage a nationally consistent approach to risk management and improve the consistency of risk management outcomes. It acknowledged that the recommendation may have significant resource implications.

COAG also identified a number of Early Harvest Reforms. PIMC is responsible for Reforms 6 (access to high risk agvet chemicals) and 13 (national scheme for the aerial application of agricultural chemicals). Given that it would have been premature to finalise these Early Harvest Reforms ahead of developing the new scheme, COAG subsequently agreed that they be progressed as part of the PIMC response to COAG. PIMC agreed that, to deliver the efficiency and effectiveness improvements sought by COAG, the whole national registration scheme for agvet chemicals would need to be reviewed — that is, regulations up to the point of retail sale as well as regulations controlling their use once sold. In this way, both Productivity Commission recommendations 8.1 (relating to efficiency and effectiveness in assessment and registration) and 8.2 (relating to control of use) are being addressed.

The initial response to the COAG direction was the development of the National Framework, which was endorsed by COAG on 16 August 2010. This RIS contains a broad set of options for achieving regulatory change within that framework.

Agvet chemicals also fall under other regulatory coverage — particularly with regard to poisons scheduling, workplace occupational health and safety (OH&S) and, in some cases, transport of dangerous goods. Overlapping the regulatory controls is a collection of quality assurance systems, some purely private, others with public-private partnerships. However, this RIS is concerned only with those regulatory aspects of agvet chemicals within the remit of PIMC. Still, quality assurance and other private schemes may come within the scope of this RIS where opportunities for joint public-private actions represent the most efficient use of regulatory and private resources.

3 POLICY PROBLEM

3.1 Reason for regulation

Use of agvet chemicals underpins the productivity of Australian agriculture and is important in many other sectors, as is noted above. Inappropriate use has the potential to cause significant social, economic and environmental problems. The potential exists for users of agvet chemical products in an unregulated market to impose external costs on others in a number of ways. At one level, inappropriate use of agvet chemicals on agricultural products may leave residues at a concentration that represents a risk to the health of consumers. Even residues at levels that are orders of magnitude below those that represent a health risk may disrupt domestic and international trade. The sensitivity of Australian consumers and Australia's trading partners to chemical residues in agricultural produce means that violation of a maximum residue limit (MRL) by one Australian producer can have a wide ranging negative effect on returns to all in that particular industry, or to all Australian produce. Countries importing Australian produce monitor for chemical and contaminant residues and some perform audits in Australia of the agvet chemical control system. Importing markets are often sensitive to residues and set maximum residue levels well below Australian MRLs, so merely meeting domestic requirements does not guarantee protection of export markets. Nevertheless, having a good regulatory base is important for the maintenance of care in agvet chemical use and of Australia's 'clean green' image.

An appropriate regulatory framework is also necessary to protect the health of users and other people who could be indirectly affected. For example, veterinary antibiotics must be used responsibly to ensure antibiotic resistance does not make antibiotics less effective for use in human health or cause adverse reactions in those people who are sensitive to antibiotics. At another level, there may be off site effects of spray drift or run off. For example, spray drift from a herbicide application on one farm may damage crops on other farms, have adverse health effects on neighbours or impose environmental costs through damage to native vegetation or pollution of waterways.

While it is acknowledged that users have made and continue to make improvements in chemical use practices, in some cases through industry initiated programs, some users of agvet chemicals may have insufficient incentive to consider the full social costs of their actions in an unregulated market for chemicals. Decisions of users based on their own costs only, ignoring the additional external costs, may result in use of chemicals that is inefficient or inappropriate from the viewpoint of society as a whole. The existence of external costs provides a rationale for policy intervention, provided a policy can be found that produces net benefits. The more effective and efficient the regulatory process, the more likely that the regulation will provide social and economic benefits.

3.2 Deficiencies of the current regulatory system

In many ways the current agvet regulatory system appears to be effective, although some stakeholders question its effectiveness in protecting human health and the environment. As well, aspects of its efficiency have been documented in a series of reviews of all or part of the current regulatory system.

In the recent reviews by the Australian National Audit Office (ANAO, 2006) and the Productivity Commission (2008), two sets of issues were identified. First is the question of efficiency of the processes of assessment and registration of chemical products and subsequent management of the portfolio of registered products. Second is a set of questions about the effectiveness and efficiency of some aspects of monitoring and control of chemical use. Here, issues arising from inconsistencies in policy and operations among states and territories are of concern, particularly in the areas of licensing, permits, training and use according to label.

Regarding the first set of issues, both the ANAO and the Productivity Commission recommended that changes be made in the way the APVMA sets its priorities and directs its effort. Additionally, the Productivity Commission extended its recommendation that assessment effort be commensurate with risk to cover the setting of priorities in management of the portfolio of registered chemicals. Regarding the second set of issues, the Productivity Commission also argued that inconsistencies among jurisdictions in control of use reduced the effectiveness and efficiency of the National Registration Scheme. It therefore recommended that a consistent approach to control of use be adopted nationally.

In consultations as part of the policy development process by PSIC, a number of stakeholders supported the broad thrust of the ANAO and Productivity Commission recommendations.

4 POLICY OBJECTIVES

The objective of agvet chemical regulatory policy is to ensure that the risks of chemical use to human health, the environment, trade and animal health are managed within acceptable limits. Those risks need to be managed within a system based on recognition that, in a broad range of situations, chemical use is a legitimate strategy for protecting food and fibre production, the environment, amenity and the community from adverse impacts of pests and diseases. The regulatory system also needs to be efficient in terms of: timeliness of decisions and actions; resources used by the regulators and regulatory burden imposed on the regulated industries and the broader community. In this context, the COAG principles of best practice regulation should be taken as a guide (Annex A). The objective in suggesting changes to the existing policies is to provide improved risk management within a more efficient regulatory framework. A primary outcome of the regulatory process should be chemical use which is sustainable in terms of economic, social and environmental considerations.

5 POLICY OPTIONS AND IMPACTS OF OPTIONS – GOVERNANCE

Problems/issues

The Productivity Commission (2008, p.32) suggested that there are four broad areas of policy and governance in which clear objectives, responsibilities and processes need to be established in order to ensure good governance. Those are:

- policy development and regime oversight;
- assessment of chemical hazards and risks;
- risk management and standard setting;
- administration and enforcement.

The Commission pointed out that policy development and regime oversight were high level considerations that were properly handled at a Ministerial level. The National Policy Framework endorsed by COAG specifies that policy should be developed, reviewed and adopted in partnership among the states, territories and the Commonwealth. It further states that there should be close and ongoing consultation with stakeholders with respect to operational policy. The details of structure and process are not addressed in the Framework and will need to be negotiated by the state, territory and Commonwealth partnership.

A second set of issues concerns the establishment of a process for effective and timely policy making. At the broadest level, responsibility for providing policy direction to the APVMA with regard to assessment and registration and for developing nationally agreed approaches to state and territory control of use regulations rests with the states, territories and the Commonwealth through PIMC. The APVMA was created by the Commonwealth, states and territories through a Ministerial Agreement in 1995. A Board of Directors governed the APVMA from 1995 until 2007, when the governance arrangements were changed to an Executive Management model. The new model means that the Commonwealth Minister for Agriculture, Fisheries and Forestry is directly responsible for the APVMA's administrative arrangements, such as appointing the CEO and the advisory board, and ensuring that the APVMA complies with its governing legislation, including planning and reporting requirements. The operation of the APVMA within the states and territories remains effective only while they remain signatories to the Ministerial Agreement. The Productivity Commission noted that these arrangements have not been successful in delivering regulatory reforms in a timely and nationally consistent manner. Consultation with states and territories highlighted that they feel they no longer have the opportunity to actively discuss and set policy direction for the APVMA.

The Commission argued that assessment of chemical hazards and risks was a science based activity most suited to being handled by an independent body. With respect to agvet chemicals, it outlined specific requirements for improving the APVMA's performance in recommendation 8.1.

With regard to administration and enforcement, the Productivity Commission recommended that the APVMA be given responsibility to manage a national system for control of use with states and territories providing services on the basis of service level agreements. The basis for that recommendation was a finding that inconsistencies among jurisdictions in control of use introduced unnecessary cost and detracted from effective risk management. Despite the concern, the Commission did not demonstrate increased risk or failure of the system.

While some jurisdictions might be comfortable with a single national agency, others would not. There is a concern that, while a single national agency might be effective in ensuring consistency, it

might not handle regional issues as well. The distance between a national agency, in any single location, and users could lead to problems in understanding the situations requiring attention and could possibly limit the effectiveness of proactive control of use activities. As well, stakeholders (for example, Veterinary Manufacturers and Distributors Association 2010, Aerial Agricultural Association of Australia 2010, CropLife Australia 2010, Animal Health Alliance 2010) point to lack of action by the APVMA to implement numerous changes identified and recommended in a number of reviews and audits of the APVMA over recent years. They cast doubt on the Authority's ability to handle additional responsibility, and they argue that the activities undertaken and expertise required for control of use is quite different to that required for assessment and registration.

A related issue is raised by the disparate and what many stakeholder see as patchy and inappropriate provision of support for policy development in the national regulatory system. A number of stakeholders point out that the APVMA undertakes a range of policy related activities which are not part of its legislative brief. Agvet chemical industry stakeholders objected to this 'public good' work being funded through levies (Animal Health Alliance 2010, for example).

While PSIC holds annual stakeholder workshops in Canberra, there needs to be a more equitable and transparent process for policy input by stakeholders. Many stakeholders cannot attend meetings interstate yet want to have influence. Also, a clear feedback process is needed to show stakeholders that issues raised have been considered and either are being progressed as resources allow (with an open tracking of these improvements) or will not be progressed for documented reasons.

Effective and efficiency regulation of agvet chemical access and use requires appropriate policy development and governance structures. The National Framework approved by COAG requires that policy be developed, reviewed and adopted in partnership among the states, territories and the Commonwealth, and that it is flexible enough to respond to state and regional issues. It also requires that policy be developed in close and ongoing consultation with stakeholders and encourages industry co-regulation.

Each of the following options would involve a national approach to policy and standard setting with the states, territories and Commonwealth working in equal partnership except for the options reflecting the status quo (Option 4). COAG noted the likely benefits from integrating a national system of control of use with assessment and registration. Nevertheless, there are several ways in which the COAG direction to design a more efficient and effective regulatory system might be met.

Those are broadly covered by *Options 1-3* below.

Governance Option 1 ***Maintain the APVMA's current assessment and registration role, with the Commonwealth, states and territories as partners overseeing the APVMA's policy and operational direction, but delivery of other regulatory functions deemed appropriate — at least those regarding training, licensing and accreditation — through a national agency, which is governed in partnership between the Commonwealth, state and territories. All other aspects of control of use would be managed by states and territories under harmonised regulations.***

State and territory control of use rules would be harmonised through one of a number of possible devices — such as template or model legislation. A national body would handle licensing, training and accreditation where states and territories would act as local agents for the national system.

Benefits and Costs

Potential gains from having a harmonised control of use regime arise primarily from the consistency of risk management and regulations that would be possible. Problems in risk management that arise from the current differences in regulatory approaches and different levels of enforcement would be reduced, or eliminated, as would costs to businesses operating in multiple states and territories.

There are essentially three broad avenues through which establishing a single a harmonised system would have impacts on businesses, consumers or the broader community through effects on environmental quality. First, greater consistency of rules among jurisdictions would reduce the costs of compliance for businesses (both direct users such as farmers and fee for service applicators) that operate in multiple jurisdictions[1]. Second, to the extent that agvet chemical assessment, registration and use were more consistent under such an arrangement, risk management could be more effective, with consequent human health, trade and environmental benefits. Inevitably, though, devising common policies for chemical use from the current diversity of policies would leave some users with reduced access and increased regulatory burden. These impacts, along with those outlined above, are discussed in more detail in section 7 on control of use.

A national licensing body would offer a one stop shop for aerial applicators, pest controllers and ground applicators. In some states, ground applicators do not currently need to be licensed and would face an increase in costs. Moving to a consistent national system of licensing would reduce some costs for businesses which operate in multiple jurisdictions.

Governance Option 2 Establish national bodies – one with responsibility for assessment and registration and another with responsibility for control of use of agvet chemicals

Under this option, new national legislation would be based on an extension of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) to include control of use. Control of use regulations would be developed to seamlessly apply the outcomes of the assessment and registration process, with suitable flexibility to account for local differences. Adopting this option would go part way to meeting the Productivity Commission's recommendation that the APVMA be given responsibility for control of use. The option of keeping control of use and assessment and registration separate is suggested in recognition of some of the potential problems of incorporating all controls into the APVMA's charter.

Benefits and costs

Many of the benefits and costs of setting up national regulators would mirror those of harmonisation in type, if not degree. In this model, the responsibility for the whole agvet chemical regulatory system would be transferred to the Australian government. This could mean that states and territories could have less influence on decisions about agvet chemicals of economic importance to one jurisdiction (for example, a chemical essential for use on pineapples could have impractical restrictions placed on its use on the basis of uses in southern states).

On the one hand, having a close link between assessment, registration and control of use could provide more consistent risk management and communication. On the other hand, there could be costs to agvet chemical users and the broader community in managing all regulation through a central agency. One question is whether a single national regulator would be in touch and flexible

[1] For example, for businesses operating across the Murray between NSW, Victoria and SA: a fee for service ground applicator needs to be licensed to operate in Victoria but not in NSW; being a farmer qualifies a person to access an S7 poison in SA, but in Victoria the requirement is to hold an Agricultural Chemical User's Permit (ACUP) with a Level 3 competency requirement; in Victoria use of some chemicals is subject to timing and other conditions within chemical control areas, in the other states it is not.

enough to respond effectively to regional issues as they arise. There is already flexibility in APVMA label instructions where differences in agriculture and climate require different treatments between regions. There may, however, be other more time-specific needs for response to local issues and circumstances.
There are several options for delivering control of use by a national regulator, each of which could have somewhat different impacts. These options include:

- outsourcing to state and territory governments;
- open tender; and
- developing its own regional branches.

A key question with any regulatory structure is how to set up and maintain effective systems for managing and using feedback between regulators and stakeholders from industry and community sectors and other government institutions. In this context, state and territory regulators may have a more direct relationship with some stakeholders than might be developed by a national agency.

For states and territories, there is an issue of maintaining critical mass in pesticide and related scientific expertise that is currently integrated in state regulatory agencies. Centralising only the pesticide aspects of this work in a national agency could leave some jurisdictions with ongoing responsibilities for related work, but without the ability to do that work as efficiently as it is done now, if at all. Open tender would thus represent a high risk to states and territories with permanent skilled staff. Any resulting loss in efficiency could be manifested in ways that would have a direct negative impact on consumers or user industries. For example, less effective or timely responses to adverse reports could result in long term trade losses to the user industry concerned. Effectively, this could mean that the most efficient way for a national agency to manage control of use would be through long term contracts with state agencies to deliver those services.

***Governance Option 3* Maintain the APVMA's current assessment and registration role, with the Commonwealth, states and territories as partners overseeing the APVMA's policy and operational direction. Delivery of other regulatory functions, including training, licensing, and control of use would be managed by states and territories under harmonised regulations.**
Control of use would be harmonised as in *Option 1*, with similar consequences for benefits and costs.

Unlike the case in *Option 1* there would be no national system for training, licensing and accreditation. Instead, a degree of consistency would be achieved by adoption of harmonised rules. Consequently, some of the costs to business of having separate licensing and training systems would remain.

***Governance Option 4* Maintain the status quo — the APVMA to maintain responsibility for assessment and registration, and individual states and territories to maintain responsibility for control of use with no harmonisation of approach**
This option would not meet the requirements of the COAG directive.

Consultation comments sought
Comment is sought on which combination of the governance options outlined above (or any not mentioned above), and in the case of *Option 2*, which mode of service delivery: regional branches; outsourcing to state and territory governments, or open tender, would be:

- most likely to deliver the timely and best quality decisions;
- most effective in ensuring that knowledge is applied to provide guidance for industry and the broader community;

- most likely to enhance compliance, either by making it easier for those regulated to comply by removing barriers to compliance or by deterring non-compliance through more effective enforcement and sanctions; and
- most likely to assist regulators and industry in making better risk management decisions.

In the case of *Option 1,* comment is also sought on how best to avoid diversion of regulatory arrangements between jurisdictions.

6 POLICY OPTIONS AND IMPACTS OF OPTIONS – ASSESSMENT AND REGISTRATION

Problems/issues

The current system seems generally accepted by industry and user stakeholders as being scientifically rigorous and reliable in managing risks, including risks from higher risk restricted chemical products. Nevertheless, as is argued by ANAO and the Productivity Commission (and supported by Veterinary Manufacturers and Distributors Association Ltd 2010, CropLife Australia 2010, Animal Health Alliance 2010), the system contains significant administrative, operational and legislative inefficiencies. Particular problems with the present system concern unpredictability, particularly related to differences in risk appetites between different assessors and between the various bodies involved in assessment, and delays in assessment for some classes of products. Constrained use of electronic communication has been a contributing problem (Grains Research and Development Corporation [GRDC] 2010a) although that has now been resolved. Difficulty sharing non confidential data remains an issue for states and territories, although potential solutions already exist (for example in the form of Govdex – www.govdex.gov.au). Some stakeholders believe the system is not designed or operated to facilitate the registration of new, innovative, products and particularly of low risk products (Australian Compliance Institute 2010).

