



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

APVMA response to the discussion
paper *“A National Scheme for
Assessment, Registration and Control
of Use of Agricultural and Veterinary
Chemicals”*

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Executive summary

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government Statutory Authority responsible for regulating the supply of agricultural and veterinary (agvet) chemicals to the Australian marketplace. The APVMA also administers the National Registration Scheme (NRS), which sets out the regulatory framework for the management of agvet chemicals in Australia. The APVMA works in partnership with state and territory governments and with the active involvement of other Australian Government departments and agencies.

In its role in the NRS the APVMA has regulated the manufacture and supply of agvet chemical products since 1994. During that time the APVMA has observed the strengths, limitations and opportunities of the current regulatory framework. It is our view that there are areas of the modern regulatory framework, particularly in relation to the assessment and registration of agvet chemical products where improvements need to be made.

The APVMA's response to the discussion paper raises a number of issues many of which pose threshold questions for the regulatory framework. The requirement for a re-registration program and time-limited approvals for labels is one example. The APVMA considers that these sort of improvements need to be made to ensure that agvet chemical products meet current standards in terms of protection of public health, worker safety and the environment.

The APVMA also considers that there are a number of improvements that can be made that would improve the efficiency of the registration process. In this submission we point out that the APVMA is required to conduct complex technical assessments on applications for registration to current regulatory standards but have to do so in a timeframe that reflects the standard of fifteen years ago. The APVMA considers that there is considerable scope for improvement in these areas.

The APVMA's position on the control-of-use framework is that the use of a chemical product needs to be underpinned by the risk assessment that allows that product onto the market. The APVMA accepts however that there are instances where legalised off-label use can occur that do not pose a risk to human health or the environment.

This submission deals with the question of confidentiality of research permits where those permits have the capacity to affect human health or the environment. The APVMA is aware of the need for the regulatory system to allow for appropriate research and development of chemical products that are necessary for agriculture and the balance that needs to be struck with the community's right to know. The APVMA considers that this is a matter that the framework needs to address.

In terms of the underpinning principles of the regulatory framework the APVMA considers that the principles established in the preamble to the Agvet Code remain relevant today. Those principles are that the regulatory framework needs to protect the health and safety of human beings, animals and the environment and the use of chemical products at the present time should not impair the prospects of future generations. The APVMA considers that the suggestions for improvement that are made in this submission are necessary for the optimal attainment of those principles. They also reflect COAG's requirement that regulation needs to be both efficient and effective.

1. INTRODUCTION

The National Registration Scheme was established in 1995. The key piece of legislation that underpins the national registration of agvet chemicals is the Agvet Code which is scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*. The Agvet Code was written in 1994 and reflects the prevailing regulatory philosophy at that time. The PIMC review allows the first real opportunity for a comprehensive re-examination of the National Registration Scheme.

The APVMA notes that there have been significant changes in the global agricultural and veterinary chemical market since 1994, particularly in the area of pesticides. The APVMA's current estimate is that in excess of 90% of pesticide products that are used in Australia now originate from an overseas manufacturer in some way, either through the manufacture of the active constituent or the formulation of the chemical product. The animal health industry has also seen a consolidation of manufacturers over this time.

The Australian agvet chemical market continues to be relatively small on a world scale. It comprises less than 2% of the global distribution of agvet chemicals. This has implications for the availability of agvet chemicals in general and domestic research and development into them. The regulatory system provides that assessments are conducted to OECD standards comparable to those of other first world nations in terms of safety to consumers and the environment.¹

The APVMA has, in recent years, given considerable thought to the regulatory framework. In 2002 it commissioned the Allen Consulting Group to report on positioning and reform activities that may be required to meet future needs and challenges. The report, "*The National Risk Management System of Agvet Chemicals – Positioning for the Future*" ('the Allen Report')² was delivered in September 2002.

¹ The international competitiveness of the Australian regulatory system for veterinary chemicals has recently been confirmed by a qualitative survey commissioned by the International Federation for Animal Health and conducted by Business Decisions Limited. Business Decisions Limited's report, '*Benchmarking the Competitiveness of the Australian Animal Health Industry (March 2007)*', found that chemical industry respondents perceived that the size of the Australian market is the biggest obstacle to innovation rather than the existing regulatory framework. This was in contrast to all other regions covered by the research where respondents identified the regulatory framework as being the biggest obstacle to innovation.

² Allen Consulting Group, '*A National Risk Management System for Agvet Chemicals—Positioning for the Future*', *A strategic review for the National Registration Authority for Agricultural and Veterinary Chemicals*, 2002. (available at apvma.gov.au)

At around the same time the the Australian Academy of Technological Sciences and Engineering (AATSE) released the report, *Pesticide Use In Australia* (Radcliffe Report), authored by Dr John Radcliffe³

The APVMA set the Allen and Radcliffe reports in the context of the then Agriculture and Resource Management Council of Australia and New Zealand's (ARMCANZ) National Strategy for Agricultural and Veterinary Chemicals in the report *Australian Agricultural and Veterinary Chemicals Management System, A Report to Government by the APVMA on recent reviews of the system*—June 2003.⁴

More recently the APVMA has been involved in submissions to a number of Productivity Commission reviews with the most notable being the Research Report into Chemicals and Plastics Regulation which was published in July 2008.⁵ Much of the material in our submission to the Productivity Commission is highly relevant to the current review. In particular the APVMA considers that the opportunity areas identified in our submission are matters that should be taken into account in the review of the current national regulatory framework.⁶

A copy of our submission to the Productivity Commission is attached and is otherwise available from the Productivity Commission's website. That submission should be read in conjunction with this submission.

The Allen Report identified a number of key drivers of future regulation in the agvet chemical area. They include:

- community attitudes to the use of chemicals;
- technological advances that facilitate the development of safer chemistries and the impact of genetically modified crops on chemical usage;
- developments in the chemical industry, particularly the consolidation of multi-national companies, with the potential to impact on access to the latest agvet chemicals in Australia;

³ J C Radcliffe, *Pesticide Use in Australia*, Australian Academy of Technological Sciences and Engineering, ANL publishing, 2002. (available at <http://www.atse.org.au/index.php?sectionid=199>)

⁴ The report is available from the APVMA website at <http://www.apvma.gov.au/publications/downloads/cox.pdf>.

⁵ The report is available at <http://www.pc.gov.au/projects/study/chemicalsandplastics/docs/finalreport>

⁶ A copy of the APVMA submissions can be found at:

APVMA Primary Submission (submission 59) -
http://www.pc.gov.au/_data/assets/pdf_file/0005/74849/sub059.pdf

APVMA supplementary submission (submission 65) -
http://www.pc.gov.au/_data/assets/pdf_file/0008/77678/sub065.pdf

APVMA response to draft report (submission DR105) -
http://www.pc.gov.au/_data/assets/pdf_file/0008/79829/subdr105.pdf

- chemical usage trends and needs in the agricultural sector;
- trade requirements and the need for international confidence particularly in agricultural exports; and
- the ongoing need for reform to ensure that regulation is optimal for Australia's needs.