On the other hand, some community groups question the risk decision rules in the system and argue for the application of the precautionary principle in assessment and registration (Landos 2010, Friends of the Earth 2010, National Toxics Network 2010).

A number of stakeholders, particularly users and trainers, have reported problems with labels. Recent amendments to the APVMA's enabling legislation have addressed some of those problems. However, there remain concerns with the complexity of labels and with user access to comprehensive and comparative information on products.

6.1 Efficiency and effectiveness in the assessment and registration process

Improving efficiency in the assessment and registration process was a key element of the recommendations of the ANAO and the Productivity Commission. The policy principles set in the National Framework adopted by COAG require that the chemical manufacturing industry and chemical users have incentives to develop and operate efficiently, and that their activities or development are not constrained unless as a necessary part of risk management. Data requirements and the complexity of the assessment should be commensurate with the level of risk, with appropriate use made of overseas data, methodologies and assessments. Further, jurisdictional boundaries should not unnecessarily restrict registrants from seeking broad scale registration of their agvet chemicals on a wide a range of pests/hosts or increase the costs to business of using those chemicals.

Some aspects of change have already been implemented. For example, the APVMA has already moved to facilitate electronic communications with applicants and registrants for all aspects of assessment and registration, including submissions of applications.

6.1.1 Risk framework

Problems/issues
The established risk framework for the assessment of applications and conduct of chemicals reviews are not well understood by regulated stakeholders. The APVMA has been subject to long-running criticism from the chemical industry stakeholders for excessive delays, inconsistency of decision making and lack of transparency in reviewing applications for approvals and registrations. As a consequence there is little incentive for companies to invest in product development and seek registration of products approved for use in other markets.

These inconsistencies and timeliness of its assessment have also impacted primary producers who have foregone revenue through lack of effective products for pest control and animal health.

Additionally, the legislation that governs the APVMA is overly prescriptive and inflexible. Chemicals generally undergo similar assessment and review processes, regardless of the potential risk of the chemical, and the roles and responsibilities of APVMA and its regulatory partners are poorly understood by stakeholders. This legislative environment means the APVMA operates in a manner that results in unnecessary costs to business, and limits opportunities for innovation and uptake of new agvet chemicals, thereby constraining future agvet chemicals and agriculture, fisheries and forestry industries productivity growth. The lack of flexibility also constrains the APVMA's ability to effectively regulate chemicals that are already in the market place.

The scale and scope of the problems with the current regulatory framework are further described in the examples below.

- Among agvet chemical stakeholders there are varying degrees of understanding of the roles and responsibilities of government agencies in regulatory processes. Members of the chemical industry with more experience and frequent interaction with the APVMA tend to have a better understanding, while smaller companies and individuals interacting with the regulator infrequently are less familiar with the risk framework. This situation results in inefficiencies for both the applicant, in making and application and for the regulator assessing it.

- Stakeholders have expressed concern that the approaches to setting standards, decision methodologies and risk frameworks are not readily available. As a result the consistency and transparency of the regulator decision making has been questioned.

- Additionally some community and environmental stakeholders question the rigour of some aspects of the science and the independence of the APVMA. It has been suggested by some that the APVMA's is not truly independent and objective in its assessment, as it is reliant upon the industry it regulates for revenue stream.

Risk framework Option 1 ***Implement a complete risk framework for agvet chemicals assessment and review***

The APVMA, in consultation with its regulatory partners including the Office of Chemical Safety and Environmental Health (OCSEH) and the Department of Sustainability, Environment, Water, Population and Communities (SEWPaC), would develop an overarching risk framework for agvet chemicals.

The APVMA and its regulatory partners would be required to develop and publish all relevant risk manuals, standards and methodologies which guide decisions about the level of risk of a particular product or active ingredient. This would add issues such as public health; occupational health; chemistry and manufacture; residues and trade; and efficacy and safety components to the environmental component, which has already been developed by SEWPaC, to form a risk framework for agvet chemicals

In addition, the APVMA would develop and publish templates and models for agvet chemical registration, for use by applicants and others who might assist them. The service-level agreements and work orders (between the APVMA and its regulatory partners) would be amended to reflect the operational arrangements as a result of the proposed reforms.

Benefits and costs
There are two aims underlying this suggested change. The first is to enable better alignment of the level of assessment with the level of risk, in line with the policy principles of the National Framework. The second is to improve transparency and consistency in decision making.

The better alignment of assessment effort with the level of risk would improve the efficiency of resources used by the APVMA and applicants. Improved transparency and consistency in decision making would have further significant benefits to applicants as they would be better able to predict the standards needed to meet assessment criteria. Consequently, there would be fewer cases in which a registrant believed that an application was sound, but where registration was delayed while more data was sought, or registration failed. As well, because of the greater predictability of assessment, a greater range of applications might be made. Given the substantial costs in preparing applications, a lower rate of failure would mean substantial cost savings for applicants. To the extent that predictability led to expanded applications, it would also provide benefits to chemical users through enhanced product access.

Providing clarity to applicants about the roles and responsibilities of the various parties involved in assessing an application, and the methodology used in the assessment process is expected to increase the efficiency of the application and approval process, by allowing applicants to submit applications which are of a higher quality. It is also expected to improve transparency and consistency in decision-making, as a lack of transparency and consistency in the assessment process contributes to the proportion of submitted applications in the incorrect category or incomplete. This reform would be accompanied by legislative change (to the Administration Act) to clearly define the respective roles and responsibilities of the APVMA's regulatory partners.

Not making this change would leave information asymmetries between the regulatory partners and the applicant with respect to the risk management approach to agvet chemical assessments.

No other alternatives were identified that would achieve this outcome.

6.1.2 Efficiency in assessment and registration

Problems/issues

Reviews by the ANAO and Productivity Commission revealed a number of inefficiencies in the assessment and registration process. Chemical industry stakeholders and some user industry stakeholders provided additional evidence of delays in assessment and unnecessary cost impositions on applicants. The following options are suggested changes to the way the APVMA operates and to its underlying regulations which might enhance the efficiency of assessment and regulation. The options could be adopted as a set or in part.

Efficiency in assessment and registration Option 1 Implement measures to improve the efficiency of the process

a) Limiting application screening to an administrative completeness check

The APVMA's initial screening phase would be limited to a purely administrative completeness check of an application, and would not involve any assessment or evaluation.

Benefits and costs

Applicants have indicated that the length and unpredictability of time spent in screening compromises their attempts to plan market releases of products. The improved delineation of screening and assessment would enhance the APVMA's timeframe, performance and efficiency by reducing total assessment time for most applicants. It would also make the total assessment time more predictable for applicants. Shorter and more predictable assessment times would mean that applicants would be able to plan and market their products more effectively. There would be consequent benefits to users in terms of timely access to new products.

It is possible that the new requirements would result in an increase in applications that were rejected at screening, with significant costs to applicants whose applications were rejected. To have an application reconsidered, an applicant would need to submit a revised application and pay a new application fee. There would be additional work for the applicant to bring the application up to standard. However, since that additional work would be the same as that currently required to improve sub standard applications, it would not represent an increased regulatory burden. The primary change would be reducing the burden on the APVMA and the consequent timeliness and efficiency improvements noted above.

The introduction of the pre-application assistance mechanisms discussed in *b)* below would assist in mitigating the risk of application failure at screening.

b) Providing an upfront pre-registration assistance session to applicants, with additional assistance to be cost recovered

In addition to its obligation to the community to explain its processes to the public, the APVMA would offer an upfront (one-off) pre-registration assistance[2] session to each prospective applicant. A set, time limited, initial amount of pre-registration assistance would be included as part of the service offered under the standard application fee for all applicants. This could help applicants determine the information and quality requirements for their applications before submission to the APVMA. It would provide greater assurance to applicants that their applications included the necessary data and would be best positioned for an effective and efficient assessment.

[2] Initial information and advice provided by the APVMA and its regulatory partners to the applicant

Applicants who wished to have further advice or clarification about their applications would then have the option to access further pre-registration assistance. This would be made available on a cost recovery basis.

Benefits and costs

The intent in offering this service would be to reduce the uncertainty experienced by some applicants, by addressing potential issues early on. Implementing this change would allow the APVMA to redirect resources from poorer quality applications of the type that currently create unnecessary queues in the regulatory system, towards efforts on higher value activities. Further, it would ensure that the APVMA could appropriately recover the cost of providing extra advice. The direct costs of such activities are currently borne by the regulator. As noted above, there are flow on costs to other applicants. Importantly, this service would not remove any avenue for applicants to access information and/or guidance from the regulator where there was a genuine need.

There would be potential for greater use of APVMA guidance and assistance by agvet chemical companies that are smaller, are new entrants to the market, or for other reasons have less experience in submitting applications to the APVMA. There would also be potential for greater use by more established agvet chemical companies seeking to ensure that their applications are accurate, and could be assessed promptly, in order to get their products to market as efficiently as possible.

c) Preventing the applicant from changing categories after lodging an application

The APVMA would be empowered to reject upfront, and at an early stage, an application it determined had been incorrectly categorised by the applicant. The application and fee, less a nominal administration fee, would be returned to the applicant if the categorisation was the only basis upon which the application was rejected. An applicant who wanted to resubmit the application under a different category could do so with a new application fee. To support this change, the APVMA would need to introduce greater guidance and clarity on the nature of and differences between application categories.

Benefits and costs

Applicants are already required to determine the category under which they need to apply. The removal of the 'negotiation' process between the applicant and the APVMA (to determine what the correct application category was) would allow for more rapid assessments and reduce unnecessary administrative burdens and costs for the APVMA. Although category changes do not occur in great numbers, the APVMA notes that those that do occur create unnecessary administrative work, such as correspondence with the applicant and other regulators, amendments to databases, and changes to the timeframes for assessment. Reforms to provide for targeted information and advice to applicants along with greater publicly available details about application, assessment and registration processes should limit any negative effect of this reform.

The suggested change would be directed at intentionally (rather than accidentally) incorrect application categorisation by an applicant. Anecdotal evidence from the APVMA suggests that application to the wrong category occurs primarily in generics and generally involves smaller generic producers. The existence of three closely related categories, each with very different data requirements, contributes to incorrect categorisation. Applicants may be tempted to try first for the category with zero data requirements. Greater experience in registering agvet chemicals and a desire for the fastest assessment possible and to avoid damage to their reputation may contribute to more effective categorisation by larger generic producers.

The cost to those applicants whose applications were rejected would be the same as that for applications rejected in screening — a full fee for a new application. The saving in resources for the

APVMA would enhance its efficiency in handling other assessments with flow on benefits to other applicants and thus to users.

d) Restructuring assessment timeframes to take greater account of elapsed time

In order to improve the timeliness of assessment of applications, the APVMA would be required to have a greater focus on elapsed time in the overall assessment timelines. The APVMA's service level agreements and work orders with its regulatory partners would be amended to accord with the restructured APVMA timeframes. This would ensure that all regulatory partners were held to the revised statutory timeframes.

Benefits and costs

Such a requirement would discourage APVMA assessors from focusing on 'easier' applications, or from beginning to assess applications during the screening process in order to comply with statutory timeframes. The change would also remove unnecessary administrative costs associated with applications remaining active but not being resolved or finalised for long periods of time. The primary benefits, though, would be to applicants in terms of efficiency and predictability of the timing of assessments.

e) Including time limits for an applicant to submit data to the APVMA

It is proposed to introduce time limits for the resubmission of data by applicants to allow the APVMA and its regulatory partners to better manage their resources. This would also allow a better understanding of the timeframes, for both the APVMA and the applicant, in connection with regulatory processes.

While the details of this option would need to be further developed, it is suggested that if the APVMA required additional data to be submitted during an assessment, the applicant would be requested to provide the identified data within a couple of months (for less complex data) or a few months (for more complex data) from the date of request by the APVMA. On receipt of the data, the APVMA would notify the applicant within 2 weeks whether the data were accepted and if the assessment would progress. The APVMA would assess the additional data within a couple or a few months, depending on the complexity of the data. The assessment would be completed without the requested data if the applicant did not respond within the timeframe set by the APVMA.

This change would keep assessments more manageable and timely for the APVMA, ensuring that its assessment queues were not extensive and that it had resources available to undertake the assessments. It should also provide an acceptable timeframe for applicants, to ensure that regulatory processes were efficient and would provide decisions in a timely fashion.

f) Extensions to timeframes based on mutual agreement

Greater emphasis would be placed on a mutual agreement between the applicant and the APVMA to any extensions of time. This would follow international arrangements, such as those employed in the United States Environmental Protection Agency (US EPA) for pesticides regulation.

A clear definition of the circumstances in which an extension of time would be suitable would be needed so that this option did not undermine the intent of the related measures outlined above. Examples might include cases where (through no 'fault' of either party) unanticipated but necessary consultation needed to occur with another regulator, or a state and/or territory agency, about a particular application before it could proceed.

The APVMA's service level agreements and work orders with its regulatory partners would be amended to accord with the arrangements for restructuring APVMA timeframes. This would ensure that all regulatory partners worked to the revised statutory timeframes.

Benefits and costs
The change would promote a better understanding between applicants and the APVMA about the timing and completion of assessment processes. Particularly towards the end of the assessment process, when an applicant was preparing marketing strategy for the products, such an understanding would be important.

g) Rejecting applications that have not been improved by the applicant in response to an APVMA request
The APVMA would be empowered to terminate materially or continually inadequate applications. Details of this suggested change would need to be further developed. However, it is envisaged that, in a case where the applicant had not made improvements requested by the APVMA, the APVMA would be enabled to reject the application. In such a case, the APVMA would have an obligation to advise the applicant within a statutory time limit, probably 10 working days. The applicant could have the application considered by resubmitting an improved application and paying the standard fee for that application. The provisions of this approach would be similar to those in pesticides registration systems in the United States, Europe and Canada.

Benefits and costs
This change would reduce APVMA resources that are currently devoted to unnecessarily time consuming activities. It could also remove some long outstanding applications from the regulatory system. In doing so, it would free up assessment resources for higher value activities.

The change could have both direct and indirect costs to those applicants whose applications were rejected. There would be direct costs to those who chose to start again and reapply. There would be opportunity costs in the form of loss of potential market returns from those who chose not to reapply.

The pre-registration assistance mechanisms outlined above should assist in limiting the number of rejections. There is a number of long standing applications which are currently in process which could be subject to the APVMA's right to terminate. Consideration would need to be given to the appropriate transitional provisions in these cases, during the development and consultation on the reform measures.

h) Using overseas data and assessments more efficiently
There would be a more deliberate and extensive use of overseas data, studies and, where possible, assessments. The APVMA already makes considerable use of overseas data under a range of circumstances. In particular, it accepts overseas data packages and toxicology assessments where these have clear applicability to Australian conditions. There are circumstances in which Australian conditions vary from those in the countries in which testing and evaluation are done. These circumstances may apply, in particular, to environmental considerations and to some efficacy tests. With regard to overseas assessments, there are some clear limitations on potential acceptance. The APVMA's assessment and consequent control of use in Australia is explicitly based on risk. Where an assessment is done within a hazard based system the results would not be transferable to a risk based system.

Benefits and costs
While the above factors place some limits on the use of overseas data and assessments, there is room for improvement in the current system (see Lloyd 2008, for example). The Animal Health Alliance (2010) suggests that a 'more pragmatic' approach to assessment and registration would facilitate user access to a wider range of new products. Actions to extend and improve use of overseas data and assessments would tie closely with those under i) (below) concerning the waiving of trade and efficacy requirements for some products.

The direct benefits of making more effective use of overseas data and assessments would accrue to intending registrants. Where such data and assessments could be used instead of separately generated Australian data and assessment, applicants would face lower total costs and sometimes earlier registration. As a result, users would have greater choice and might sometimes face lower chemical product prices. As the starting point would be to maintain the rigour of the assessment process, there would be no increase in human health or environmental risk.

i) Limiting requirements for efficacy or trade data in some applications

Under this option, the APVMA would not assess efficacy or trade components for certain classes of applications. For classes of applications, efficacy[3] assessments could be excluded given that i) the manufacturer would bear ultimate responsibility for proving product effectiveness, ii) the chemicals or products were not used on food and iii) the chemicals were not the only control or management of a disease or pest, but rather managed as part of a wider suite of control measures. For certain classes of applications, such as for veterinary products for companion animals where there was no trade risk and such animals were not exported commodities, trade[4] assessment could be excluded. Aspects of the assessment concerning human health and the environment would not be modified.

Benefits and costs

Some registrants and the APVMA indicated that excluding efficacy modules is likely to reduce costs to both business and the regulator, while excluding trade modules would have benefits to a lesser extent.

This option would offer the potential for certain agvet chemicals to be assessed more quickly, and therefore be available for use sooner, if the APVMA determined that they did not need to undergo efficacy and/or trade assessment. The change would also offer benefits to applicants, by removing or reducing costs. In the current system, the APVMA charge for the non food trade module is $1,175 and assessment takes in the order of 5 months. The charge for efficacy and host crop safety modules is between $500 and $1,865 with a 3 to 5 month assessment period. Costs of generating data can be much more significant than charges. Some industry estimates indicate that generation of efficacy data for a single crop in a single region can cost in the order of $20,000.

This approach would reduce barriers to competition within the agvet chemicals industry. Some individuals or companies might choose to apply to the APVMA if they have previously been discouraged based on the potentially onerous requirements to produce data and information to support efficacy assessments.

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.

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 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

[3] Applicants are expected to be able to show that when their product is used according to label directions, it is effective for the purposes claimed, and that application to the target will not cause any unintended effect.
[4] Applicants are required to provide information on whether use of the agvet product may affect on trade in the agricultural products it is used on.

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. In this context, an additional concern is the potential flow on effects to the regulatory system as a whole from the absence of efficacy testing. If users find that such an approach leads to less than effective products appearing on the market they may lose confidence in other aspects of regulation. Such a loss of confidence could lead to users taking less notice of label instructions and, in particular, it could lead to less effective risk management.

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. For this reason this option involves a proposal to exclude trade data only for products designed to be used outside trade related industries.

j) Providing an optional accelerated assessment process

Consideration could be given to an optional accelerated assessment process for applicants who wished for their products to proceed through assessment more quickly. Assessments through the process would be charged for on a full cost recovery basis.

Benefits and costs

This optional service would potentially have direct benefits to applicants by allowing them to plan and market products more effectively in cases where timing was critical. Particularly for products used in cropping industries, seasonal availability can be critical. To the extent that applicants took up the option and that new products could be released onto the market in a more timely manner there could be flow on productivity benefits to users.

The costs to applicants of taking up the option would be substantial. Current APVMA charges account for only around 20 per cent of the Authority's total resource costs.

The charges on the optional assessment package would not represent a regulatory burden as use of the service would be purely voluntary. Application of a full cost recovery charging regime would, however, open up broader questions of cross subsidies within the APVMA's activities and the question of levy funding. In this context it would be important to ensure that the adoption of a full cost priced accelerated assessment process did not disadvantage applications made through the normal application process. Only if that could be done effectively would the adoption come with an assurance that some chemical users would not be disadvantaged through lessened access to products not channelled through the accelerated process.

Efficiency in assessment and registration- Option 2- Retain the status quo

As is noted in the discussion above, each of the individual elements of the option for change would involve both costs and benefits. There are also some design questions that may need to be resolved before implementing change — see, for example, issues discussed in *i) Limiting requirements for efficacy or trade data in some applications* and *j) Providing an optional accelerated assessment process.*

The option of making none of the changes suggested above would allow continuation of delays in the regulatory process. The APVMA would remain inconsistent with other Australian Government regulators and international regulators (such as the US EPA), which operate under more efficient regimes. Applicants would be subject to excessive regulatory requirements and costs associated with generating unnecessary data. Resources in the APVMA (and possibly its partner regulators) would be unnecessarily directed towards activities that were not needed or relevant.

Adoption would not be consistent with the policy principles of the National Framework, nor would it meet the COAG directive.

6.1.3 Assessment and use information

Problems/issues

Industry stakeholders have noted that differences in crop pest disease distribution, along with inconsistent views about product efficacy between states, have resulted in the approval of multiple use patterns on an approved label to cater for differences between jurisdictions. The design and approval process for labels can be expensive and time consuming, and consequently can delay user access to approved products. As well, the complexity increases the potential for confusion, and thus heightens risk for users who operate across jurisdictions.

The National Framework (approved by COAG in August 2010) requires that instructions on labels and in other media be clear, easily understood, up to date and enforceable. It also requires that information on product use be up to date and accessible through the most efficient media. It also requires that the national registration authority not be required to determine those instructions for which it does not have direct responsibility.

Recent changes implemented by the passing of the *Agricultural and Veterinary Chemicals Code Amendment Act 2010*[5] have clarified and refined the APVMA's responsibilities for approving only that part of the label that constitutes the Relevant Particulars. Under the new arrangements, registrants will be responsible for designing final labels that are consistent with the *Labelling Standard* which is currently being written. They will also be responsible for ensuring that labels for existing registered products remain consistent with the *Labelling Standard*.

Option 1 is designed to ensure that the *Labelling Standard* is effective and would address the labelling identified above.

Option 2 is independent of *Option 1*, representing a potential enhancement of ease of access to comprehensive details on product use information.

Assessment and use information Option 1 Develop a common approach to product efficacy across jurisdictions to limit label complexity and label approval effort

Essentially there would be two changes under this option. In the first, bearing in mind that the label must provide a basis for enforcement, there would be a program within the APVMA to ensure that the *Labelling Standard* provides an effective basis for label design by:

- incorporating findings from the most recent APVMA Registration Liaison Committee (RLC) Working Group[6] meeting and more recent work by the APVMA;

[5] http://www.austlii.edu.au/cgi-bin/sinodisp/au/legis/cth/num_act/aavccaa2010462/longtitle.html?stem=0&synonyms=0&query=agricultural%20and%20veterinary%20chemicals%20code%20amendment%20act

[6] The RLC Working Group findings were as follows (Bennet-Jenkins 2009).

- Information relating to the key risks to be grouped and arranged in a set order.

- devising a process for incorporating user and trainer knowledge of the effectiveness of instructions;
- developing standard terminology and a glossary of terms; and
- implementing an effective compliance program.

Secondly, with regard to crop-pest distribution and approaches to product efficacy, differences among states and territories would be reviewed to ensure that unnecessary multiple handling by registrants and regulators and unnecessary complexity in labels was avoided. Inevitably, there would still be cases where labels would require different sets of instructions for each of a number of regions. In those cases, there might still be a process of an applicant seeking approval of label components from each of a number of regulators. There would be some direct costs of review to regulators.

Benefits and costs

There would be two primary sets of costs associated with the program to ensure effectiveness of labels. First, there would be costs to the APVMA in the redesign process. Second, to the extent that labels needed to be redesigned as an outcome of the process, there would be direct costs to registrants. On the other hand, more effective communication through labels could lead to substantial benefits to users in terms of greater precision and effectiveness of chemical use. Further, there would be risk reduction benefits from users having a clearer understanding of how to use, and how not to use, agvet chemical products.

Control of use regulators also indicate that having clearer and more effective labels would improve their ability to ensure compliance. Thus there could be additional benefits, in terms risk management, from more effective enforcement.

Statements by chemical and user industry stakeholders suggest that there would be significant benefits from harmonisation of state and territory approaches to labelling, in terms of reductions in the cost of designing labels and having them approved, the timeliness of label approval and reduced user confusion. Under *Option 1,* an applicant would less frequently need to design specific additions to a label to suit different approaches in several jurisdictions. The costs to applicants would be reduced. Labels would be approved and products released onto the market in a more timely fashion. Users would benefit from that timeliness.

Assessment and use information Option 2 Require that companies put all their market labels on a single web based database

There is a considerable body of accessible use information on company websites and on Pubcris and agvet chemical information systems such as 'Infopest'[7] (although the long term status of Infopest may depend on the outcome of the national policy review). There is no single, comprehensive collection on the web, particularly of comparative information, that contains both labels and permits in a searchable user friendly format.

- 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, i.e. 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 the best result, are not restricted by prescriptive "do not" statements.

[7] http://www.dpi.qld.gov.au/4790_4885.htm

Benefits and costs
There would be evident benefits from having a comprehensive, accessible, database of use information. The primary benefits would accrue in terms of reduced search costs for users and potentially reduced costs from misuse and environmental harm.

There would be costs to registrants of loading labels on the site and ongoing costs of ensuring that the material on the site was up to date.

There would be some site set up and maintenance cost to regulators.

Assessment and use information Option 3 Make no changes beyond those directly required by the Agricultural and Veterinary Chemicals Code Amendment Act 2010
None of the potential benefits outlined above would accrue. There would, however, be no database cost to registrants. Not adopting *Option 1* would mean that there would be ongoing costs to registrants and users from continuing complexity of labels. There would be direct costs to users in the form of productivity losses and continued higher than necessary risk from the continued existence of some poor quality labels.

Consultation comments sought
Estimates are sought on the costs of redesigning a label.
Comment is also sought from registrants on the likely cost of complying with *Option 2*.

6.1.4 Facilitating registration of low risk products

Problems/issues
A number of stakeholders in chemical user industries, particularly those representing organic producers or others with 'low chemical preference', have suggested that the current regulatory system inhibits access to appropriate chemical products. As well, there can be circumstances in which chemicals widely used in other circumstances can be caught up in the full regulatory review when they are proposed for agvet use. On the one hand, a regulatory system that makes access to genuinely low risk products difficult or expensive can impose significant productivity costs on user industries. This can also lead to higher risk by encouraging the use of more hazardous chemicals, but already registered, products. Some stakeholders point to overseas examples of schemes for facilitating access to lower risk products. On the other hand, some regulatory agencies question whether it is possible to be sure of the risks from use of a chemical product without first having a risk assessment.

Facilitating registration of lower risk products Option 1 Develop a reduced risk/low risk program
This option would involve establishing a two pronged program to facilitate registration of reduced/lower risk products, including a program element that:

- encourages the substitution of lower risk, but conventional, products for existing registered products; and
- facilitates registration of products that could be classified as 'low risk' products.

The first of those program elements would operate along the lines of the Conventional Reduced Risk Pesticide Program operated by the US EPA (2010). Under that program, conventional products that can be demonstrated to present lower risk than existing registered products are given expedited assessment and establishment of MRLs.

The second program element would be focused on facilitating registration of products that are inherently low risk. Under this program, applicants would have the opportunity to nominate a product as potentially suitable for concessional treatment. The APVMA would make a provisional decision on the product's suitability at initial screening. An example of such a program is that operated by Health Canada's Pest Management Regulatory Agency (PMRA) for registering low-risk biochemicals and other non-conventional pesticides (Health Canada 2007).

To qualify for inclusion in the Health Canada program, a product must have some or all of the following characteristics:

- low inherent toxicity to non-target organisms;
- is not persistent in the environment;
- is widely available to the public for other uses and has a long history of equivalent exposure to humans and the environment with minimal toxicity;
- has a non-toxic mode of action (that is, its pesticidal action is not the result of target organism toxicity);
- is unlikely to cause pest resistance.

The Health Canada program also involves joint assessments with other national regulators, or recognition of assessment of other national regulators, where opportunities exist.

A program element would be designed for identification and registration of low risk products by:

- providing an expedited review or reduced data pathway, where possible;
- maximising use of overseas low risk regulatory findings;
- reduced fees.

Details of the two elements of the program, timing concessions and charges are yet to be decided and are matters for further consultation.

One limitation to both elements of the program may be the difficulty in identifying a low risk product before a full assessment has been completed.

Benefits and costs

Without more detail of the two program elements, it is not be possible determine the impacts in more than general terms. To the extent that the program was successful in identifying and facilitating registration of low risk products, the risk from the portfolio of registered chemicals could be lowered.

Under either program successful applicants would bear lower assessment costs and have earlier access to markets. In the second, low risk, element of the program applicants might also face lower data and preparation costs.

Consultation comments sought

Comment is specifically sought on:

- the extent of timing and fee concession incentives that would be needed to interest applicants in the lower risk substitution program;
- likely products or product groupings for the second element of the program.

6.1.5 Facilitating access for minor uses

Problems/issues

There is a wide variety of uses for agvet chemicals which have important productivity implications for the potential users but are likely to provide limited market return for the producer of any single suitable chemical product. Facilitating the servicing of these minor use demands while managing the risks is an ongoing problem in all regulated agvet chemical markets. Full assessment of a product for a minor use so that the use can be included on label provides the best option from a risk management and user access point of view, but is not always possible. The current regulatory system contains some impediments to such assessment.

A number of chemical and user industry groups have argued that appropriate extensions to data protection can be expected to make some improvement in inclusion of uses on label (see Biological Farmers of Australia 2010, CropLife Australia 2010 and Animal Health Alliance 2010 for a general discussion of the issue). Nevertheless, there are limits to the circumstances in which further protection is appropriate and to the likely effectiveness of such protection. It is far from clear that data protection for addition of a use of a generic chemical is effective, for instance. The specific problems of data protection for generic products, and some possible solutions are discussed by Pulse Australia (2010), Departments of Health, Agriculture and Food, and Water Western Australia (2010) and the Australian Veterinary Association (2010).

At another level, the APVMA's current enabling legislation is based on the presumption that existing registrants (or other applicants from within the chemical industry) will be the sole applicants. It does not make it easy for users to initiate an assessment and registration for an additional use on label. Such action is possible, though, as is demonstrated by the grains industry use of APVMA Category 25 applications for extension of uses on label (GRDC 2010b). In these applications the user industry provides the necessary data and applies for registration with the cooperation of the registrant.

Even with the best endeavours to include uses on labels, there will be unmet demands for minor uses of chemicals. For this reason minor use permits and other permissible uses play a key role in providing access to chemicals for a wide range of agricultural industries and other sectors. Many users with minor use needs may either have the resources to finance and manage an application on their own account or have access to an industry program (mostly through Research and Development Corporations [RDCs]). Others may not. The gaps appear to be significant. Particularly when an application needs to be supported with overseas data or with local efficacy data some users may face significant problems. Even the industry programs that exist may not be sufficient to service their industry needs. Additionally, some potential users questioned the data needs for permit applications and raised the prospects for greater use of overseas data or registrations (Tasmanian Agricultural Productivity Group 2010, Turfgrowers Association of NSW Inc. 2010, Nursery and Garden Industry Australia 2010).

Minor uses, by definition, do not individually account for large amounts of agvet chemical use. In aggregate, however, there is significant economic value at stake in minor uses. There are two broad policy threads that can improve access for minor uses:

- encouraging access for uses which have been fully risk assessed and can be included on label;
- managing risks and developing authorisations for minor uses for which full risk assessment is not feasible — these are considered in section 6.3 on permissible uses.

There are both complementary and substitutional elements between the two potential sets of actions. More efficient processes for encouraging inclusion of uses on label would lessen the demand for permissible uses off-label and the need for a targeted program.

<u>Facilitating access for minor uses Option 1</u> Facilitate inclusion of minor uses on labels

This option would involve a number of enhancements to intellectual property rights related to uses on labels or permits along with actions to ease the process of assessment and registration of minor uses. A key change would be to extend data protection to cover:

- data provided for minor use or other permits;
- data for out of patent chemicals, concerning;
  - chemical review, or;
  - additional minor uses.

As well, the option would involve developing a system of use protection where a registrant of a generic product provided data in support of extending the uses on an existing label[8]. Users would be legally required to use that registrant's product rather than any other product (of identical composition) for which data had not been produced in support of a registration. The intent would be to provide a potential pay-off from the effort of data generation and application. The approach would work only with a compliance program including record keeping (requiring batch numbers) in place. It therefore needs to be considered in a coordinated manner with policy arrangements for record keeping and enforcement**.**

Action would be taken to remove any unnecessary barriers to the migration of permitted uses onto labels and to facilitate user requested/supported registrations. Further work would be undertaken on crop groupings for registration. The option would involve improved coordination with overseas regulators and recognition of overseas assessments, where possible. That would include global joint reviews and consideration of conditional registrations, on the basis that local efficacy data will be provided within a set period. At a more general level, assessment requirements would be modified to match efficacy requirements to the risks of the particular case. There would also be further investigation of the possibility of modifying liability law — such that in cases where local efficacy requirements were lessened there was a compensating reduction in the registrant's liability.

Additionally, there would be consideration of encouragement of extension of uses on new and existing labels by providing favourable treatment in assessment such as:

- expedited assessments;
- fee waivers;
- credits tradable to other products within the assessment and registration system (for example, for expedited assessments, fee waivers or extended data protection for major use applications).

A registrant's decision to include a use in an initial application for registration of a product or an application to add a use will be based on an estimate of likely commercial returns from that registration. Other factors considered are liability, risk and market placement. On the one hand costs of data generation and other application costs are key determinants of net return. On the

[8] For a product still under patent data protection alone may be sufficient to provide a market return from addition of a use to label, since the product itself is protected. For a generic product that is unlikely to be true. Producers of similar, or identical products, can simply point out that similarity and undercut any attempt by the successful applicant to extract a market return for the data and application costs.

other hand is the importance of the registrant's ability to extract a competitive advantage from a registration.