The APVMA considers that these drivers remain highly relevant to the national regulatory framework today.

Our submission builds on the information that the APVMA provided to the Product Safety and Integrity Committee Secretariat (PSIC) and the consultants during the preparation of the Discussion Paper.

PSIC established a number of working groups to assist it in gathering input as part of the review. The APVMA chaired the working group on registration and assessment and the outcomes and recommendations of that working group are incorporated into our submission.

The Productivity Commission recommended that the APVMA should have a statutory obligation to ensure that the costs of chemical assessments are commensurate with the risks of the chemicals concerned. COAG agreed to the imposition of that statutory obligation. Our detailed response to the recommendation as made by the Productivity Commission in relation to that recommendation is at Attachment A.

Our response to the Discussion Paper deals with three areas. They are:

- Registration and Assessment;
- Low-Risk Products; and
- Control-of use.

2. REGISTRATION AND ASSESSMENT

The APVMA accepts that there are issues with the current framework as far as registration and assessment are concerned. One such issue is that the definition of “agricultural chemical product” in the Agvet Code is quite wide and results in the APVMA having regulatory responsibility for things such as biocides, pool and spa sanitisers, timber preservatives, anti fouling paints and certain surface disinfectants. The same observation applies to the definition of “veterinary chemical product”. The NRS gives the APVMA regulatory responsibility across a broad range of products that may not traditionally be viewed as pesticides or veterinary medicines. The APVMA notes that this issue is under consideration as part of the COAG Early Harvest Reforms whereby consideration is being given to excluding certain product classes from the capture of the Agvet Code.

Our comments on some specific issues relevant to registration and assessment are below.

2.1 Risk-Based Assessment and the Precautionary Principle

The Agvet Code establishes a risk-based assessment for agricultural and veterinary chemicals that is underpinned by known scientific knowledge. The current statutory test that the APVMA must apply when deciding whether or not to register an agricultural or veterinary product is set out in s.14 of the Agvet Code. It requires the APVMA to undertake an assessment in terms of health, safety, efficacy and international trade and be satisfied that any risks can be appropriately managed before the product can be registered.

The APVMA notes that there is a growing community debate as to whether Australia should regulate agricultural and veterinary chemicals based on the precautionary principle. The APVMA expects that the public consultation phase of the review will attract a degree of comment about the possible adoption of the precautionary principle. The decision on whether to adopt the precautionary principle is a policy matter for government and is not one on which the APVMA intends to express a view.

In applying the current statutory test the APVMA exercises caution where scientific opinion is divided or scientific information is incomplete⁷. If that statutory test remains then the APVMA would recommend the way the APVMA applies the test, ie exercising caution where scientific opinion is divided or scientific information is incomplete, be formally incorporated into the Agvet Code.

The Registration and Assessment Working Group considered that the current risk-based assessment approach provided the necessary level of protection of public and environmental health. The Working Group considered that the framework should provide a mechanism for clear direction on important policy issues that can arise in applying risk-based assessment methodologies. This aspect is addressed later in our submission.

2.2 Re-Registration and Re-Approval

Unlike some other regulatory systems, such as the US and the EU, the Australian regulatory system does not have a 're-registration' component. In the Australian regulatory system once a product is registered it remains registered as long as the annual renewal fee is paid or the APVMA takes positive regulatory action to cancel the registration. Labels remain approved as long as the product remains registered. In the case of active constituents there is no requirement for renewal of their approval. Active constituents remain approved unless the approval holder requests cancellation of the approval or the APVMA takes positive regulatory action to cancel it.

Under the current framework there is no requirement on a registrant to 'defend' the ongoing registration of their product or the approval of their active constituent after a certain period of time. The APVMA considers this to be a weakness in the current regulatory framework especially when it is considered that the bulk of products that are currently registered and the active constituents they contain were inherited from the individual registration systems that operated in each State and Territory up until 1995. Approximately 4,000 chemical products were transitioned into the NRS in 1995.

⁷ Friends of Hinchinbrook Society Inc v Minister for the Environment (1997) 142 ALR 632

The APVMA has experienced a number of occasions where its authorisation of a product which met the scientific standards in terms of the data and assessment methodologies that existed at the time it was registered, no longer meets contemporary standards. This can be because the quality of the original data that underpins the continued authorisation does not meet contemporary standards. However it can also be because although the original data remains adequate, standards have changed since the original authorisation and the data needs to be tested against those new standards.

Under the existing arrangements there is no clear legislative path that allows the APVMA to require that underpinning scientific knowledge to be brought in line with or reviewed for compliance with contemporary standards. The APVMA first needs some indication of likely undue harm that would warrant taking regulatory action against the product.

The APVMA considers that it should not be the role of the regulator to monitor the alignment of the scientific justification underpinning such registrations and approvals with contemporary standards. Rather, it should be the responsibility of each individual product registrant to ensure the ongoing safety of their products and adequacy of their labels in-line with contemporary scientific thinking and evidence. The same observation applies to active constituent approval holders. The APVMA considers that the use of its chemical review powers in Division 4 of Part 2 of the Agvet Code to update the relevant scientific knowledge to contemporary standards is an inappropriate exercise of those regulatory powers. Those powers are designed for circumstances where there is a genuine trigger for regulatory intervention, such as adverse experience reports or advances in scientific learning that illuminate or suggest previously unknown risks of undue consequences.

The APVMA supports the introduction of a re-registration and re-approval requirement in the Agvet Code.

2.3 Statutory Timeframes

The APVMA has historically struggled with timeframe performance with those products that require some form of technical assessment in the “mid range”. The timeframe for these applications varies between five and eight months. The APVMA continues to experience difficulty in completing the assessment for this class of applications within the statutory timeframes. The difficulties arise in part from the wide range of different proposals that these applications cover and the consequent variation in data required and the issues that arise in the assessment of the data.

It has to be pointed out that the complexities of scientific assessment for pesticides and veterinary medicines have increased since 1994. The scientific and regulatory environment is not the same as it was. Unfortunately the timeframes under which these complex assessments need to be taken still are.

The APVMA estimates that the early disclosure requirements and data protection protection, which were introduced in 2005, together with the requirement to approve final printed labels, introduced in 2003, have increased the administrative burden of processing applications by approximately 30%. There were no timeframe adjustments made when these requirements were introduced.

The APVMA considers that it is inefficient and inappropriate for the regulatory framework to expect the APVMA to conduct registration assessments to contemporary standards but to be constrained by a timeframe that represents a standard that was set 15 years ago. Equally, the APVMA considers that a regulatory framework that creates expectations for applicants of an indicative time to market, but which cannot be met, is inefficient and leads to an ineffective system.