Benefits and costs

In some circumstances improved data protection may provide sufficient incentive for registrants to apply for expansion of uses. Data protection gives a registrant exclusive access to the data used in supporting a registration (of a chemical, product or use included on label) for a fixed time period. It is designed to provide an incentive for chemical producers to generate new products and applications by providing them with a time limited competitive advantage from having done so. Improved data protection would provide an incentive for greater inclusion of uses on label. Some chemical industry stakeholders have argued that more effective data protection would essentially solve the problem of label coverage of minor uses, although evidence of such a strong effect is not apparent. The costs of extending data protection seem likely to be minimal, though. Changing the legislation would involve some administrative cost and the reduction in access to data would impose some opportunity cost on competitors in the chemical industry, mostly concerning generic products.

Appropriate extensions to data protection could be expected to make some improvement in inclusion of uses on label. Nevertheless, there are limits to the circumstances in which further protection is appropriate and to the likely effectiveness of such protection. It is far from clear that data protection for addition of a use on a generic chemical would be effective. Users may simply apply similarly registered products off-label, either at the urging of their sellers or independently, rather than paying a premium for the product with the new use on label. In this context, the development of a system of protected uses could be useful. A registrant who provided data and other material in support of an addition of a use to a label would be granted exclusive rights to service that use for a specified time period. For the reasons outlined above with respect to data protection for generic products, use protection would be effective only if there was effective enforcement. Records of use, including batch numbers, will be needed to ensure enforcement. Adoption of use protection could, therefore, involve some increase in enforcement costs. Prices to users of the protected product would also be expected to be higher.

Liability issues provide a serious impediment to the registration of minor uses on label. Minor uses often involve high value production, so damage to only a small proportion of treated produce could be expensive. This consideration may make a registrant hesitant to apply to add a minor use to a label on the basis of lower efficacy data requirements. The registrant may need full efficacy testing to be confident enough to proceed with a registration. The cost of full testing may be prohibitive given the small size of the minor use market. Therefore it may be important to investigate ways in which a registrant's liability might be limited in order to facilitate minor use registration.

The set of favourable treatments for registrants suggested in exchange for minor use registrations represents a way of expanding incentives. The aim in using these devices would be to provide a commercial value for registrants to compensate for the cost of data and registration effort in cases where the direct market returns would not be sufficient. In the absence of direct government financial support, any fee waiver or other such preferential arrangement for minor use applications will involve a degree of cross subsidisation within the activities of the national registration authority.

Facilitating access for minor uses Option 2 Retain the status quo

This option would leave in place a significant set of disincentives for registrants to add uses to labels. A broad spectrum of agvet chemical users would continue to face a shortage of legal chemical use options. Consequently, there would be productivity losses or illegal use of registered chemicals.

6.1.6 Access to high risk chemicals

Problems/issues

COAG identified improvement of regulations for access to, and use of, high risk chemicals as Early Harvest Reform 6, which was to ensure that:

> *Access to high risk agricultural and veterinary chemicals is restricted to those with the necessary competencies in order to ensure that they are not misused and, as a result, withdrawn from the market.*

There are two threads of policy relevant to high risk chemicals: products declared as Dangerous Poisons as classified under Schedule[9] 7 (S7) in the *Standard for the Uniform Scheduling of Drugs and Poisons*, which is given legal effect through the *Therapeutic Goods Act 1989,* and products declared as Restricted Chemical Products (RCPs) by the APVMA. The APVMA may declare a product an RCP where it finds the product to have a particular risk (or risks) to human health or the environment, or has specialised competency or equipment requirements to be applied safely and effectively. Where the Authority does declare a product an RCP, access is confined to 'Authorised Persons' (under state and territory legislation). There can be inconsistencies between conditions of access and use intended by the APVMA and state or territory definitions of an Authorised Person. As well, there appears to be less than effective coordination between the APVMA, control of use regulators, and users and trainers in establishing the conditions of use.

Associated with the declaration of the chemical as an RCP, the APVMA produces a set of access and use conditions. Those conditions generally include the required competency. They may also include specifications of, or restraints on, equipment to be used and situations in which the chemicals can be used.

Historically, there have been problems in translating the APVMA declaration of an RCP into appropriate training and/or other requirements needed to define an 'Authorised Person'. Industry stakeholders and control of use regulators have pointed to sometimes ineffective consultation about practical aspects of the APVMA's requirements. Early in the RCP regime, the APVMA provided little guidance on competency or use requirements. Thus the degree of correspondence between the APVMA's findings from a risk assessment, and the control of use definition of an 'Authorised Person' can vary from state to state.

The differences in arrangements between jurisdictions are quite complex. However, a contrast between two examples illustrates the problem in ensuring consistency between the requirements established in the APVMA assessment and declaration process and application in control of use. In Victoria a user must hold an Agricultural Chemical User's Permit (ACUP) or a Commercial Operators Licence (COL) to access a RCP. A base qualification for an ACUP is Australian Qualifications Framework Level 3 (AQF3) training and any specific AQF4 training identified by the state as

[9] Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules according to the level of regulatory control of the availability of the medicine or chemical required to protect public health and safety. This is regulated by the Therapeutic Goods Administration under the Department of Health and Ageing.

necessary for access to a particular RCP is added. On the other hand, in Western Australia control of use of agvet chemicals operates under the state's health legislation. Under the legislation, response to an APVMA declaration of a chemical as an RCP is straight forward if the chemical is classified as an S7 poison. If it is not, and the APVMA's declaration is based on risks to plants, animals or the environmental instead of, or in addition to, human health, there is no simple process for applying the APVMA requirements. Consequently, there is a risk that those requirements may not be adhered to.

Access to high risk chemicals Option 1 Implement a coordinated national program for control of access and use of high risk chemical products

The program would continue to be based on the current APVMA process for declaring a product an RCP under the Agvet Code and confinement of legal access and use to persons designated 'Authorised Persons'. However that process would be enhanced by ensuring that:

- the national registration authority was required to consult with users, trainers and control of use regulators in arriving at the competency standards, equipment requirements and any additional conditions in setting the definition of an 'Authorised Person' or authorised use for an RCP;
- to the extent that it was practical to do so, the competency standard prescribed for persons using an RCP would include the chemical competencies at Level 3 (AQF3) within the National Training Packages, plus any competencies at AQF4 deemed appropriate by the APVMA on a case by case basis;
- 'Authorised Person' and any associated use conditions for an RCP be identical to that decided by the APVMA in declaring a product an RCP.
- establishment of powers for control of use regulators to require users[10]:
    - to keep records and submit records when required by the regulators, and;
    - to abide by instructions with respects to application method, disposal or any other factor found relevant to mitigating risk;
- targeted monitoring of the health of users and of aspects of plant, animal and environmental conditions specific to the particular chemical and use.

Additionally, access and competency requirements for S7 poisons would be harmonised.

How these two sets of changes would be achieved would depend on the governance approach chosen — but in the case of a harmonised approach (*Options 1* or *3* in section 5), it would require the same definition of an 'Authorised Person' in all states and territories.

Benefits and costs

The RCP system is designed to reduce risks to human health, animals and the environment, where the APVMA identifies particular risks and methods of managing those risks. To the extent that the conditions established in that process were followed more closely, the effectiveness of the management of those risks would be improved. Additionally, having the same set of rules across jurisdictions would reduce costs for businesses which operate across state and territory borders. Under this option there would be better coordination of both the process of establishing conditions for RCPs and the actual control of access and use. The primary benefits from adoption of this option would be from more effective risk management. More extensive use of the expertise of users, trainers and control of use regulators in developing conditions of access and use would allow the national registration authority to design conditions of use and competency for an 'Authorised Person' that had the potential to deliver more effective risk management. Making sure that the

[10] This would require negotiation with other agencies, such as health and environment regulators, who could be called on to implement RCP regulations.

definition of an 'Authorised Person' in control of use legislation was the same as that in the national registration authority's design of those conditions would better ensure that the potential was realised.

The current list of RCPs includes chemicals found in a number of vertebrate pest control products, termite control products, soil fumigants and herbicides for use against aquatic weeds. Users who could be subject to more stringent product use, equipment or training requirements as a result of the policy change include urban pest controllers, farmers and fee for service applicators who work for farmers, environmental and land management agencies. As is noted above, in some jurisdictions there is already a one to one correspondence between the APVMA's access, use and competency determinations and those of state and territory control of use regulators. In those jurisdictions adopting this option would have no direct effect on users. In other cases users may have to undergo additional training or face restrictions on access.

There are minimal restraints on the APVMA's capacity to declare a product an RCP, and no additional restraints are proposed. Therefore, it is not possible to predict which individual or groups of users would bear some greater cost as the result of this reform over the long term. It can reasonably be suggested that insisting that any additional requirements are consistent with an APVMA risk assessment and with practical advice from users and control of use regulators should ensure that any additional cost has a reasonable pay off in terms of improved risk management.

Access to high risk chemicals Option 2 Maintain the status quo

This option would not meet the conditions of the COAG directive with respect to Early Harvest Reform 6.

Consultation comments sought

Comment is specifically sought on:

- costs of specialist training courses, or alternative ways of establishing competency for current RCPs, such as pre-emergence termiticides and vertebrate poisons;
- costs of record keeping.

6.2 Other aspects of the operating environment

The policy principles set in the National Framework adopted by COAG require that agvet chemicals are supplied and used safely and responsibly. They also stipulate that an appropriately conservative approach be taken where the science is uncertain or incomplete. The standard setting roles and responsibilities of the national registration authority, and other agvet chemical standard setting bodies, must also be clear.

6.2.1 Enhancing the provision of expert advice

Problems/issues

A review of the APVMA's management arrangements has identified the cost effectiveness of the advisory board[11] as an area for potential improvement.

Enhancing the provision of expert advice Option 1 Replace the advisory board with expert advisors

The APVMA advisory board would be removed. In its place expert advisors (s) would be utilised by the APVMA's Chief Executive Officer (CEO) on an 'as needs' and flexible basis, from a pool of suitable

[11] Note: The Minister for Agriculture, Fisheries and Forestry is directly responsible for the governance of the APVMA.

candidates who have a range of appropriate expertise (e.g. health, environmental, economic, industry and community representatives) on agvet chemical issues.

Benefits and costs

Removing the requirement for the APVMA to maintain an advisory board and replacing it with expert advisors would provide for a more efficient and effective way of providing the advisory function. Expert advisors would be able to review issues and provide recommendations to the APVMA's CEO as required. For example, the CEO may wish to seek advice from advisors in relation to recent issues such as spray drift or biopesticides. The aim would be to enable the CEO to have the flexibility to convene an appropriate mix of experts depending on the issue at hand to determine frequency of meetings and reporting.

There would be no direct cost impacts of the change.

6.2.2 Improving legal interaction with the APVMA

Problems/issues

In response to serious concerns about the use of an unregistered pool chemical product, the APVMA issued a recall notice in March 2004 to protect the public from further risk of serious harm or death. However, the manufacturers and distributers involved were successful in obtaining a stay of this APVMA decision in the Administrative Appeals Tribunal pending completion of its review. This resulted in the unregistered chemical continuing to be available on the market during this time.

Consultation comments sought

Comment is sought about the appeal process around APVMA recall and enforcement actions. Stakeholder feedback is sought on a practical solution that:

- would be effective in protecting human life and the environment;
- would balance safety and environmental standards with procedural fairness, and;
- would provide for an agile and responsive regulator.

6.2.3 The precautionary principle

Problems/issues

The operating environment in which assessment and registration of agvet chemicals is performed includes the statutory criteria for assessment and the specification of risk tolerance and assessment process. An unambiguous and clear statement of acceptable risk could have an important bearing on the efficiency of assessment and registration**.** Protection of human health has primacy in the regulatory system, and in instances where there is uncertainty about the science an explicitly precautionary approach is to be taken.

There are some suggestions, however, that precaution should be taken to another level.

The precautionary principle Option 1 Adopt the precautionary principle in all instances where the science is uncertain

Under this option all of the conditions described above would be adopted. This option would involve inclusion of the precautionary principle in the Agvet Code.

A number of community groups support the adoption of the precautionary principle (for example, Break O'Day Catchment Risk Group 2010, Choice 2010, National Toxics Network 2010, Landos 2010). Advocates of the principle see its application as a way of protecting human health and the environment from a variety of chemicals and practices seen to be actually or potentially damaging.

The APVMA's assessment and registration activities are explicitly risk based. Adopting the precautionary principle in chemical agvet chemical assessment and review would not mean substituting for that risk based approach. Where the science is known, there is no argument for recourse to the principle. Adopting the precautionary principle could make a difference to instances where there is uncertainty about the science, however.

The original statement of the principle 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.*

Thus, in its original form, it applied to questions of environmental protection, only. Nevertheless, the logic of the principle can be applied to other areas, such as human health (Martuzzi and Tickner 2004, Anto 2005).

Interpretations of the precautionary principle can be represented as ranging across a spectrum from flexible to highly prescriptive (Weier and Loke 2007). Flexible interpretations provide more room for consideration of costs and benefits of alternative choices. A substantive likelihood of harm is needed to trigger precautionary actions. At the other end of the spectrum, highly prescriptive interpretations leave limited room for choice. In such an interpretation, any likelihood of harm may require a precautionary action. In prescriptive interpretations the responsibility for producing further scientific evidence, given that some reason for precaution has been identified, is most clearly with the proposer of the action which triggers precaution (for agvet chemicals, the applicant or registrant). In a flexible interpretation that responsibility may not be so clearly with the proposer. With its explicit consideration of cost effectiveness, the Rio Declaration is toward the flexible end of the spectrum. Weier and Loke 2007 point out that existing application of the principle in Australian legislation also tends to be flexible, rather than prescriptive.

Benefits and costs

The precautionary actions that a chemicals assessment and registration authority can take are of three types. First it can call for more scientific evidence, where the existing level of evidence would be likely to trigger a precautionary response. Where such options have been exhausted the authority has two remaining options (although both may not always be practical). It can choose not to have the chemical registered. In at least some cases, it may be able to devise access and use conditions that will allow the chemical to be used without exceeding the precautionary trigger.

Since the precautionary actions that can be taken are actions to close market access to chemicals (or to restrict their uses), the cost effectiveness considerations concern the impact of such closure (or restriction). In estimating cost effectiveness the authority would consider such factors as the size and value of activities affected and the nature of effect. Thus deregistering a chemical that had many effective substitutes would tend to be considered less serious, in terms of cost effectiveness, than deregistering one that had no substitutes in some, or all, uses. Similarly, faced with a precautionary trigger for a chemical that was critical to protection of human health (against mosquito borne disease, for example) but also widely used for other purposes, the authority might choose to restrict its use to only human health protection.

The direction and nature of the consequences for agvet chemical applicants, registrants and users that would result from adoption of the precautionary principle is clear. The extent of those consequences would depend on the exact interpretation of the principle adopted. Adoption of the precautionary principle would impose both some direct costs and some uncertainty on actual and potential registrants. Direct costs to applicants for new registrations would take the form of greater

data and analytical costs in preparing applications, where there were initially any scientific uncertainties. For existing registrants there would be a greater probability of needing to defend a registration. There might also be indirect costs in the form of greater uncertainty about the outcome of an application or review.

The prospect for uncertainty of outcome under the precautionary principle is illustrated by the principle's application in the European Union. In 2000 the precautionary principle was adopted by the Commission for the European Communities and codified in EC regulation (European Commission 2000). Sunstein (2005, p.23) reported how the European Court made a series of conflicting decisions involving varying degrees of risk, in each of which the Court claimed to have taken a precautionary approach — despite some detail in the Commission's instructions for applying the principle.

It is worth noting here the distinction between the EC's hazard based approach to chemical regulation and the risk based approach used in Australia. EC regulation is focused on the intrinsic hazard of a chemical, rather than on a practical evaluation of its risks in responsible use. Thus under the EC approach a chemical can be banned even though it has been demonstrated to be safe to humans or the environment with responsible use. This can be a quite different result to that which would result from adopting the precautionary principle within a risk based approach such as is currently taken in Australia.

For users, both the direct and indirect costs to applicants and registrants would have impacts of a similar type. Both would lead to some lesser availability of chemical products. In some cases lesser availability might not have a significant impact. In other cases users may still have options, but only at higher cost. In still other cases users might lose access to any product appropriate to the use, with consequent productivity losses. The nature of these potential costs is spelled out by CropLife Australia (2010) and the Animal Health Alliance (2010) and lies behind concerns raised by Pulse Australia (2010), National Farmers Federation (2010) and Victorian Farmers Federation (2010). Clearly with a highly prescriptive interpretation of the precautionary principle in mind the Australasian Compliance Institute (2010) observed that 'It is not possible to demonstrate any product is "safe".'

A flexible application of the precautionary principle in assessment and registration of agvet chemicals might not significantly impede access to agvet chemicals directly. It should be borne in mind that there is a considerable degree of caution built into the existing assessment framework, including the APVMA's conservative approach in cases when the science is uncertain. The Community Consultative Committee (APVMA) suggested that what the APVMA currently does is not inconsistent with the precautionary principle. The National Aquaculture Council (2010) went further in suggesting that the Authority currently takes too little note of the need to establish 'serious or irreversible damage' and 'cost-effective measures'. Moving to an explicitly precautionary approach may not involve a big change if it is sufficiently flexible to require a consideration of the costs of actions and to require substantive evidence, or a substantive probability, of possible harm to trigger a precautionary response.