The APVMA notes that some other regulators, most notably the EU and the US, have an agreed timeframe system where applicants and the regulator can, for non-administrative type applications, agree on a negotiated timeframe for completion of the assessment of data. The APVMA also notes however that those systems are complemented by a data close-off in that data requirements are agreed before the application is made. Once the applicant submits all the data it considers meets the requirements it is not entitled to submit any further data to the regulator for assessment. The regulator then makes its decision on the agreed data before it within the agreed timeframe and there is no further contact between the regulator and the applicant.

Unlike the EU and US systems the Agvet Code confers the specific power on an applicant to provide additional data at any time during the period when an application is under assessment by the APVMA. However it does not contain any corresponding provision for the extension of statutory timeframe or payment of additional fees for the additional data assessment.

The APVMA has attempted to move to a flexible approach, reflective of the EU and US systems, in that it will adopt a project management approach to applications. The agreed target date for the completion of such applications centres on the registrant's anticipated date of release of the product to the market, with key milestones being agreed on data submission to ensure the assessment is finalised by the agreed date. This system is artificial in that the key performance indicator set by the regulatory framework, namely the statutory timeframe, is rendered largely irrelevant by the agreement made between the APVMA and the applicant.

The APVMA supports the introduction into the Agvet Code of an agreed timeframe system for applications that involve data assessment.

2.4 Data Cut-Off for Registration and Chemical Review

The Agvet Code confers a specific power in s.11(3) for an applicant to provide additional information at any time during the evaluation process of a registration application. Under the current legislative model the APVMA must examine that additional data. Our experience to date has been that this can result in great delays in finalising the assessment, particularly when the data is provided when the assessment is complete and the APVMA has indicated that it intends to make its regulatory decision.

The concept of data cut-off is a fundamental shift from the current assessment framework. The term “cut-off” refers to the regulator and the applicant agreeing that as part of the application process, a point is reached where the applicant agrees that it has submitted to the regulator all the data that it has planned to submit. The regulator then conducts its assessment on that data and the applicant is not entitled to submit any further data.

Although there is no corresponding legislative power in relation to chemical review, our experience has been that the situation is the same as for registration. When a chemical is under review it is open to not only the registrant but also user-groups, to provide additional data at any time to the APVMA during the review process. It can be very difficult to bring chemical reviews to finality. The ANAO made this observation in its recent audit of the APVMA and recommended that the review process be re-examined (Recommendation 6)⁸. The APVMA has halted its consideration of that recommendation pending the outcomes of the review of the national framework.

A current example of the situation with chemical review is chlorpyrifos, which was placed under review in December 1996. Although the approval of the active constituent was affirmed in October 2000, the APVMA has not been able to finalise the review of the registration of the products and the label approvals for two reasons. Firstly, the APVMA has been awaiting residue data to be generated and secondly, in recent times, new information has come to light about a potential new environmental toxicological endpoint. Although there are some matters of which the APVMA can be satisfied in relation to the registration and label approval it cannot ignore the new scientific information and is unable to finalise the review in the absence of necessary data.

The APVMA considers that the regulatory framework should contain a ‘shut the gate’ provision on data assessment for both registration applications and chemical reviews to allow data assessment to be finalised in a timely way.

⁸A copy of the ANAO Audit Report can be found at:
http://www.apvma.gov.au/about/reporting/docs/anao_audit_report_2006.pdf

2.5 Conditions of Authorisation to Market

As noted above the Agvet Code in its current form reflects the regulatory philosophy that prevailed in 1994. The Agvet Code contains a number of provisions that are aimed at ensuring good product stewardship by registrants. The obligation on a registrant in s.161 to provide adverse information about their product after it is registered is one example. The regulatory framework seeks to achieve provision of such information by the imposition of an offence on the registrant for non-compliance with the obligation. The APVMA considers that a framework that attempts to achieve positive product stewardship outcomes for chemical products through negative sanction-based measures is ineffective.

The APVMA considers that positive product stewardship outcomes that are achieved by an obligation on the registrant should be attached as a condition of registration of the product. An example of such an obligation is the Periodic Safety Update Reports that registrants of veterinary medicines are required to provide to the European Medicines Evaluation Agency as part of their ongoing registration of a new veterinary medicine.

The APVMA considers there are two broad areas where positive product stewardship outcomes should be applied as conditions of registration. They are ensuring ongoing product quality in accordance with the registration specifications and the provision of updated safety information to the regulator.

2.6 Product Issues and Policy Guidance

The APVMA has experienced a number of situations in which a single application for registration of a product has raised a wider policy issue. One example is pesticides for use in food crops that are bio-accumulative in humans but on current scientific evidence do not cause harm to humans. Under the current framework the APVMA has to assess such applications based on known science. There is however a wider policy question for government as to whether the community should be exposed to new sources of bio-accumulative pesticides irrespective of the current level of toxicological knowledge. This is not a question the APVMA can answer and is something that the APVMA considers should be determined by government.

The APVMA considers that the absence in the regulatory framework of a mechanism where such determinations can be made is a major weakness. The regulatory framework needs such a mechanism in order to provide regulatory certainty to the APVMA, the chemical industry and transparency to the community.

The APVMA should be empowered to refuse an application for a product without any need for scientific assessment where government has made a determination that a product with such characteristics (eg bio-accumulation) should not be registered. The APVMA considers that chemical companies are entitled to know those classes of products or compounds that will not be accepted so that they can plan their research and development investment decisions accordingly. Equally, the community is entitled to know what the risk appetite of the regulatory framework is for such classes of products.

We consider that the absence of such a mechanism is a weakness in the current system because it results in the APVMA having to deal with what is a wider policy issue in the context of a single application. Another example is the use of antibiotics in food-producing animals where those antibiotics are “last line” antibiotics in human medicine but there are other antibiotics available to treat the disease in the animal. Presently the APVMA has to conduct an assessment of, and the applicant has to generate, data on antibiotic resistance of each compound and use pattern. This is costly and leads to uncertainty for the regulator, the chemical industry and the community. The ability to seek formal direction on whether the regulatory framework should entertain applications for registration of such compounds would remove that uncertainty.

The APVMA considers that the regulatory framework should contain a formal mechanism to allow for policy determinations on classes of products.

2.7 Compliance Powers

As noted above, the Agvet Code reflects the prevailing regulatory philosophy that existed in 1994. The APVMA considers that the current compliance powers are inadequate as they do not contain the full breadth of powers that are available to other modern Commonwealth regulators. Modern regulatory compliance frameworks contain a mix of administrative, civil and criminal enforcement tools. In general terms, the current administrative enforcement tools in the Agvet Code are less than ideal. The lack of a civil penalty regime is a major weakness.

A useful comparison is the *Water Efficiencies Labelling Standards Act 2005*. That Act establishes a cooperative scheme between the Commonwealth, the States and Territories to provide for national water efficiency labelling and standards. Part 7 of the Act sets out the offences, Part 8 deals with enforcement powers and Part 9 deals with the powers of inspectors. The Act contains a mix of administrative, civil and criminal enforcement powers. It includes a civil penalty regime for the issuing of infringement notices, the capacity to publicise offences, the ability to accept enforceable undertakings and to compel the giving of information. Whilst other regulators such as ASIC, TGA and ACCC have different specific legislative provisions they have roughly the same mix of powers.

The APVMA considers that the compliance component of our regulatory responsibilities would be more effective and efficient if the Agvet Code contained a modern combination of enforcement tools.

2.8 Total Risk

The APVMA notes the observations in the Discussion Paper on total risk. Our understanding is that the ongoing status of the APVMA's registration assessment could be informed by information that is gained about the nature and effects of the legal and illegal off-label use after the product has been registered. In many ways the total risk concept is something that the APVMA does apply in relation to chemical reviews in that, to the extent that the information is available to us, the APVMA takes into account the actual uses of the product that have occurred since the initial registration. Under the current framework the APVMA acknowledges however that the availability and quality of use information could be greatly improved.

The Discussion Paper discusses the importance of the existence of usage information when assessing total risk. Although the APVMA has a statutory function "to collect, interpret, disseminate and publish information relating to chemical products and their use" there is no national system which allows that use data to be obtained. In addition to providing a good information base as to the national position for the use of agvet chemicals in Australia, it can also be used to target particular types of issues such as antimicrobial resistance.

The APVMA considers that the national regulatory system would be greatly enhanced if there were national comprehensive data on the use of agvet chemicals.

2.9 Research Permits

The APVMA issues a range of permits to allow persons to use unregistered chemical products for the purposes of research. Many of these permits allow for research and development to be conducted in relation to new agvet chemical products as well as for academic research. The research can be carried out in a variety of situations. Some of those situations can have the potential to affect humans and or the environment. The research into whether an existing registered product would be effective in forest situations is one recent example.

The APVMA has traditionally viewed such permits as commercial in confidence because of the confidentiality provisions in the Agvet Code. The APVMA is certainly aware of the investment chemical companies make in research and development but questions whether the current framework provides sufficient transparency in a modern regulatory environment.

The APVMA believes that as part of the development of the new national framework, government should consider whether the existence of those research permits that have the potential to affect humans and or the environment should remain confidential.

3. “LOW RISK” PRODUCTS

3.1 Data Requirements

Typically products referred to as low-risk are those for which much is known about their hazards, uses and consequently risk potential⁹. In essence low-risk means that the hazards and risks are known and in the context of the proposed use they are relatively benign. Where these things are known and the regulator is already satisfied that the use of the product in the manner intended would not be likely to have an undue effect in terms of the statutory criteria, data assessment is clearly not necessary. In some cases a reduced assessment may be applicable. In this way the modular fee assessment structure established by the Regulations to the Agvet Code allows assessment effort, and commensurate costs to be aligned with risk.

Where no assessment is required the applicant is not required to provide data and the direct costs of assessment and the indirect costs of data generation to the applicant are reduced. Similarly where only limited assessment is needed the direct and indirect costs are commensurately reduced. The modular fee system allows for the alignment of assessment effort with that which is required.

3.2 The Path for Identification of Low Risk Products

As noted by COAG in its response to Recommendation 8.1 of the Productivity Commission, the quantification of risk is an assessment outcome. A product cannot be said to be low-risk until its hazards have been objectively determined and the potential sources of exposure when it is used as proposed have been identified and considered. The path for a product to be identified as low-risk therefore involves the initial demonstration of these matters against the statutory criteria. The requirements set out in MORAG provide considerable freedom for that to be achieved through either the submission of local or international data and or relevant scientific argument.

In reality a considerable amount of pragmatism is applied when considering requests for ‘low-risk’ data and assessment concessions. For example the presence of a substance in a food standard would generally be sufficient to satisfy the regulator that the substance in an agvet product would not be an undue hazard to the safety of people exposed to it or be likely to have an effect that is harmful to human beings.

⁹ Noting that Risk = Hazard X Exposure potential

The APVMA notes that some industry stakeholders have postulated that data requirements are excessive and that low-risk products need to be identified earlier. Problems often do arise where applicants assert that a product or substance is low-risk but are unable to support that assertion and address the statutory decision criteria with relevant scientific argument or other evidence. Without evidence to support such assertions it is difficult for the regulator to be satisfied of its statutory obligations.

We are aware that where registrants wish to claim low-risk concessions in the US, the USEPA requires the registrant to provide a data package to the regulator before the actual registration submission is made. The purpose of that early package is to demonstrate the low-risk characteristics of the product.

The APVMA considers that the regulatory framework should have a mechanism similar to that of the USEPA for the identification of low-risk products. The APVMA also considers that a key part of that mechanism is the option for industry to prepare a model for registration of a particular product that is proposed as “low-risk”.

4. CONTROL-OF-USE

The APVMA considers that as a national control-of-use regime underpins the assessment and authorisation process, that regime should not allow uses that have not been considered by the assessment and authorisation process where those uses have the potential to cause risk or harm. Our detailed analysis in support of this view is at Attachment B.

In addition to our submission on control-of-use, the APVMA makes the following points:

- irrespective of what the control-of-use framework might eventually be, the current system in which compliance with the label instructions is predicated on the presence of a prohibitive statement on the label (eg. Do Not ...) is the wrong philosophy for a modern control-of-use regime. The regulatory framework should promote adherence to positive instructions on labels and should not seek to achieve this solely through the imposition of prohibitions.
- the regulatory framework should contain a mechanism whereby non-legislative measures that are used in control-of-use, such as quality assurance programs, best management programs etc can be integrated with the legislative framework.
- the current regulatory framework provides that the APVMA's risk assessment must assume that users will follow the label because it is a statutory requirement. We are of course aware that off-label use for which the risks have not been assessed does occur. The APVMA considers that the hazards and risks posed by such use are undefined and unknown.

It is our understanding that some legalised off-label use regimes place the onus for risk assessment when using a product off-label on the user. We consider it would be extremely difficult for a user to comprehensively take account of all the risks, such as the overall impact on dietary exposure, and that there is greater potential for undue impacts to occur. Some such impacts may be chronic effects that may not present for several years. The key issue in this regard is that the permitted off-label usage is not just restricted to minor use situations where potential exposures could be argued to be constrained, but also to major crops where exposure potentials are significant. The key method through which risks may be identified is monitoring and as chemical detection methodologies are often chemical specific, regulators generally need to know what they are looking for in order to detect it.

The Productivity Commission recognised that some off-label use could occur without having the potential to pose risks that had not been considered and accounted for in the risk assessment and risk management process. The Commission highlighted that PSIC had already identified some off-label uses as falling into this category, including use in a crop for which the product is registered to control a pest or disease that is not listed on the approved label and use in a crop for which the product is registered at a lower rate or frequency of application.

The APVMA considers that the national control-of-use regime should not allow uses that have not been considered by the assessment and authorisation process where those uses have the potential to cause risk or harm

The APVMA supports the limited off-label use as noted by the Productivity Commission.

5. CONCLUSION

The APVMA welcomes the opportunity to comment on the Discussion Paper.