On the other hand, such a degree of flexibility would be unlikely to satisfy all, if any, of those stakeholders who have called for application of the principle. Friends of the Earth (2010) suggest adoption of a highly restrictive interpretation of precaution — calling for a restatement of the Rio Declaration which has the requirement for cost effectiveness deleted.

Adopting the precautionary principle Option 2 — take an explicitly precautionary approach to human health and maintain the current risk based approach on all other matters

Under this approach an explicitly precautionary approach would be taken to human health matters, when the science was uncertain. Assessments by the national registration authority would continue on a risk based approach with a conservative approach taken to matters other than human health when the science was uncertain.

Benefits and costs

The approach would continue to deliver effective management of the risks, with some more assurance on human health. It might not meet the expectations of some community stakeholders. On the other hand it would be unlikely to impose substantial additional costs on registrants or users.

6.3 Permissible uses

Overlapping the issue of access for minor uses and minor use permits is the question of other permissible uses not on labels. A number of avenues exist for allowing access to chemicals for uses that are not on the label. Minor use permits provide a primary direct avenue of permissible access for minor uses in crops, aquaculture, some minor livestock industries and non agricultural sectors. Permits also provide access for emergency uses and research. Almost in parallel to those permits are rights, with conditions, for veterinarians to prescribe registered veterinary medicines and to compound and prescribe unregistered medicines. Those rights provide an avenue for managing the health of companion animals and single animals of major food producing species as well as allowing treatments more broadly in minor livestock and aquaculture industries. Inconsistencies between jurisdictions, however, result in some problems, including unintended competition from compounders with registered chemical products.

In coming to the conclusion that there should be uniform approach to off-label use of chemicals, the Productivity Commission argued that differences in enforcement of label conditions reduced the relevance of APVMA assessments (as some of the actual risks were not assessed in that process) and reduced the effectiveness of the APVMA. APVMA assessments are often far from comprehensive in coverage of potential uses. The coverage of uses assessed is a matter for the commercial judgement of the applicant, and additional uses are costly to have assessed. For some products, therefore, some off-label uses may not add to risks. Evidence from produce monitoring in Victoria — which has the most liberal off-label use regulation for crops — has not revealed residue or public health problems.

The Commission also argued that differences in approach could cause confusion for businesses operating in more than one state or territory and thus lead to higher cost for those businesses and less effective compliance. That observation is consistent with the experience of some industry stakeholders (see, for example, Turfgrowers Association of NSW Inc 2010, Aerial Agricultural Association of Australia 2010, GRDC 2010a, Australian Cherry Growers Association 2010). As well, both the GRDC and Australian Cherry Growers Association indicated that the variance in compliance between jurisdictions makes development of industry stewardship programs difficult.

There are several further classes of off-label access some of which are both more variable between jurisdictions and more contentious. With regard to crops, interpretations of legitimate uses range from strict use of the label conditions to use of broad classes of chemicals on crops not on the labels in some or most circumstances. The Productivity Commission identified the task of harmonising the use according to label as being one of the most important reform needs. Some systems of off-label access by right involve risks that have not been assessed in the regulatory system.

Policy principles approved in the National Framework provide for a scheme which allows uses outside the approved uses in certain circumstances or with specific approvals. They also require a scheme which contains a mechanism to restrict approved uses but does not constrain particular activities unless doing so is a necessary part of risk management. The scheme needs to achieve a balance between the community's right to know and commercial interests.

Arrangements for access to chemicals for minor uses may be viewed in terms of a hierarchy of regulatory devices: access on label; minor use permits, and permission for some uses off-label without permits. The design of the regulatory system should be such that on label access is considered first. Minor use permits should be the primary backup. Other permissible use arrangements should be put in place only to cover access for uses which cannot be managed either on label or by permit and which do not represent unacceptable risk.

6.3.1 General access categories and permits

Options 1 and 2 below are potentially complementary.

General access categories and permits Option 1 Establish a set of broad permissible uses on the basis of assessed risk

On the basis of assessed risk, and as is appropriate to that assessment, establish:

- a set of categories of use that can be regarded as safe along the lines of those identified by PSIC (rates lower than, and frequency less than, those on label and pests not on label [on crops or animals that are on label]) and any others identified as meeting risk criteria;
- a list of chemicals that are Generally Regarded as Safe (GRAS).

PSIC has already established use at lower rates or lower frequencies than on label and use for a pest not on the label as being legitimate classes of use that do not involve unacceptable risk. The legal status of using agvet chemicals in these ways varies between jurisdictions, however. Adopting *Option 1* would make either of the above actions legal in all jurisdictions (involving change for lower rates in the ACT and for different pests in NSW, ACT and WA). There would need to some exclusions, in particular the allowance for pests not on label would not include vertebrate pests.

The aim in developing a GRAS list would be to simplify choices for users of some non toxic products and avoid the costs of having such products entangled in the agvet regulatory system. The current assessment and registration system is based on a case by case examination of products at the instigation of applicants from the chemical industry. The consequent assessment and registration process is appropriate for potentially proprietary products which are toxic — the use of which could involve risks to human health, plants, animals or the environment. There are other chemicals, though, which are widely used for other purposes, or which can be shown to be safe, but which might also have applications as agvet chemicals.

Seeking to establish a list of chemicals that could be classified as GRAS would involve inverting that approach for a class of chemicals. A number of countries have a GRAS list for chemicals that can be used as food additives or in food preparation. Those include the list compiled by the US Food and Drug Administration and that provided by the New Zealand Food Safety Authority (2010). In each of those cases the process of having a substance added to the GRAS list begins with an application from a business, interest group or individual and an assessment by the regulatory agency. The end result of a successful application, though, is a listing of the substance as GRAS, rather than registration of a proprietary product. The basis of the approach is summed up by the US Department of Health and Human Services Food and Drug Administration (2004).

'For a GRAS substance, generally available data and information about the use of the substance are known and accepted widely by qualified experts, and there is a basis to conclude that there is consensus among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use.'

Benefits and costs

To some extent, accepting lower rates and frequencies than on label as legitimate might simply be recognising in law what occurs in practice. It is difficult to see how instructions on the pests for which a product should be used could be enforced. The ability to use products at lower rates and frequencies can be critical to success in integrated pest management. The freedom to do so can have important productivity benefits in that context. Outside the discipline of integrated pest management, however, there might be cases in which use at lower rates and frequencies contributed to the build up of resistance. In such cases the result would be lower productivity, both for those users choosing lower rates and frequencies and for those who used strictly according to the label. (Note that in jurisdictions without compulsory user records, neither use rate nor frequency seems enforceable.)

A process of establishing a GRAS set would be one of establishing a list of substances and uses which involved no known or definable risk. The direct benefits to chemical users of such a system would be twofold. First, it would facilitate identification of and access to a range of substances which had been shown to be safe. Second, to the extent that the search for substances suitable to include on the list was successful, it would increase user access to appropriate products with consequent productivity benefits. There would be costs to applicants in acquiring or generating relevant data and preparing applications.

In providing users with information on safe options, a GRAS system might encourage farmers and other chemical users to choose lower risk options. That would have flow on benefits to the broader community.

Those applying for substances to be added to the list would bear the costs of obtaining data and preparing applications, however, such costs would not represent an additional regulatory imposition. Assessment of applications and maintenance of the GRAS list would involve direct costs to the national registration authority. Against that there might be some decrease in applications for registration of relatively low risk products and for minor use and other permits. Some care would be needed to ensure that users do not read too much into the approval list – with consequent compliance cost to regulator and consequently to registrants.

General access categories and permits Option 2 Enhance the efficiency of assessments for minor use permits

Adoption of this option would involve examining measures to speed up the permit approval process and to simplify data requirements for some applications. Incorporating greater flexibility in requirements for local efficacy data and working to find ways of incorporating more input from overseas data, assessments and approvals would be important in meeting the latter requirement. While a number of stakeholders have suggested that there is a need for improvement in the permit system, how that should be done is less certain. Feedback on options for improvement is explicitly sought.

Benefits and costs

If successful, measures to make more effective use of overseas data, assessments and registration decisions in the permit assessment process could reduce costs for both applicants and the national registration authority. Any measure that made the assessment process more simple and less time

consuming, without compromising risk management, could have benefits for applicants. Local efficacy data need to be generated for a minority of permit applications. Still, in those cases the process can be both expensive and time consuming. Having greater flexibility in matching efficacy requirements to risk might make a significant difference to the cost and timeliness of access to chemicals for some applicants. It is not apparent that additional health risk would be involved in many cases, but in some cases there could be a need to consider possible additional environmental risk.

General access categories and permits Option 3 Status quo — maintain the current permit system without modification and allow no additional classes of permitted use
This would leave some possibly unnecessary restrictions on use and difficulties for permit applicants.

Consultation comments sought
Comment is specifically sought on:

- aspects of minor use permits most in need of improvement;
- the most effective ways to enhance the timeliness and efficiency of the minor use permit system.

6.3.2 Permissible uses for crops

Options 1, 2, 3 and *4* represent alternative approaches to managing off-label chemical access for crops. The options are not necessarily mutually exclusive. Rather, it might be possible to the four levels as a hierarchy of off-label access. Under such an arrangement, it would be legitimate for users to access a product for a particular use under the conditions of *Option 4*, for example, only if access for that use was not available under any of the conditions listed under *Options 1-3*.

Permissible uses for crops Option 1 **Confine *legal access to uses on labels and permits, or as allowed under the broad categories identified above.***
This option would reduce legal access for users in jurisdictions that currently have off-label arrangements. Four jurisdictions will be most affected by this option:

Victoria
Users have the freedom to apply agricultural chemical products to crops off-label provided that they do not use restricted products (RCPs and S7 poisons) and provided that they do not use any agvet chemicals (restricted and non-restricted) at a higher rate or more frequently than that specified on the label, or in contravention of a specific label restriction. Additionally, it is a user's responsibility to ensure that nil residues are present in the treated commodity.

South Australia
Horticultural users currently have off-label access to products within the confines of approved Quality Assurance programs.

Northern Territory
Crop users in the Northern Territory currently have access to agricultural chemicals for any use that has been approved in any state,

Western Australia
Under the new 2011 Regulations, agricultural users currently have off-label access to products:

- for an unregistered pest, so long as the crop is registered in WA,
- at a lower rate, concentration and frequency than is stated on the label and

- for a crop and pest combination, registered in another State or Territory, so long as that use is not prohibited in Western Australia.

Benefits and costs

To the extent that the change resulted in an actual reduction in off label use it could also result in a reduction in risks that had not been assessed by regulatory authorities before the product use. Use of any chemical product on crops and in situations for which its use has not been assessed would involve some unassessed risk. In this context, though, information published by the Department of Primary Industries Victoria (2009) is not suggestive of significant risk in the current Victorian system in terms of good agricultural practice or human health[12]. While the results reported here do not cover risks to the environment, Victoria is in the process of developing a targeted environmental monitoring program.

Set against any such gains from risk reduction would be the negative productivity effects consequent to loss of access. For those producers who currently have off-label access, a cut in access to key chemical products could lead to substantial losses in product quality, quantity, or both. Such losses could be particularly likely in the case of minor uses for which there are few, or in some cases an absence of, on label registrations.

The degree of industry cooperation with regulators that currently exists in Victoria and South Australia might be more difficult to maintain under this option. There is a risk that blocking legal access to products for minor uses would drive such chemical use underground, making effective monitoring and risk management more difficult. The costs to regulators of monitoring and enforcement might, therefore, be increased.

Permissible uses for crops Option 2 Extend legal access to include specific additional uses based on crop groups or similar extensions

This option would have the access conditions under *Option 1* as the base, but would additionally provide a targeted system of access for minor uses. The targeted extension to access would involve;

- establishing a list of species and crop groups where extrapolation of use patterns within the group would not significantly increase risk;
- providing for a system of access that would authorise specific uses not currently on labels, subject to risk management procedures such as a checklist self assessment (similar to the UK's LTAEU[13] system which is discussed further below).

The most evident approach to assembling a list of approved uses would be to apply extension of data within crop groups. Perhaps the most extensive version of this approach was the UK Long Term Arrangements for the Extension of Use (LTAEU) list. That list was made up of a large number of approved minor uses specified in terms of crop/chemical/situation/application method etc. [14]

[12] 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. The results for 2007-08 are consistent with those from the monitoring program over a number of years.

[14] The list is now obsolete, having been replaced with Specific Off-Label Approvals (SOLAs), which are similar to APVMA permits. The change was made necessary by changes in the EC regulatory approach.

The UK LTAEU list was established on the basis of UK specific chemical needs and risk assessment. Establishment of a similar list for Australian industries and condition would involve an initial assessment of risks by the APVMA.

The impact on users of developing a list would obviously depend on that list's product and use coverage. Nevertheless, acceptance of the approach would almost certainly extend legal access available for minor uses without permit in those states and territories which currently do not have off-label arrangements. On the other hand, some users in jurisdictions which currently have off-label arrangements would have reduced access. For example, the restriction to minor uses would mean that those users in Victoria who currently access products off-label for major uses and those in South Australia who potentially have such access would lose that access[15].

Benefits and costs

To the extent that access was broadened and eased in terms of timing, there would be productivity gains for users. To the extent that the conditions of *Option 2* increased access for minor uses they would have potentially substantial positive productivity effects. Having access to an effective chemical product for a minor use can be critical to product quality and sometimes to crop survival. Timing of availability can also be critical. In the context of timing, the conditions of *Option 2* would provide for immediate access to a product for minor uses.

Once a list of uses was established there would also be cost savings to users who would otherwise have had to make permit applications. The national registration authority would consequently need to direct fewer resources to permit assessment and administration. There is currently a degree of cross subsidy of minor use permit activities within the APVMA from other activities. Thus, establishment of a minor use list could allow the authority to devote more resources to facilitating assessment, providing a long term gain to applicants and registrants. Against those savings there would potentially be substantial upfront cost in the assessment of uses necessary to compile a list that met risk management criteria.

For those users who experienced decreased access under this option, the benefits outlined above would be reversed. They would bear increased costs for permit application (in the case of minor uses) and suffer productivity losses.

In designing the list of approved uses it would be necessary to consider the potential impact on the incentive to apply for inclusion of uses on labels and permits. The existence of a use on the list would limit or remove the incentive for a registrant to apply to have the use on label. Similarly, the incentive for individual users, Research and Development Corporations or industry bodies to seek inclusion of the uses on labels or permits could be low. That would mean that the further risk assessment that would normally be involved in those application and assessment processes would not take place.

Permissible uses for crops Option 3 Extend legal access to minor uses broadly defined but with exclusions of specific uses or chemicals, or of classes of uses or chemicals

Access under this option would be designed as a backup to the primary means of access on label and permit. A set of conditions would be established to allow use of some chemical products for crops

[15] In addition to off-label access for users who are participants in PIRSA approved horticulture industry QA schemes, the legal machinery exists for approval of off-label access South Australian defined major crops (which differ somewhat in definition from APVMA major crops. Users in those industries would first have to gain approval from their industry bodies for approval to be granted. As yet this has been very limited uptake.

not on the label under certain defined conditions. That set of conditions might include a requirement to report use to regulators, in order to assist regulators in defining priorities for research and monitoring. The emphasis would be on setting conditions under which uses were deemed approved, rather than specifying approved uses as in *Option 2*. At a minimum, the conditions would exclude RCPs and Dangerous Poisons and confine use extensions to a set of defined minor uses. They would not include uses in major food crops or species.

There would also need to be a restraint on use of chemical products off-label when another chemical product was registered for that use. The most obvious restraint would be to require that, where there was a chemical product either registered, or with a permit for the use, it would be illegal to apply any other registered chemical based on the same active constituent if that use was not on the label.

The arrangement under *Option 3* would include a targeted monitoring program for both residues in crop products and environmental effects. That monitoring program would be backed up by a requirement for users to keep auditable records — possibly with the responsibility to report use to the regulator. Consideration could be given to extending the criteria for defining RCPs beyond the set currently used to prevent inappropriate off-label use of some products. There might also be a need to require that users report off-label use to control of use regulators, to allow informed and effective risk management.

Compared with the current situation, users in states and territories who do not have off-label arrangements would have broader access to chemicals for crop protection than is currently the case. The restriction to minor uses and to cases where no chemical was registered for the use would reduce access for some users in Victoria who currently have off-label access for major uses. However, the change would not leave those with a minor use without at least one treatment option. In South Australia horticultural users in approved QA schemes would continue to have off-label access. In addition, horticultural users outside those schemes and broadacre users would have off-label access for minor uses.

Benefits and costs

The nature of benefits of this option would be broadly the same as for *Option 2*. What would differ, in addition to the distribution amongst users noted above, would be the size of the effect. With a more open ended definition of permissible uses *Option 3* would provide broader productivity benefits than *Option 2*. *Option 3* would also involve fewer productivity losses to users who currently have off-label access.