The APVMA considers that the current review of the national regulatory framework shows a number of opportunities where improvements can be made to the regulatory framework both in operational effectiveness and the setting of regulatory policy.

The APVMA has identified a number of opportunities in this submission, which it considers will augment public confidence in how the regulatory framework ensures the protection of human health, animals and the environment. We consider our recommendations in relation to those opportunities are consistent with COAG's objective that the regulatory framework be efficient and effective.

Attachment A:

Productivity Commission Chemicals and Plastics Study - Recommendation 8.1

1. General Comments

Recommendation 8.1 is that the APVMA should have a statutory obligation to ensure that the costs of chemical assessments are commensurate with the risks of the chemicals concerned. The Productivity Commission's underpinning rationale to Recommendation 8.1, is provided in Chapter 4. The relevant section of that Chapter (section 4.3, p.59) reflects on the principles established in Chapter 2 as forming the rationale for regulation and the basis for the Commission's approach to the chemicals and plastics study.

The APVMA notes that the Commission made an identical recommendation in relation to NICNAS.

Section 2.1 of the Commission's report¹ (p.14) establishes that regulation might be appropriate to address the sources of market failure associated with the supply and use of agvet chemicals (externalities, information failures etc), but only where the costs of such intervention are outweighed by the benefits and the form of regulatory intervention is the most cost-effective. The Commission defined *effectiveness* to mean how well regulation achieves an intended policy outcome (e.g. health outcomes) and *efficiency* in terms of economic efficiency - essentially how well resources are used to benefit the well being of the whole community.

On this basis the approach for the consideration of the stock of regulation established by the Commission through Chapter 2 is the economic concept of net community benefit. As the Commission noted "*stated objectives² are sometimes inconsistent with efficiency*" (p. 17) and "*there is more likely to be a net benefit if regulation is tailored to the risk posed by a chemical in a particular circumstance (its use), rather than the blunter approach of intervening whenever there is a hazard*" (p.14). The Commission also suggested that the key question for government in considering regulation is how far it should reduce risk on the basis that incremental reductions in risk may initially deliver net benefits, but that a point will eventually be reached where the costs exceed the benefits – the point where the marginal costs of taking additional action exceed the marginal benefits from a net community benefit perspective. In the Commission's view the objective of minimising risk regardless of the consideration of such costs and benefits is inappropriate as it could make the community worse off on a net basis (p.16).

¹ A copy of the Commission's report can be found at:
<http://www.pc.gov.au/projects/study/chemicalsandplastics/docs/finalreport>

² Stated in the preamble to the regulation, or by the government that formulated it.

In this regard the Commission noted that Commonwealth, state and territory governments had agreed to take account of the costs, benefits and risks when formulating regulations through the Best Practice Regulation principles. At the heart of those principles is the Regulation Impact Assessment process, which requires governments to demonstrate a need for regulatory intervention, to show that the proposed intervention would deliver a net benefit and to detail why alternatives are not appropriate. Indeed the fundamental principle of the Australian Government's principles of best practice regulation is that regulation has to be "*effective* in addressing an identified problem and *efficient* in terms of maximising benefits to the community, taking account of the costs"³. The APVMA considers that the COAG response to Recommendation 8.1 reflects that core principle in its second paragraph.

The Commission's underpinning rationale leading to Recommendations 4.1 and 8.1 in terms of effectiveness and economic efficiency is reflected in the text leading to those recommendations. Our understanding of the preceding text to Recommendation 8.1 is that the intent of the recommendation is to foster economic efficiency in regulation and the pursuit of the overall objective of net community benefit from the economic rationalism perspective.

The issue policy-makers need to consider is whether the pure economic rationalist approach to *efficiency* of the Commission aligns with stakeholder's expectations for the protective function of regulation. We believe there may be some misalignment in this regard as at its extreme the pure economic rationalist perspective would find a net community benefit where the authorisation of a chemical was found to be deleterious to a few (small group of people, small area of the environment etc) but to have positive benefits to the rest of society (e.g. through more food produced), meaning the benefits outweigh the costs. In this sense the Commission's economic definition of *efficiency* in relation to regulation may potentially have some points of misalignment with contemporary community expectations for regulation. From the perspective of those stakeholders the term *efficiency* in relation to regulation may relate more to the cost-effectiveness with which regulation and regulatory frameworks achieve the stated objectives as democratically determined by the Parliament rather than the pure economic rationalist interpretation.

As noted by the Commission's discussion in Chapter 2 the stated objectives of regulation as determined by Parliament may not always coalesce with economic efficiency. As such from a policy determination perspective it would seem important to delineate between the economic rationalist approach and recognise that some stakeholders may hold different perspectives. We believe it important for the economic rationalist view to be set within the context of the broader political environment. Noting the significant export orientation of Australian agriculture it would also seem important for its discussion to reflect on regulatory approaches and expectations overseas.

³ OBPR Best Practice Regulation Handbook (p.1)

The complete COAG response to Recommendation 8.1 recognises the intersection of economic rationalism with broader community regulatory expectations in noting that:

- regulation must be “*effective and properly deal with the risks posed by the chemicals concerned and efficient in terms of maximising the benefits to the community, taking account of the cost*”;
- the quantification of risk is an assessment outcome;
- assessment effort should be risk-based and that the current modular assessment structure allows the tailoring of assessment costs to match product risks (obviously once the nature of the risk has been established by implication of the previous dot-point).

The COAG response indicated that “...*the Commonwealth will explore the potential for embedding additional guiding values in legislation, consistent with the principles underpinning the Commonwealth best practice regulation requirements*”. In this regard we note that there is a difference between regulation-making and the making of regulatory decisions within a regulatory framework in terms of the application of the Best Practice Regulation principles. In their current context these principles apply to regulation-making but not directly to administrative regulatory decisions within regulatory frameworks, unless requirements for cost-benefit analysis are specified as a statutory requirement for such decision-making. In the current regulatory framework the basis for regulatory decision-making is provided by the Agvet Code which is limited to specific science-based decision-making parameters.

We also note that the Commission found that the outcomes of regulation (in terms of impacts on health, environment etc) can be difficult to measure. Added to this are the time-response of some key outcomes (i.e. the period within which effects may be observed), particularly in relation to chronic effects. Because of these factors the optimal point at which marginal benefits equals marginal costs from regulatory intervention (the most economically efficient point) may be difficult to establish without itself imposing a significant cost. The current regulatory framework provided by the Agvet Code emphasises the protective function of regulation through its decision making criterion (e.g. section 14) and regulatory decisions are thus made on that basis.

This is not to say that the regulator should not be cognisant of the costs imposed on the regulated community in its administration of the regulatory framework and decision parameters provided by the Parliament to achieve the determined objectives (outcomes) and whether any requirements are necessary to achieve those stated objectives. Indeed the preamble of the Agvet Code indicates that the system should be “cost-effective, efficient, predictable, adaptive and responsive”. The APVMA considers the key point is that on a micro basis (such as product by product) the additional costs associated with cost-benefit assessment on a product by product basis may exceed the potential benefit, may have the potential to create a point of misalignment with community expectations and that there may be some practical feasibility issues surrounding the equitable administration of such

approaches. It would be critical that any associated legislative obligation be politically viable and be possible to administer efficiently and effectively.

2. Costs to applicants

The relevant cost in satisfying recommendation 8.1 is the sum of the direct costs of APVMA activities plus all of the costs imposed on the applicant as part of the assessment process (costs of trials, reporting and preparation of application). We believe this is correct, however it is important to note that the Commission also lacked information relating to costs of collecting the necessary data etc. In fact the Commission stated that “*The Commission has not received any data from participants on the costs of data collection for registering a product with the APVMA*” (p.211). Indeed such data is hard to obtain and APVMA requests for such data in the past have struggled to yield objective figures. This has been recognised in some of our previous submissions such as that to the Productivity Commission’s ‘Annual Review of the Regulatory Burdens on Business – Primary Sector’ (sub65⁴) where we encouraged the Commission to promote further research in the area of quantitative cost effects of regulation. The only attempt to quantify such costs we are aware of is that of the European Crop Protection Association in its report ‘*The cost of new agrochemical product discovery, development and registration in 1995 and 2000*’⁵.

Under the current legislative framework the APVMA is required to be satisfied of all statutory tests (e.g. those set out in section 14 of the Agvet Code) before it grants an authorisation. That is it must be satisfied that, amongst other things, the use of the product in accordance with the instructions it approves (ie the label):

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

⁴ Available from the Commission’s website at http://www.pc.gov.au/_data/assets/pdf_file/0009/68337/subdr065.pdf.

⁵ The report is available from http://www.ecpa.be/files/ecpa/documentslive/18/12344_Study%20-%20Cost%20of%20Discovery%20and%20Development%20-%20final.PDF.

The APVMA cannot 'waive' its satisfaction (its risk-management obligation) for any of these decision-making criteria. It must be satisfied of all of them before granting an authorisation. However if it is already satisfied of some or all of the criteria through some other means the modular assessment framework allows it to not charge a fee or conduct an assessment where none is required. In this way the modular assessment structure allows assessment effort, and commensurate costs, to be tailored to that which is necessary in order for the regulatory objective to be satisfied.

Often assessment costs are affected by the complexity of the molecule (the chemistry) proposed for registration, with complex molecules often requiring more assessment and commensurate data. Ultimately the decision as to which molecules to propose for registration lies with the chemical proponent.

Attachment B:

Control of Use – Determining the Level of Compliance with Label Instructions

The APVMA understands that COAG’s expectation for a “*single national framework to improve the efficiency and effectiveness of the regulation of agricultural and veterinary chemicals*” was informed by the Productivity Commission’s analysis¹ and is largely communicated in its response to Recommendation 8.2:

“COAG notes that the integration of regulatory activities up to the point of retail sale with a national control-of-use regime would encourage a nationally consistent approach to risk management and improve the consistency of risk management outcomes, underpinning the assessment and authorisation process (registration and permit)”

The key themes in this response relate to risk management and the relationship between the risks posed by the actual use of the chemical and the risk assessment conducted for the product during the authorisation process. That risk assessment considers the risks associated with the uses prescribed on the label and stipulates commensurate risk mitigation measures for those ‘authorised’ uses. The risks associated with uses not prescribed on the label ie off-label use, are unassessed and hence are undefined, unless otherwise considered through the off-label authorisation process built in to the current regulatory framework - the permit scheme. As a result the appropriate management or mitigation of the risks associated with unauthorised off-label use presents as a challenge and potentially compromises the effectiveness of the scheme to protect people, animals and the environment from undue harm, as well as its effectiveness in mitigating trade risk.

The rationale for regulation, including control-of-use

In economic theory, producers in a market may not bear the full costs of an economic activity, such as the use of agvet chemicals in the production of agricultural commodities. An *externality* of an economic transaction is an impact on others, which has not been taken into account, or otherwise paid for, by the individual who undertakes the activity e.g. environmental impact or public health consequences. Detrimental impacts are termed external costs or negative externalities. Unaccounted negative externalities create market failure, or inefficient market outcomes, as the full costs of the activity (e.g. chemical application) are not borne by the

¹ See *Chemicals and Plastics Regulation, Research Report* (Productivity Commission 2008) <http://www.pc.gov.au/projects/study/chemicalsandplastics/docs/finalreport> pages 218-228.

individual who undertakes it. Market failure may also occur where there is incomplete information and all market participants, including producers and consumers, are not aware of the full costs. The existence of a market failure is the primary justification for government intervention in the market via regulation.

The broad nature of the potential externalities associated with the application of pesticides was outlined by Radcliffe ²(2002, p.32) in his discussion of the economics of choosing, using and regulating pesticides³. Indeed such market failure was the basis for his argument justifying government regulation of agricultural chemicals in Australia on economic policy grounds. Using residues in food as an example it is clear that determining the full nature of the risks, or the chance of externalities occurring, associated with off-label chemical use is a complex task particularly in relation to cumulative risk through dietary exposure⁴ and beyond the means of individual chemical users. With consideration of the transport of produce between various national and international markets such externalities can be of significant consequence. Further, perverse incentives may exist to encourage risk taking in terms of off-label use, which may go undetected where incomplete information exists in the market. The incursion of a pest or disease that threatens to render a crop worthless, impacting on a grower's return is one example.

It is particularly important to consider that the type of externalities that may be posed by the off-label use of agvet chemicals may not be immediately visible. For example the impact of chronic exposures may take years to present. This is particularly relevant when considered in the context that those who may be exposed to the undue effects, through avenues such as residues in food, are generally not aware that they are being exposed in an unsafe manner as they have incomplete information about the risk. The risk assessment process uses the best available scientific evidence to consider the risks associated with the uses prescribed on the label in terms of the 'totality of risk' and stipulates commensurate risk mitigation measures for those 'authorised' uses. This ensures that likely exposures to people and the environment are within safe limits. No such risk assessment has been conducted for unassessed off-label use. As such unassessed off-label use has the potential to pose significant social costs through undue effects that may not be evident in the short-term.

It is because the risk assessment process is complex, resource intensive and serves a protective function for society, and that perverse incentives may encourage risk-taking in terms of chemical application, that government assessment and prescriptive risk management of agvet chemicals

² A copy of the Radcliffe Report can be found at <http://www.atse.org.au/index.php?sectionid=199>

³ The costs and benefits of pesticide regulation were also outlined by Fernandez-Cornejo *et.al.* (1998) Issues in the Economics of Pesticide Use in Agriculture: A Review of the Empirical Evidence. *Review of Agricultural Economics*, 20(2), p.462-488.