On the other hand, the extent of any increased risk from more extensive off-label use could be greater under *Option 3*. An effective targeted monitoring program would be an essential part of risk management. There would be additional costs of monitoring in those states and territories where this option involved extension of off-label access. Whether the bulk of the increased monitoring costs would be borne directly by governments or by industry would depend on the funding model adopted. If a requirement for users to report off-label use was included that would involve some additional cost burden on users.

Permissible uses for crops Option 4 Adopt a system where approved agronomists or other advisors could permit off-label use of some agricultural chemicals

The intent in implementing this option would be to provide a facility to allow users limited access to some agricultural chemicals on the professional advice of agronomists in parallel to that available for use of veterinary medicines through veterinarians' prescribing rights.

A number of conditions underlie veterinarians' prescribing rights. First, there is an animal welfare imperative to ensure the availability of prompt emergency treatment for livestock and companion animals. That imperative does not exist for plants. Second, there are safeguards in terms of the expertise and regulatory oversight of veterinarians. In particular:

- veterinarians have professional training (in toxicology and related fields) that is directly relevant to treatment of animals and of some relevance in the management of chemical risks to human health;
- veterinarians have established professional associations and codes of practice;
- state veterinary control boards have regulatory oversight of veterinary activities, including the power to deregister practitioners.

No similar regulatory arrangements or professional standards which are directly relevant to chemical risk management currently exist for agronomists. Nevertheless, many agronomists may have at least some degree of relevant training. It would be necessary to establish a legal framework within which approved agronomists could operate and rights, responsibilities and liability could be established. At a minimum it would seem that there would need to be a form of approval and accreditation requirement to ensure that only agronomists with appropriate competencies were included in the program. Issues of legal liability and shared responsibility would also have to be resolved[16].

Benefits and costs

Implementation of this option would require identification of a pool of agronomists with appropriate skills in chemical risk assessment. The impacts of an agronomist's scheme would depend on the precise nature of the scheme. Clearly, though, there would be costs of initial investigation of design, in setting up of an approval system and ongoing costs of maintenance, monitoring and enforcement of that scheme. To a greater or lesser extent those costs might be cost recovered through fees and charges. Structural details and cost recovery options would be matters for further consultation and a Cost Recovery Regulation Impact Statement, should further development of this option be supported. Most likely there would also be training costs for participating agronomists.

On the other hand, the successful establishment of such a scheme would facilitate, and probably expand, legal access for minor uses. It would therefore have benefits to agvet chemical uses in terms of increased productivity in user industries. Properly set up and managed, such a scheme might achieve such gains whilst still managing risks within acceptable bounds.

Consultation comments sought

Feedback is specifically sought on practical, cost and benefit aspects of *Options 1-4*, particularly:

- in regard to adoption of a more restrictive approach than currently applies in some states and territories, as outlined in *Option 1,* the extent of potential*:*
    - user productivity, or opportunity, costs;
    - decrease in risk;
    - any likely impact on incentives to register more uses on label;
- with regard to the adoption of a less restrictive approach, such as *Option 2* or *3*;
    - any practical issues in establishing an appropriate list (*Option 2*) or appropriate bounds (*Option 3*);
    - potential user productivity benefits;

[16]In this context industry programs such as Agsafe may have particular relevance. In a related context, Fertcare Accredited Advisors, is an industry scheme has been established for fertiliser recommendation.

  - potential increase in risk;
  - any likely impact on incentives to register more uses on label;
- the level of interest from agronomists in such a scheme such as that outlined in *Option 4*.

6.3.3 Veterinarians' prescribing rights

Problem/issues

Veterinarians treat a wide range of companion animals (such as horses, dogs and cats) and food producing animals (such as cattle, sheep, pigs and poultry). To allow them to offer effective treatment for a wide variety of species and situations, veterinarians are given rights to prescribe and registered, or compound, prescribe and use unregistered chemicals. Those rights are most extensive for treatment of companion animals, where animal welfare is the primary concern. Prescription rights are more limited in the case of food producing species, where the possibility of contamination of food supplies must be taken into account. Nevertheless, those rights are important to the maintenance of productivity in minor food producing industries and sometimes to emergency response or protection of animal welfare in major food producing species.

The Productivity Commission did not investigate veterinary chemicals specifically but assumed that functioning of regulatory arrangements was similar to that for agricultural chemicals.

There is already a reasonable level of harmonisation already for veterinary chemicals through the adoption of agreed national principles. Nevertheless, there are still significant differences in prescribing rights between states and territories. For example, all jurisdictions make a distinction between categories of food producing and non food producing species but there are differences in how the categories are defined and which species are included. The inclusion of minor food sources, such as bees and aquaculture species, is varied across the jurisdictions.

Additionally, there are differences in veterinarians' rights to prescribe and use both registered chemical products and unregistered products in food production species, particularly those not classified as Major Food Production Species (or Major Trade Species in those jurisdictions which have a specific trade classification). Such differences between jurisdictions in aspects of veterinary regulation add unnecessary complexity to business operations and attempts at cooperation between regulators.

A number of industry stakeholders and regulatory agencies have argued that weaknesses in the current specification of prescribing rights and compliance regimes allow substantial substitution of unregistered compounded products for registered products. Such substitution can increase risks of health and trade incidents. It can also have the potential to undermine the incentive for chemical companies to submit products for assessment and registration with consequent costs to users of registered products.

The National Framework calls for the maintenance of veterinary prescribing rights in a form that provides for the protection of animal health and welfare without creating unacceptable risks to human health, trade or the environment. It also requires that those rights do not substitute for the registration of veterinary chemical products or the use of existing registered veterinary chemicals. *Option 1* is designed to overcome the weaknesses in the current system of prescribing rights.

Veterinarians' prescribing rights Option 1 Harmonise veterinarians' prescribing rights across jurisdictions to ensure legitimate user access to chemicals without compromising the assessment and registration system for veterinary chemicals.

Regulations would be changed in two ways:

- veterinarians would retain rights to compound and prescribe products but those products would be limited to instances where there was no appropriate registered product for the use, and;
- definitions of food producing species would be harmonised.

Benefits and costs

The proposed changes would create direct benefits to suppliers of registered products who currently face competition from unregistered products. There would be some decrease in risk associated with the move to registered products. There might also be an improved incentive for chemical producers to register more new products, with consequent user productivity and amenity benefits.

Some policy and legislative development costs would be involved. The main ongoing cost to regulators may be some increase in monitoring and enforcement activity. There would be revenue losses to those veterinarians who currently exploit the loopholes between jurisdictions.

Veterinarians' prescribing rights Option 2 Maintain the status quo

As is noted above, there are not large differences between jurisdictions. Submissions in response to the discussion paper, however, suggest a number of areas for improvement. It is questionable whether this would satisfy the spirit of the COAG directive.

6.4 Management of the chemical portfolio

Problems/issues

With regard to management of the portfolio of registered chemicals, the National Framework calls for regulatory effort to be directed toward management of aggregate risk. Consistent with that direction, agvet chemicals should continue to be registered only if they are assessed as meeting contemporary health and safety standards. The APVMA's existing chemical review program does not allow it to focus this level of rigour on all chemicals. For this reason options for reform are set out below.

Around 9000 chemical products are currently registered by the APVMA, many of those having been registered by state regulators prior to formation of the National Registration Scheme. Many of those products have been used extensively over long periods of time with no evident harm. On the other hand, assessment methods, acceptable levels of risk and knowledge of the effects of a chemical may change over time, sometimes raising questions about the continued validity of a registration.

The APVMA has a risk prioritised chemical review process in place. Arguably, though, it is not sufficiently resourced and suffers from a number of limitations, some imposed by the Authority's enabling legislation. The APVMA can require that the science that underpins the continued registration of a product be raised to current standards only if there is evidence of likely undue harm from that product. Effectively, the onus is on the regulator to ensure that all registered active constituents and products meet current standards. When the Authority does initiate a review there is no cut off date by which supporting data or argument needs to be provided. Furthermore, unlike the case for registration of new products, there is no statutory timeframe for the completion of a review. The current review system allows registrants to provide additional data or argument at any stage during the review process. Continued reconsideration of the outcomes of the assessment in light of any newly submitted data creates inefficiencies in the process and lengthens review timeframes.

Stakeholders have questioned aspects of the chemical review process with varying perspectives[17]. Community groups suggest that the APVMA's chemical review program is weak, pointing to comprehensive review programs in the US and EU and asking why products that have been deregistered in some other countries continue to be registered in Australia. Assurance that all registered chemicals and uses meet current standards is weakened by the chemical review limitations outlined above and the absence of an explicit requirement that registrants be able to demonstrate that products meet current standards, and limits on the APVMA's powers to ensure that products meet current standards.

On the other hand, registrants suggest that aspects of the review process are unpredictable. The absence of a clear exposition of the acceptable level of risk may play a key role here. Chemical industry stakeholders argue that regular comprehensive reviews of registered products would be costly, and in most cases unnecessary. At issue here is the capacity of the regulatory system to ensure that all registered products are up to current standard, without undue costs. *Options 1, 2* and *3* offer quite different cost profiles for portfolio management.

Policy principles agreed by COAG in the National framework require that the registrant is responsible for ensuring that a registered product continues to meet current standards. They also require that the chemical management and review process are efficient, responsive and timely and that regulatory effort is directed toward management of the aggregate risk.

<u>Management of the chemical portfolio Option 1</u> Develop a targeted re-application program to expand the ongoing risk prioritised reviews as currently carried out by the national registration authority, but supported by:

- ***the components of a layered system of checks and review outlined below;***
- ***the process would be purely an administrative check by the national registration authority, according to a basic checklist that certain registrants would need to provide a certain time (for example, 10-15 years) following their initial registration;***
- ***conditions of full chemical reviews are modified such that;***
  - ***there were cut off times for data submission, and;***
  - ***there were fixed times for completion of reviews***

The registrant would be required to provide a checklist to the national registration authority periodically for the authority to verify that registration conditions continue to be met.
The check list would:

- cover matters such as ensuring that the original assessment method, acceptable level of risk and data package remained valid;
- be designed so that not all products were examined at once;
- be progressively introduced on a risk basis, for example, commencing with 'old' products not previously assessed by National Registration Authority/APVMA.

The registrant would only be required to provide additional information when there was an indication that products did not meet current standards. A timetable would be published to give transparency to registrants and the community of when checks are due. Full chemical review would be required only when evidence from the above process or other sources, such as adverse incident reports, indicated that one was warranted on risk grounds.

[17] This is borne out by submissions in response to the discussion paper Rose and Sheppard (2009) and to the Policy Discussion Paper *Better Regulation of Agricultural and Veterinary Chemicals.*

Benefits and costs

Option 1 is designed to provide an improved assurance that the portfolio of registered chemicals meets current standards. It would be similar to review programs implemented in some other countries, for example the program undertaken by the US EPA under the *Pesticide Registration Improvement Act 2003*. However, even a risk prioritised review process could involve substantial costs for the national registration authority and for registrants.

The primary costs for registrants would be data generation costs and staffing costs of producing analytical components for assessment. That cost would depend, in part, on the assessment components the national registration authority would need in order to undertake a review or a re-registration. In some cases a registrant may be required to submit new data sets for only some assessment components. As points of comparison, some industry estimates indicate that the generation of efficacy data for a single crop in a single region can cost in the order of $20,000, and the current APVMA charge for an application for a new active constituent is approximately $50,000.

To the extent that adopting that option raised the costs to registrants of maintaining their products on the market, there could be a reduction in availability of products to users. Faced with substantial data costs, some registrants could choose to withdraw products from the market, rather than seeking to retain registration. Such action would be particularly likely for products with only small market profiles. From a user point of view this could lead to some combination of two negative effects: First, there would be an overall decrease in access. Second, in some small market segments the reduction in product availability might lead to price rises for the remaining products.

To estimate the impacts and further develop this option, it is necessary to conduct further consultation with key industry stakeholders to gain a better understanding of the implications for individual registrants and agvet chemical companies.

Key areas for further design work and consultation would be:

- the criteria that would drive the targeted provisions;
- the level of data and support that would be required as part of a re-application, review and/or re-registration — that is, whether applicants would be required to provide completely updated data sets for all criteria, or only specific data for selected criteria;
- the level of assessment to be undertaken by the APVMA on receipt of a re-application, and whether an alternative fee structure would be applied to the re-application process;
- the process(es) for determining if a product should be re-registered; and
- the protocols for making maximum appropriate use of existing information, including data, analysis and, where appropriate to effective risk management, findings from overseas reviews.

***Management of the chemical portfolio Option 2** Require re-registration of all active constituents, with:*

- ***initial full review required for all chemicals originally assessed before a defined cut off date;***
- ***periodic re-assessment given to both the length of the period and the completeness of the assessment requirement within the context of a risk management framework;***
- ***a layered system of checks and review as in Option 1 applying to products in which those active constituents are used;***
  - ***there are cut off times for data submission, and***
  - ***there are fixed times for completion of reviews***

This approach would leave out the risk-based targeting, and require review across the board.

Benefits and costs
This option could represent a lower risk approach, but the initial full review requirements with periodic reviews thereafter would involve substantial costs to registrants. It is likely that some registrants would choose to allow the registration of products to lapse, rather than bearing the cost of the review. In this context, registrant's choices would be based on commercial judgement, so it is quite probable that some low risk, ,low volume active constituents could be withdrawn. It is quite possible that users would have to move to higher risk products in some cases.

An absence of risk prioritisation would inefficient, and inconsistent with the policy principle of the National Framework which states that the effort in the management of the chemical portfolio is directed toward the management of the aggregate risk.

Management of the chemical portfolio Option 3 Maintain the status quo
If *Option 3* is adopted, stakeholder concerns about health and safety, and the overall effectiveness of avget chemical regulation, will continue to exist. However, this option would avoid the imposition of additional regulatory burden on registrants.

Consultation comments sought
Comment is sought specifically on:

- the likely costs of data provision and other associated costs of the review process;
- the level of review costs that would discourage registrants from persisting with registration of different categories of products;
- the opportunities for use of overseas data, assessments and reviews, and
- any of the issues outlined as 'key areas for further design' under *Option 1*.

6.5 Supplier compliance – importers, manufacturers and retailers/distributors

Problems/issues
A number of stakeholders have questioned the clarity and level of resourcing of the APVMA's compliance policy. Further, some have observed that the APVMA lacks a full modern set of powers to ensure compliance. The National Framework calls for regulatory powers, monitoring and enforcement efforts that are sufficient to ensure that the chemicals supplied are in accord with those that were assessed. It also calls for recognition of industry stewardship and quality control systems, and for suppliers as part of that regulatory mechanism. *Option 1* involves the creation of a complete set of compliance powers for the national registration authority for inclusion in the Agvet Code. The suggested policy change would be set in the context of providing effective backup to a well developed and resourced compliance strategy.

Supplier compliance Option 1 Provide the national registration authority with a complete, modern set of compliance tools
Under this option, the national registration authority would be provided with a more comprehensive, graduated and contemporary compliance enforcement regime with more powers in the middle range than exist in the APVMA's current compliance and enforcement system. Penalty provisions would be proportionate to the degree of non-compliance. The length of time over which the authority could use evidence and undertake proceedings would be extended in the agvet legislation. The legislation would also provide for greater publicity and transparency of the compliance management framework and outcomes.

A more complete set of compliance options would include:

- alternatives to litigation for use in certain circumstances, such as issuing infringement notices, enforceable undertakings, improvement notices and injunctions;
- enhanced deterrence (to avoid non-compliance by applicants and registrants) through publicising the national registration authority's compliance framework, recent compliance actions and examples;
- offence formulations and penalties tailored to better match the degree and seriousness of non-compliance;
- measures to allow the authority to provide information to courts in relation to the commercial benefit (to the applicant or registrant) of non-compliance, in relation to any recourse actions; and;
- enhanced investigation powers for the authority, including the ability to introduce a 'notice to produce and attend', maintaining individual rights whilst ensuring that companies cannot elude responsibility, such as enhancing the authority's powers to issue warrants and seize of information.

The suggested change would make the authority's compliance enforcement options more consistent with those of other Australian Government regulators, such as the Therapeutic Goods Administration and the National Industrial Chemicals Notification and Assessment Scheme. It would also follow the Attorney General's guide to framing compliance and enforcement powers. A range of compliance response options would allow the penalty to be commensurate with the nature of the offence.

Benefits and costs

Changes under this option would impose costs on non-compliant agvet chemical suppliers. They would result in improved compliance with the Agvet Code through improved enforcement powers. They would do so by removing inefficiencies in APVMA's current compliance regime, such as instances where unnecessary criminal investigation and prosecution effort is required when a different and lower cost compliance approach would be more appropriate. Additionally, there would be improved opportunities to appropriately follow up and take action where the applicant or registrant has intentionally acted in contravention of agvet chemical regulations. This could extend to removing the continued perception of weaknesses in the authority's effectiveness as a regulator of agvet chemicals in Australia.