⁴ The dietary exposure assessment considers the proportion of the Acceptable Daily Intake (ADI) that is consumed by existing 'authorised' chemical uses (measured via the National Estimated Daily Intake - NEDI). There are a number of chemicals for which the ADI is at or near 100% (i.e. the 'risk cup' is already full). Unauthorised off-label use increases the risk of potentially harmful exposures, a key issue which users in jurisdictions in which such use is legalised are unable to account for.

through a prescriptive risk-based label is justified and desirable to society in order to guard against or correct market failure. It is also for these reasons that the responsibility for risk assessment is not left to users, as is the case for industrial chemicals which use basic hazard-based labels⁵.

It is therefore imperative that the control-of-use framework effectively underpins the chemical assessment and authorisation process by ensuring compliance with the risk management strategies determined through the assessment process. A failure to restrict use to that for which an assessment has been conducted poses unknown and unmitigated risk. The conduct of unauthorised off-label use also confounds regulatory decisions about the ongoing availability of chemicals for which concerns have been identified and the likely effectiveness of risk management controls where confidence in regard to ‘actual use’ cannot be established. Control-of-use is the key mainstay of the risk management framework in this regard and there is thus a strong economic rationale for an *effective* control-of-use framework to underpin the necessary risk-management of agvet chemicals and to ensure desirable risk-management outcomes.

Approaches

The Discussion Paper broadly outlines two approaches to the risk management of agvet chemicals namely enforcement and monitoring. These approaches are on a continuum with high enforcement and low monitoring at one end, and low enforcement and high monitoring at the other. The APVMA considers that an effective control-of-use regime would necessarily combine the enforcement of compliance with label instructions with monitoring approaches. However in order for monitoring to be relevant as a stand-alone tool it would need to encompass the full gamut of risk areas that could well be costly and difficult to administer. In this regard the targeted monitoring of risk-management outcomes is generally most effective as a support tool to other enforcement activities, particularly as a measure of the overall effectiveness of those activities to manage risks and an indicator of areas where investigative or enforcement resources may be prioritised.

Although monitoring is a key tool in ensuring the adequacy of risk management measures, its overall utility is somewhat reliant on the reliability of regulatory intelligence as to actual chemical use. The analytical methodology for detecting chemicals is often compound specific and it is generally not possible to test for every conceivable possibility. There is also the issue of sampling size and frequency in order to obtain appropriate coverage.

For monitoring to provide effective protection against undue risks regulators therefore need to know what chemical they are testing for (i.e. in produce, the environment *etc*) in order to increase

⁵ The fundamental differences between risk-based and hazard-based labelling systems in terms of achieving outcomes were addressed in the APVMA’s second submission to the Productivity Commission’s chemicals and plastics study (submission 65, available at http://www.pc.gov.au/data/assets/pdf_file/0008/77678/sub065.pdf). The diagram included in that submission is reproduced as Appendix 1.

the possibility that they will detect breaches. This means that approaches highly dependent on monitoring, perhaps at the expense of enforcement, to identify risks for subsequent management are highly reliant on grower's advice, adequate grower records and other intelligence as to the chemicals being used. As noted above perverse incentives may exist for such information to be withheld.

It is also perhaps important to note that the identification of hazards with the potential to pose risk (social costs) to people, such as unauthorised residues in produce in the marketplace, and subsequently attempting to manage them is not necessarily the most effective way of administering the protective function of regulation. It is generally more effective to prevent unauthorised and unassessed chemical use before it occurs or to identify it early before the adulterated produce reaches the market and there is an opportunity for exposure to occur. It is for this reason that there would seem to be a need to combine the enforcement of compliance with label instructions with monitoring approaches in order to achieve consistent and effective risk management outcomes.

Previous reviews – defining the control-of-use model

Previous reviews of Australian agvet chemical regulation have provided consistent recommendations in relation to control-of-use. In its discussion of the future management of agvet chemicals the Allen Consulting Group (2002, p.31)⁶ noted that local and international communities are becoming less tolerant of risk and expect high levels of assurance from regulatory systems in “...ensuring food safety and good agricultural practice”. They also noted the significant export orientation of Australian agriculture and highlighted the potential risks to major export markets if the regulatory system fails to be effective. The report suggested “*Significant differences in State approaches and resourcing of the control of use function detract from a seamless system and contains the seed for a significant adverse effect in the future*” (p.31). Radcliffe (2002, p.247) expressed similar views, flagging inconsistent control-of-use management as an issue of concern.

The Productivity Commission reflected on the Radcliffe and Allen reports as well as other available information. In arguing for a uniform approach to the effective risk management of agvet chemicals it suggested that off-label use and the inconsistent enforcement of agvet label instructions leads to several costs, including:

- impacts on regulatory effectiveness (i.e. greater potential for externalities) as the relevance of the detailed risk-assessment process is reduced, compromising the effectiveness of the associated risk management measures;

⁶ A copy of the Allen Report can be found at:
http://www.apvma.gov.au/publications/reports/docs/national_risk_man_system-allen.pdf

- reduced incentive for product registrants to invest in innovation and seek to have new uses assessed and authorised for inclusion on product labels. If off-label use is permitted the additional sales of having the new use on the label may be nil, particularly for chemicals where there are a number of generic competitors. The Commission highlighted that such disincentives might particularly affect the decision to add minor uses to an application;
- potential confusion for chemical users and advisors operating across jurisdictions leading to compliance issues, which impacts on regulatory effectiveness; and
- the potential for anticompetitive effects to growers operating in different jurisdictions.

Whilst the APVMA considers that the Productivity Commission clearly envisaged that an *effective* national control-of-use framework for agvet chemicals would necessarily constrain use to that in accordance with label instructions, it did not support a blanket prohibition on all off-label uses⁷. Rather it recognised that some off-label use could occur without having the potential to pose risks (or produce externalities) that had not been considered and accounted for in the risk assessment and risk management process. The Productivity Commission suggested that such arrangements could provide a low-risk method of facilitating chemical access and highlighted that PSIC had already identified some off-label uses as falling into this category, including:

- use in a crop for which the product is registered (same application rates and timing) to control a pest or disease that is not listed on the approved label;
- use in a crop for which the product is registered at a lower rate or frequency of application⁸; and
- use on a crop and pest combination registered in another state⁹.

The APVMA supports such an approach as it is consistent with contemporary risk management expectations and would not pose risks outside those for which an assessment had been conducted through the authorisation process. Hence there would be no increased risk to operators, consumers or the environment. Opportunities may also exist for levels of flexibility in the off-label use of products labelled and marketed specifically for use in the home garden, particularly

⁷ See footnote 9 on page 223 of the Commission's report.

⁸ It should be noted that such approaches may lead to sub-optimal pest control (such as the development of resistance) with associated social costs (Radcliffe 2002, p.34).

⁹ The differential registration of crop/pest combinations between states is anachronism from the prior state-based systems. New products (or more specifically new use patterns) are registered in all states (nationally).

where any associated risks are solely to the user and cannot directly or indirectly impact others. Such situations are however likely to be quite limited¹⁰.