For improving compliance, this suggested change would have benefits for the majority of compliant suppliers and for users. Compliant suppliers would benefit from the removal of competitive non-compliant products from the market. The broader community would gain from the improved effectiveness of risk management implied by more effective compliance with directions derived from the assessment and registration process. Users would benefit to the extent that with better compliance they would have greater assurance of effectiveness and safety of the products they purchased. On the other hand, some users might lose opportunities to access non-compliant but effective products at lower prices.

***Supplier compliance Option 2* Retain the status quo**

Not adopting *Option 1* would mean that the level of compliance within the agvet chemical industry in Australia would remain at the current level.

7 CONTROL OF USE

Problems/issues

There is a good deal of similarity in the basic set of policy tools used by control of use regulators in different states and territories. The manner in which those tools are applied, the regulatory effort with which they are applied and the policy detail, is varied. The Productivity Commission recommended the adoption of a national policy for control of use primarily because it found the negative impacts of differences in regulation between jurisdictions to be excessive. Areas of particular concern for the Commission were differences in licensing and training requirements and in approach to off-label uses. In recommending the development of a national system for control of use the Commission (p.228) stated that, at a minimum, that system should contain '...uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.'

There are good reasons for some differences in regulation between jurisdictions. The need to respond to some issues that are regionally concentrated means that state and territory based regulatory systems will display some differences. On the other hand, regulatory differences between jurisdictions can cause confusion and impose costs on users that operate across multiple states and territories.

The level of regulatory effort invested in control of use varies across jurisdictions. As in the case for management of product compliance, inadequacies in this area have the potential to damage the integrity of the regulatory system. Gaps in the regulatory powers and enforcement tools may also limit the effectiveness of some regulators. A consequent weakness in coordination and consistency between jurisdictions limits the effectiveness of control of use at a national level.

Control of use of agvet chemicals encompasses a wide range of monitoring, surveillance, informing and enforcement activities. It has complex relationships with assessment and registration processes, licensing and training and governance structures. The potential impacts of any of the following options may, therefore, depend in part on choices that are made with respect to other aspects of agvet chemical regulation.

The National Framework requires that the setting of regulatory powers, monitoring and enforcement is sufficient to:

- ensure early detection of problems;
- allow effective traceback and emergency response; and
- is carried out efficiently, using industry co-regulatory approaches where it can be shown that
    - coordination avoids duplication of monitoring and enforcement effort;
    - the co-regulatory regimes provide effective risk management.

To be effective in that sense, control of use regulators would need to have a comprehensive set of powers designed to ensure the protection of human health, trade and the environment (including non-target plants and animals on site), the property of neighbours and the public. The set of powers would :

- be sufficiently broad to allow effective monitoring, sampling, traceback and enforcement;
- be flexible, allowing graduated action targeted to the most effective solution for each set of circumstances, rather than relying on prosecution as the first or primary regulatory response, and including powers such as the ability to;
    - prevent sales of contaminated produce
    - deny access to chemicals for non compliers;

  - require retraining for non compliers;
- include provision for establishment and enforcement of conditions such as buffer and exclusion zones;
- include notification provisions (including neighbour notification); and
- be restricted only in ways intended to prevent the imposition of unreasonable regulatory burden.

The actual structure of regulatory powers, monitoring and compliance activities could depend to some extent on the governance structure of the national regulatory framework. If harmonised state and territory delivery of control of use was adopted (Governance *Option 1* or *3*), control of use could be delivered through a diversified structure of regulatory powers. Each state or territory would be responsible for implementing a mutually agreed set of regulations and keeping those up to date. A national system for the regulation of agvet chemicals use could not be easily or efficiently operated under several different sets of powers. So the initial challenge would be to develop a common set. There would be an ongoing need for cooperation in adapting regulatory powers and the details of regulation under those powers to changing requirements over time.

On the other hand, if control of use was delivered through a single national regulator (Governance *Option 2*), a single set of regulatory powers would be necessary for that regulator to operate. Under this option the national control of use agency would develop a full set of regulations, with suitable allowance for regional differences. Potentially, a national regulator could deliver control of use functions through its own regional branches. Alternatively, control of use functions could be carried out by individual state and territory agencies under service level agreements with the national regulator (along the lines recommended by the Productivity Commission).

A set of agreed standards would be established for monitoring, surveillance and the design and use of regulatory powers. This would include a process for deviating from agreed standards, which could be used, for example, in response to regional differences. The details of that process would also depend on the choice of governance structures.

7.1 A national system of use controls – monitoring, auditing, surveillance and traceback to ensure safe use

Monitoring, auditing, surveillance and traceback to ensure safe use Option 1 Establish a national program for monitoring residues of agvet chemicals and contaminants in agricultural commodities and the environment, integrated with effective auditing and surveillance

The program would require a sufficient level of resources to allow effective monitoring, auditing, surveillance, and response to incidents and feedback within a harmonised approach to residue/contaminant monitoring, including:

- effective use of local intelligence to guide monitoring and enforcement efforts;
- integration with monitoring schemes such as the National Residue Survey, Freshtest and The Australian Total Diet Study (formerly known as the Australian Market Basket Survey);
- analytical/diagnostic capability, database systems and interrogation capacity to respond to current and future requirements;
- capability and resources to undertake timely and effective traceback activities and follow up policy actions, including;
  - tools to undertake traceback investigations;
  - underlying legislative obligations (such as vendor declaration);
  - ability to constrain movement of contaminated produce and assign residue status to livestock and properties;

- a statutory requirement to report any detected breach of an MRL to the regulator[18];
- clear and effective links between agvet regulators and other regulators with related or overlapping responsibilities.

Aligning the components within each jurisdiction's regulatory system will create change. The set of regulatory powers, monitoring and traceback systems and compliance tools necessary to ensure effective control of use is broad ranging and complex. The emphasis in developing a harmonised set of regulatory powers across the jurisdictions would be on structuring a set which allowed both effective responses to adverse incidents and strategic development of regulations to manage emerging issues. It would also provide regulators with the tools to drive behavioural change, rather than relying on punitive legal action as the primary device. The underlying purpose would be to allow regulators to protect human health, trade, environment and property.

A duty of care and shared responsibility for decision making on chemical use would be key component of the new legislation (for example, employers directing workers, consultants advising farmers), including recognising the need for chemical users to both take account of label requirements and to assess and manage any site specific issues not anticipated on the label.

Control of use regulators would have a comprehensive set of powers designed to ensure the protection of human health, trade and the environment (including non-target plants and animals on site) the property of neighbours and the public. The set of powers would:

- be sufficiently broad to allow effective monitoring, sampling, traceback and enforcement;
- be flexible, allowing graduated action targeted to the most effective solution for each set of circumstances, rather than relying on prosecution as the first or primary regulatory response, and including powers such as the ability to;
  - prevent sales of contaminated produce;
  - deny access to chemicals for non compliers;
  - require retraining for non compliers;
- include provision for establishment and enforcement of conditions such as buffer and exclusion zones;
- include notification provisions (including neighbour notification where practical and appropriate).

Option 1 would include adoption of a uniform set of primary risk and incident management tools and processes. It would also involve a more coordinated and complete system of monitoring, with a provision to allow the primary production industry or state government agencies to do supplementary testing. Currently there appears to be a significant degree of variation in the levels and composition of monitoring between jurisdictions.

At this time it is not possible to state the particular combination of instruments that would make up a harmonised set. Determining the set of instruments will be part of the implementation phase of the National Framework. That process will require further consultation.

[18] As currently operates in Queensland. This system works well in Queensland with any reports of above MRL or ML being sent to the Standards officer by fax or email to a common inbox (standardsOfficer@deedi.qld.gov.au). Once it has been checked that there is an actual MRL or ML violation, an investigation is actioned (or a referral is made if there is an interstate sample). This increases monitoring at no extra cost to government. As most cases are dealt with by extension and do not result in prosecution there has been no negative feedback about the Queensland legislation. Also Victoria has provisions in its Control of Use to require commercial laboratories to notify the Department about the detection of contaminated produce.

It is, therefore, not possible to predict with any accuracy and detail what the impacts on users and other industry and community stakeholders will be. Nevertheless, there are some changes are clear. It is possible to predict some impacts of those changes and of the broad influence of moving from sets that vary between jurisdictions to a more harmonious set of regulations.

Benefits and costs

The Productivity Commission highlighted the costs to businesses in the current fragmented system where businesses operate across multiple states and territories. Affected businesses include fee for service applicators, farm businesses and users of treated produce such as supermarket chains. Operating under multiple sets of rules can be costly to businesses in a number of ways. It can impose duplicate sets of operating and training strategies duplicate licensing requirements and increase the probability of compliance errors. Harmonising the regulations would reduce business costs by removing the need for duplication and minimising confusion.

More effective co-regulatory arrangements would avoid duplication of record keeping, auditing and related activities both for regulators and for users. For example, in the absence of a co-regulatory agreement a farmer participant in a QA scheme would face separate record keeping responsibilities to the scheme and to the regulator. There might be a good deal of overlap in the two sets of recording requirements, but only by accident would they be the same. In a worst case scenario, such a set of dual recording responsibilities might require two complete sets of records in different formats with slightly different content. Adoption of harmonised co-regulatory arrangements would mean that the potential for integration of regulatory requirements and those of QA, stewardship and other industry schemes across state and territory boundaries would be significantly expanded, which would provide benefits to participants in those schemes and improved market returns.

More complete and coordinated monitoring systems would also provide more effective risk management. In particular, problems with effective monitoring, traceback and response capabilities could be resolved more quickly. Improved coordination across jurisdictions would make it easier to identify and respond to patterns of non compliance and other common problems from use, thus raising the overall standard of compliance. Potential benefits would include gains to user industries as a result of more timely and efficient resolution of international and other trade incidents. There would also be benefits to the community through better human health and environmental risk management.

The move to a nationally consistent system would not be without some costs to users in some jurisdictions. Those costs would mainly be increased reporting costs (MRL breaches). For some users there might also be increased costs of complying with more strict regulations.

The main direct costs of improved monitoring would be those of lifting the standard of monitoring in some states. The increased burden in this instance would largely be a cost for regulatory agencies. A properly targeted program, however, would see much of that burden imposed on a small percentage of users who currently do not maintain high standards of compliance.

Consultation comments sought

Comment is sought on desirable inclusions or limits to regulatory powers. Comment is also sought on the opportunities/limits and benefits/costs to industry participants of co-regulatory arrangements and the likely costs of MRL breach reporting responsibilities.

Monitoring, auditing, surveillance and traceback to ensure safe use Option 2 Maintain the status quo

All jurisdictions have monitoring, surveillance and traceback programs and capabilities. Those programs vary in focus and intensity. The variation between jurisdictions in current effort indicates that risks are not well managed across the system. Cross border differences provide some difficulties for businesses that operate across more than one state or territory. Adopting this option would not satisfy the requirement of the COAG direction to develop a single national framework.

7.2 A national system of use controls — record keeping

Record keeping Option 1 Establish at a national level a requirement for users to keep records of use

All commercial and occupational users of agvet chemical products would be required to keep auditable records of use (users of household would be exempt). Veterinarians are already required to keep records, so the change would apply only to some users of agricultural chemicals. Similarly, all fee for service applicators — pest controllers, aerial and ground applicators — must currently keep records (except in the ACT). All users of agricultural chemicals who supply through QA schemes are also required to keep records. Where there were co-regulatory arrangements in place, a regulatory requirement for record keeping would not add to the burden for these users. Currently there is no general requirement for farmers and other individual users to keep records in WA, Queensland and ACT[19].

Benefits and costs

A universal record keeping requirement, backed up by a targeted and periodic audit, would provide a basis for traceback and risk management that is more effective and consistent across jurisdictions than is currently the case.

It would increase the regulatory burden in some jurisdictions for some users. Users affected would mainly be farm users who are not currently in QA schemes and who are located in jurisdictions that do not currently require record keeping.

Record keeping Option 2 Retain the current system — record keeping requirements varying according to jurisdiction

Absence of record keeping requirement, particularly for farmers outside quality assurance schemes in some jurisdictions, can limit the effectiveness of traceback efforts. As is implies above, it would maintain a lower regulatory burden for some users.

Consultation comments sought

Comments are sought from businesses that would be affected by an additional record keeping requirement and the cost of keeping records.

8 TRAINING AND LICENSING

Problems/issues

An important part of risk management is ensuring the competency of chemical users. The specific competencies and the overall level of competence required depends on the risks. Risks, in turn,

[19] Queensland has exceptions where there are specific record requirements in the regulations. Similarly, records are required for use of restricted products in WA.

depend on the particular chemical product, the use and the situation in which the product is used. Thus it would be reasonable to expect different competency requirements for different tasks and situations. To some degree such differences are apparent in the current system. Nevertheless, there is a great deal of variation between jurisdictions in competency, training, accreditation and licensing requirements. In part this may reflect different risk management priorities of the agencies concerned and different approaches to risk management. The result is a relationship between risk and training requirements that appears incomplete and nationally inconsistent.

There is an inconsistent application to different parties (businesses and/or individuals) of different legal instruments (licensing or accreditation) by different agencies in each of the jurisdictions for varying risk management objectives. For example, a commercial ground sprayer of insecticides can operate with nil requirements, accreditation of individuals, licensing of individuals or licensing of businesses and individuals depending on the jurisdiction. Those differences do not reflect consistent application of risk management tools.

Mutual recognition of licensing operates as a mechanism for achieving a degree of uniformity and effective compliance. As well, the content and standard of training courses under the Australian Qualifications Framework (AQF) is common to all states and territories. These two things alone are not completely effective in ensuring policy consistency. In practice, one aspect of mutual recognition may work against an effective training system. It may create pressure for some jurisdictions to lower their standards to create a level playing field.

Different regimes can impose substantial costs to businesses operating across borders. Where those differences are not risk based any additional costs represent waste. On the other hand it may be difficult for an individual state or territory regulator to ensure compliance when dealing with businesses which are headquartered in other jurisdictions. The Productivity Commission identified that, at a minimum, the new control of use regime should adopt a new national policy approach to training and licensing for users of agvet chemicals. .

Agvet chemicals are used by a diversity of commercial and home applicators in a wide range of situations with different inherent risks. For that reason competency requirements are also diverse. The National Framework calls for a set of competency requirements which applies consistently across jurisdictional boundaries. It also calls for the level of competence required to be commensurate with the identified level of risk and for access to chemicals to be linked to user competency.

Also, where appropriate, consideration should be given to using industry initiatives as the instrument to ensure compliance.

There are several dimensions to risk that are relevant to training and licensing regulation, including:

- the extent of use;
- the situation in which a product is used;
- nature, toxicity and number of chemicals used; and
- whether or not specialist equipment or application techniques are needed to use a product.

At the broadest level, greater risk is likely to be associated with a greater extent of use, use of a greater number of chemicals and use of more toxic chemicals. Additionally, there are particular situations in which risks are higher, particularly in urban agvet chemical use and in enclosed spaces ─ such as spraying protected crops or fumigating storage facilities. For these reasons there is already a hierarchy of controls, from licensing and close regulation of urban pest controllers, to lighter

regulation of farmers and farm contract sprayers, to limited regulation of low volume household use. The issue is how to improve, rather than replace that set of training and licensing requirements.

8.1 Fee-for-reward users

Licensing is one mechanism used to ensure competency, which assists regulators in monitoring and traceback in cases of adverse events and enforcement activities. It also provides assurance to consumers that the service will be provided by competent operators.

Under the current system, licences are regulated and administered differently in each jurisdiction by the relevant state and territory government departments. Licensing requirements are aligned with a layered set of training requirements. Fee structures for the administration of licences vary in each jurisdiction, but application and renewal fees are a relatively small source of revenue for those government agencies.

There are some key differences across the jurisdictions in terms of which activities require a licence. For example, ground sprayers in NSW, as well as businesses in amenity horticulture do not currently require a licence. However, this could potentially change if licensing standards and requirements are harmonised on a national level, in which case the licence requirement would be new for these users.

Currently, the ACT has no licensing requirements, but other jurisdictions have similarities in terms of licensing requirements for ground spraying, aerial spray activities and the possession and use of various agvet chemicals. Some jurisdictions also require businesses and technicians to hold licences to operate in the pest management field.

This section addresses the need for a national licensing scheme, and activities that might include?

Adoption of *Option 2* would be potentially complementary to adoption of *Option 1* and would make sense only if *Option 1* was adopted as well.

Fee-for-reward users Option 1 Develop and adopt a national licensing scheme for all fee-for-reward users of agvet chemicals which could embrace dual business/operator and/or business only licensing

Competency criteria could be established for a single national licensing scheme for each occupational category. Either the business and operator, or the business only (as was recommended for aerial operators by the PSIC Aerial Spraying Working Group) could be licensed, depending on what is considered appropriate for that particular professional category. Adopting this option would satisfy COAG Early Harvest Reform 13 — to adopt a national scheme for the aerial application of agricultural chemicals. Under this option, businesses and, at a minimum, supervisory staff involved in amenity horticulture would also be licensed. The administrative cost to issue a license and the cost of operating a national licensing scheme would be covered by licence fees.

Benefits and costs

For all affected businesses and individuals, the national license would replace existing state and territory licenses, which would reduce the administrative burden and ensure consistency through national standards. This would also improve the efficiency of monitoring, traceback and enforcement. This would be particularly beneficial for businesses that operate across borders, as the direct cost of licences would be reduced.

The specific competency requirements for national licences for each occupational group has not been fully assessed (the exception being aerial agriculture), nor has the operation of a national scheme been costed. It is, therefore, not possible to estimate the license fees that would need to

apply and as such, the direct impacts on businesses costs are undefined at this stage. However there would be additional direct costs to some operators.

Fee-for-reward users Option 2 Recognise an approved accreditation of the business to meet licensing requirements

Currently, industry accreditation programs exist to train and certify users in accordance with the various standards required in the jurisdictions in which they operate. Some of these industry accreditation programs work to the standards within the Australian Quality Training Framework (AQTF). The competency levels and training programs are used by the APVMA to ensure that regulatory outcomes that require training and/or licensing are able to be appropriately implemented and enforced at state and territory level. Under this option, all industry accreditation program standards would be harmonised, and, pending assessment, would be accepted as qualification for a licence.

Benefits and costs

Where opportunities for co-regulation exist, there is potential to avoid duplicate efforts by participants in the accreditation scheme and the regulators, noting that some administrative costs would be involved for both parties.

Fee-for-reward users Option 3 Maintain the status quo — variable arrangements between jurisdictions

This option would not meet the conditions of the COAG directive to develop a single national framework or satisfy COAG Early Harvest Reform 13.

Consultation comments sought

Comments are sought on:

- the numbers of contractors likely to be affected by extending licensing requirements to all fee for reward applicators in all states and territories;
- competency standards and numbers of workers in amenity horticulture.

8.2 Farmers and other occupational users

The suggestions below are intended to apply to 'commercial users'— where a 'commercial user' is a person who uses an agvet chemical as part of his or her employment (veterinarians excepted since their activities are separately regulated), business or occupation. This would include all agricultural, pastoral, and institutional uses (for example local council, government agency, statutory authority or as part of a business). The requirements discussed here would exclude personal uses by householders of items such as home and garden products and personal pesticides offered for retail sale in hardware shops, nurseries and supermarkets.

A distinction is made here between fee for reward users and other commercial users. In essence that distinction relies in part on a model of an individual farmer as the user. That may not always be reasonable in terms of the degree of risk and effectiveness of risk management. Some farm businesses and non-farm institutional users have multiple partners or employees involved in relatively large scale use of agvet chemicals. There may be a case for considering those organisations in the same way that fee for reward users are considered. That possibility is addressed in *Option 2*.

Farmers and other occupational users Option 1 Establish a nationally agreed power to set competency requirements for users, with those requirements to be based on risk and to be consistent with the levels assumed in the assessment and registration process

Under this option, a common approach would be taken to user competency requirements across states and territories. Any requirements set would need to be risk related. In that context, the requirements would need to be coordinated with those for access to high risk chemicals (section 5.2.3). Whether a base level of competency would be set under this option, and if it was, at what level it would be set would be a matter for further consultation.

Benefits and costs

Community and chemical industry stakeholders expect t chemical users to be competent to apply chemicals (Landos 2010, CropLife Australia 2010, for example). The GRDC (2010) and South Australian Research and Development Institute (2010) refer to substantive research demonstrating benefits from training through improvements in knowledge and performance in using chemicals appropriately. A number of stakeholders suggest taking training requirements one step further by restricting access to chemicals to qualified users (see, for example, Australian Pork Limited 2010, Forest Industries Association of Tasmania 2010, Australian Olive Association 2010, Landos 2010). Most of those who suggested accreditation for access suggest that the level of training should be commensurate with the risk (for example, Australian Groundsprayers Association).

The APVMA, in registering products and approving label directions assumes that users have the skill to follow label instructions. The formal training level at which users are judged competent to use chemicals independently is AQF level 3 units of competency. Current requirements for landowners (farmers) vary from nothing to requiring a permit, with underlying training requirements for access to some products. There are two overlapping issues here. The first concerns the actual competence and practice of agvet chemical users. The second concerns assurance of other members of the community, as consumers of food and as neighbours for example, of that competence. Establishing a nationally consistent set of competency levels would contribute to resolutions of both of these issues.

Adoption of a national base level of competency would impose costs on some users (mainly in the form of training fees, costs of the trainees' time and travel)[20]. It would be important here that increasing the regulatory burden on compliant operators was not a used as a primary way to change the behaviour of a small proportion of non compliant users. In this context the Australian Dairy Industry Council and Dairy Australia (2010) argues that mandatory training is a regulatory cost and should be used to fill gaps only. To maximise the net pay off from training requirements, levels of competence required would need to be related to risk. It would also be important to consider alternative ways of delivering training (such as e-learning options) for those users who could not easily attend conventional training courses. In a similar vein, consideration would need to be given to alternative ways of demonstrating competence, additional to attendance at training courses. Farmer and farm worker training in agvet chemical use arose through agricultural industry moves to improve user competence and provide assurance of that competence to customers. Training requirements exist for QA schemes. Consequently, a large number of farmers and farm workers are trained. The number of users who are currently untrained is unclear though. The Department of Environment and Climate Change NSW (2009) assumed that extending a training requirement to all occupational users would require an additional 5 per cent of total users to be trained. On the other hand, there are some indications that as few as 50 per cent of farmers are trained in some states.

[20] Current indicative costs for a 2 day course are around $350. NSW assumed an average 2 day course cost of $316 with opportunity costs of $299 at average weekly earnings, giving an estimate of total cost of $615 not accounting for any travel costs.

Farmers and other occupational users Option 2 Adopt a national licensing scheme for 'commercial users' of agvet chemicals which could embrace dual business/operator and/or business only licensing

This option would be designed to include more complex farm and other businesses and institutional users, but exclude individual farmers and other individual users whose activities would be included under the conditions of *Option 1*.

Benefits and costs

As is the case for fee for reward users, the definition of the boundaries of 'commercial user' and the details of competency requirements for national licenses have not yet been investigated (the exception being aerial agriculture), nor has the operation of a national scheme been costed. At this stage it is not possible to estimate the license fees or the direct impacts on businesses costs.

It is clear, however, that development of this option would involve an additional licensing requirement for organisations which are currently not required to be licensed. Against those costs, adoption of this option could have effectiveness (risk reduction) benefits in recognising that the operation of some farm businesses and institutional users of agvet chemicals involved similar circumstances and risks to those experienced by fee for reward users.

Farmers and other occupational users Option 3 Maintain the status quo — different requirements in each jurisdiction

This option would not meet the conditions of the COAG directive.

Consultation comments sought

Comments are sought on the:

- appropriateness of setting a base level of competency;
- most appropriate base level of competency;
- likely costs of additional training, including costs of time and travel
- appropriateness and likely impact on businesses of adoption of a licensing requirement as suggested under *Option 2*.

8.3 Sales personnel and advisors

Recommendations for off-label use by sales personnel or advisors can pla*y an imp*ortant part in the effectiveness and safety of use of agricultural chemicals (as is discussed in 6.3.3, the actions of veterinarians are regulated separately). All control of use legislation places the onus for proper use on the chemical user. In Victoria, where a person who provides advice to another that results in improper use, that person is also in breach of the Victorian control of use legislation. For on farm use that is either the farmer or contract applicator. Anecdotally, a number of contractors have complained to their industry associations that some advisors are recommending off-label mixes of chemicals, higher rates, or use on crops that are not on the label in jurisdictions where these actions are not legitimate. Where the advisor refuses to amend a recommendation, the contractors may then be placed in the position of having to choose to falsify their application records or refuse work.

There is no formal training or licensing requirement for an advisor or reseller to make recommendations to a chemical. However, it is recognised that some may have some knowledge depending on the subjects undertaken as part of a tertiary qualification. With regard to sales personnel, there is a large scale industry program directed at ensuring that sales staff are trained and act responsibly, in the form of Agsafe.

Options 1 and *2* are potentially complementary.

Sales personnel and advisors Option 1 Develop a system to ensure that advisors and sales personnel are competent and make appropriate and legal recommendations

This option would involve a general competency requirement for sales personnel and advisors. The nature and level of competency required would need to be the topic of further consultation.

Benefits and costs

To the extent that users rely on sellers and advisors, a program to ensure that this group has training appropriate to the products they sell or advise on would provide benefits in risk management. As is noted above, there is currently no regulatory training or accreditation requirement for either sales personnel or advisors. While members of either group may offer advice, the legal liability for a product use decision is the users.

On the other hand a requirement that all personnel in a large sales force be trained could involve a substantial cost. Similarly, requiring that there be a minimum standard of professional development for advisors also involves a cost. The size of the latter cost is unclear however, as some advisors may already have appropriate training. There is potential overlap between these considerations and the proposal for accrediting agronomists, *Option 4* in section 6.2. However, the primary issue concerns acceptance or otherwise of major the existing scheme, Agsafe.

Sales personnel and advisors Option 3 recognise an industry developed scheme that ensures that trains and accredits advisors and sales persons to ensure they are competent

Adoption of this option would allow acceptance of industry schemes, provided that they were assessed as being effective. Given that a training requirement was adopted (*Option 1*), there would need to be backup arrangements for those sectors or individuals who were not participants in the scheme(s).

Benefits and costs

Recognition of existing or developing industry systems for ensuring competency would appear to be a lower total cost way of achieving a competent result. There would be additional costs to industry participants only if regulators chose a higher competency level than that currently used in the scheme.

Sales personnel and advisors Option 2 Maintain the status quo

Agsafe would continue to have substantial coverage in training or accreditation requirements for sales personnel or advisors. The might, however, be ongoing risks from some advice. With the acceptance of shared responsibility implied in control of use *Option 1*, fewer problems may occur.

Consultation comments sought

Comment is sought from:

- users about the extent of reliance on advice, and quality of that advice; and
- sellers and advisors on the likely costs of training.

9 CONSULTATION

Consultation with industry, community and government stakeholders on the specific options presented in this statement is scheduled to commence in February 2011. A consultation strategy is being developed to allow PSIC members to engage with other relevant state, territory and Australian Government agencies and with key industry and community stakeholders. Those consultations will afford PSIC and other government members the opportunity to have an informed policy discussion, in consideration of stakeholder views, and will provide the basis for the development of a preferred option for the new regulatory model.

The forthcoming consultation represents the fourth stage of an ongoing examination of regulatory reform options. The first stage involved the preparation and release for comment of a discussion paper (Rose and Sheppard 2009) by consultants engaged to support PSIC's efforts. The consultants were informed by a first round of meetings with some key stakeholders in August and September 2009, and a wide range of material available from previous studies, including those by the Productivity Commission, ANAO and Allen Consulting Group (2002).

The consultants held a second round of discussions with stakeholders in early December 2009. In response to a request for comment on the discussion paper, a total of 94 formal submissions were received from stakeholders. The early consultations were use to inform PSIC's development of the National Policy Framework for the Assessment, Registration and Control of Use of Agvet Chemicals — which was endorsed by COAG on 16 August 2010. Most of the material in stakeholder submissions dealt with issues of operational detail. That material has already provided key input to the process of designing the set of options presented in this statement.

In order to further inform the policy process, PSIC established four working groups with a brief to develop policy options and make observations about the advantages and disadvantages of those options in respect to:

- corporate governance and policy setting;
- assessment and registration;
- control of use; and
- training and licensing.

A number of industry and community stakeholders, along with regulatory agencies, participated in those groups. The findings of the working groups, along with material in submissions received in response to the discussion paper, made an important contribution to the final set of options presented in this statement.

With the release of the consultation RIS, it is planned that a second round of discussions with stakeholders will be held in March 2011. These meetings will be held in all of the states and territories and provide opportunity to engage in broader discussion of the issues identified in the consultation RIS.

Invitations will be sent to stakeholders who have expressed interest in this work. Others interested in participating should contact the Product Safety and Integrity Committee secretariat via email at: PSIC@daff.gov.au.

Further, all stakeholders will have an opportunity to submit written comments on the content of the consultation RIS. A summary of specific information and feedback sought from stakeholders in this RIS is contained in Table 1 Specific feedback/data sought from stakeholders . Both the community consultations and the written comments will be used when formulating the final advice to COAG on the structure of the new national framework for the regulation of agricultural and veterinary chemicals.

Table 1 Specific feedback/data sought from stakeholders

Issue	Information sought	Page
Governance	Comment is sought on which combination of the governance options outlined above (or any not mentioned above), and in the case of *Option 2*, which mode of service delivery: regional branches; outsourcing to state and territory governments, or open tender, would be: • most likely to deliver the timely and best quality decisions; • most effective in ensuring that knowledge is applied to provide guidance for industry and the broader community; • most likely to enhance compliance, either by making it easier for those regulated to comply by removing barriers to compliance or by deterring non-compliance through more effective enforcement and sanctions; and • most likely to assist regulators and industry in making better risk management decisions. In the case of *Option 1* (harmonised state and territory law) comment is also sought on how best to avoid diversion of regulatory arrangements between jurisdictions.	11
Assessment and use information	What are the costs of redesigning a label? What would be the likely cost to registrants of complying with *Option 2* (all labels placed on a single website)?	23
Facilitation of registration of low risk products	What timing and fee concession incentives would be needed to interest applicants in the lower risk substitution program? What are likely products or product groupings for the second element of the program (expedited reviews and use of overseas regulatory findings)?	24
Access to high risk chemicals	Estimates of costs of specialist training courses, or alternative ways of establishing competency for current RCPs, such as pre-emergence termiticides and vertebrate poisons. What are the costs of record keeping?	30
Improving legal interaction with the APVMA	Feedback on a practical solution to the appeal process for APVMA recall and enforcement actions that would: • be effective in protecting human life and the environment; • balance safety and environmental standards with procedural fairness; and • provide for an agile and responsive regulator.	31
General access categories and permits	Feedback on: • aspects of minor use permits most in need of improvement; • the most effective ways to enhance the timeliness and efficiency of the minor use permit system.	35

Permissible uses for crops	Feedback is specifically sought on practical, cost and benefit aspects of *Options 1-4*, particularly:
	• in regard to adoption of a more restrictive approach than currently applies in some states and territories, as outlined in *Option 1,* the extent of potential*:*
	  ○ user productivity, or opportunity, costs;
	  ○ decrease in risk;
	  ○ any likely impact on incentives to register more uses on label;
	• with regard to the adoption of a less restrictive approach, such as *Option 2* or *3*;
	  ○ any practical issues in establishing an appropriate list (*Option 2*) or appropriate bounds (*Option 3*);
	  ○ potential user productivity benefits;
	  ○ potential increase in risk;
	  ○ any likely impact on incentives to register more uses on label;
	  ○ the level of interest from agronomists in such a scheme such as that outlined in *Option 4*.
		41

Management of the chemical portfolio	Comment is sought on: • the likely costs of data provision and other associated costs related to the review process; • the level of review costs that would discourage registrants from persisting with registration of different categories of products; • the opportunities for use of overseas data, assessments and reviews, and any of the issues outlined as 'key areas for further design' under *Option 1*.	46
A national system of use controls — regulatory powers	Feedback on desirable inclusions or limits to regulatory powers. Comment on the opportunities/limits and benefits/costs to industry participants of co-regulatory arrangements and the likely costs of MRL breach reporting responsibilities.	21
A national system of use controls — record keeping	Comments are sought from businesses that would be affected by an additional record keeping requirement and the cost of keeping records.	52
Training and licensing — fee-for-reward users	Estimates of the numbers of contractors likely to be affected by extending licensing requirements to all fee-for-reward applicators in all states and territories. What are the current competency standards and numbers of workers in amenity horticulture?	54
Training and	Comments are sought on the:	57

licensing — farmers and other occupational users	• appropriateness of setting a base level of competency; • most appropriate base level of competency; • likely costs of additional training, including costs of time and travel • appropriateness and likely impact on businesses of adoption of a licensing requirement as suggested under *Option 2*.	
Training and licensing — sales personnel and advisors	Comment is sought from: • users about the extent of reliance on advice, and quality of that advice: and • sellers and advisors on the likely costs of training.	58

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ANNEX A COAG PRINCIPLES OF BEST PRACTICE REGULATION

COAG has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:

1. establishing a case for action before addressing a problem;

2. a range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;

3. adopting the option that generates the greatest net benefit for the community;

4. in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:
    a. the benefits of the restrictions to the community as a whole outweigh the costs, and
    b. the objectives of the regulation can only be achieved by restricting competition;

5. providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;

6. ensuring that regulation remains relevant and effective over time;

7. consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and

8. government action should be effective and proportionate to the issue being addressed.