Chemical use in crops, animals and other situations for which a risk assessment has not been conducted poses potential risks of undue harm to people, animals and the environment as well as to trade. The magnitude of that risk is unknown as the potential for acute and, perhaps more importantly chronic adverse impacts, which may not emerge for many years, has not been quantified through the risk assessment process. In light of the Allen Consulting Group's report of local and international community expectations in relation to risk and risk management (p.31) it is the APVMA's view that the posing of such 'unquantified' and 'uncontrolled' risk is inconsistent with contemporary expectations for risk management, particularly in terms of food safety and environmental protection and fails to meet national and international stakeholder and community expectations.

The level of control-of-use enforcement considered necessary by the Productivity Commission for an *effective* and *efficient* national regulatory framework would restrict use to that in accordance with label instructions, with some minor exceptions to authorise off-label uses where no potential exists for those uses to pose risk outside that considered and accounted for through the risk assessment process. Such an approach was clearly considered by the Productivity Commission to be necessary to underpin the assessment and authorisation process of registration and permit. It also provides confidence and surety in terms of risk management consistent with contemporary expectations. Noting that the COAG expectation has been informed by the Productivity Commission's analysis and is consistent with these principles, the APVMA considers the parameters outlined by the Productivity Commission would seem to provide the most appropriate reference point upon which to form the basis of a national control-of-use regime with respect to the desired level of compliance with label instructions.

The APVMA considers that the national control-of-use regime should restrict use to that in accordance with label instructions, with some minor exceptions to authorise off-label uses where no potential exists for those uses to pose risk outside that considered and accounted for through the risk assessment process.

As noted in the Allen Report (p.31) inadequate resourcing of the control-of-use function constrains the effectiveness of the scheme to appropriately manage risk. As such if resourcing is not addressed appropriately through the current review it is likely that neither improved or consistent risk management outcomes will eventuate from any control-of-use reforms stemming from the review.

¹⁰ In relation to off-label use in the 'home garden' it would be necessary to consider from a policy perspective whether it is appropriate to establish a framework that authorises people to pose risk to themselves (which may generate social costs such as adverse health effects) and has potential for that risk-taking to spill over to others, such as family members consuming home grown produce or exposed as bystanders. Any benefits from such flexibility in 'home garden' situations may be negated by the potential costs.

Control-of-use and minor use

The term ‘minor use’ is defined by the *Agricultural and Veterinary Chemicals Code Regulations 1995* to relate to the use of a product that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product for that use. In essence minor uses are those for which there is limited or no economic incentive for chemical registrants to invest in the research and development necessary to satisfy the company liability and regulatory requirements associated with the inclusion of the use to a product label. It does not necessarily follow that ‘minor use’ equates to ‘little’ chemical use and ‘small’ risks of undue consequences.

Since the COAG decision in relation to Recommendation 8.2 there have been reports in the media of concerns that a national control-of-use model consistent with that outlined by the Productivity Commission and COAG expectations may unduly limit growers’ access to chemicals and exacerbate minor use issues¹¹. However such concerns are difficult to qualify. A number of jurisdictions (e.g. NSW, WA, QLD, TAS, NT) currently operate models that are relatively aligned with that outlined by the Commission. Furthermore there are very few primary production industries operating in jurisdictions where off-label use is legalised that are unique to those jurisdictions as those industries also occur in other jurisdictions. As such mechanisms such as off-label permits will most likely already exist to deal with chemical access issues to meet pest and disease challenges in a large proportion of situations, which could be extended to those jurisdictions where such concerns arise.

As was previously outlined, determining the full nature of the risks (or externalities) associated with off-label chemical use is a complex process which is generally well beyond the means of individual growers. With consideration of the potential risk of undue impacts associated with the use of agvet chemical products it is perhaps important to consider the appropriateness from an *effectiveness* perspective of facilitating chemical access through simply legalising off-label use¹². Doing so represents a significant departure from the economic rationale for the regulation of agvet chemicals (see Radcliffe 2002, p.32-37), particularly as there is generally incomplete information between the primary producer and the consumer in terms of chemical use and where perverse incentives, or even a lack of awareness of the potential effects, may encourage risk-taking with chemical application.

Efficient regulatory frameworks provide one means of facilitating chemical access, however a role remains for governments to support primary industries by facilitating and incentivising the conduct of the necessary research and development to ensure growers have access to the

¹¹ Such concerns have primarily been raised by grower advocacy groups. For example the Victorian Farmers Federation (VFF) expressed concern through an article in the Weekly Times Newspaper on 25 March 2009, ‘Anger on chemical ban plan’. On 10 June 2009 CropLife Australia issued a corresponding media release which is available from the CropLife Australia website at http://www.croplifeaustralia.org.au/default.asp?V_DOC_ID=2174.

¹² It is important to note that legalised undefined off-label use, as currently occurs in some jurisdictions, permits off-label use to occur in an undefined scale in both minor and major use situations.

chemicals they require and that the risks of use are known and managed appropriately. Indeed this is recognised in the USA and Canada where chemical access is facilitated through public investment in minor use initiatives such as the US IR-4 Program and the Canadian Minor Use Pesticide Program. Holm *et.al.* (2007, p.204)¹³ described the justification of the IR-4 Program to centre on the lack of economic incentive for the crop protection industry to invest in specialty crops, the value of specialty crops to the US economy and the importance that the US government and society place on food safety¹⁴.

The UK Pesticides and Safety Directorate (PSD) similarly recognised the importance of risks associated with unauthorised minor uses and used to operate 'Long Term Arrangements for Extension of Use' (LTAEU) to authorise the use of certain pesticides for specified minor uses, subject to certain conditions. The authorised extensions within that scheme were prescribed, and hence determined to not pose additional risk to operators, consumers or the environment than that from registered uses. The LTAEU system was discontinued in 2005, however we understand that the PSD and the UK Horticultural Development Council (HDC) worked to fill any knowledge or data gaps (and were resourced to do so) to convert the LTAEU's into specific off-label approvals (termed SOLA's). Importantly, as in the US and Canadian systems, the UK minor use framework works to identify and manage the risks associated with off-label use through facilitating growers access to chemicals. Such approaches align to the contemporary expectations for risk management outlined above.

As was discussed above, the Allen report (p.29-31) highlighted that inconsistencies and resource constraints in the control of use function "...contains the seed for a significant adverse effect in the future". Providing chemical access through the legalisation of unassessed off-label chemical use on a national scale would logically increase the risks of an unintended consequence and be difficult to reconcile with contemporary risk management expectations. Furthermore, as identified by the Productivity Commission legalised off-label use reduces the incentive for product registrants to conduct the research and development necessary to include new uses, including minor uses, on product labels. As such over time legalised off-label use can have the effect of exacerbating the minor use problem as less uses are proposed for inclusion on product labels. It can also have the effect of discouraging the chemical industry's investment in innovative 'softer' chemistries, leading to a reliance on older chemistries¹⁵.

Although the Productivity Commission (p.213-215) suggested that the case for public investment in minor use initiatives was unclear, this was largely on the basis of rectifying a failure of the market to provide chemical access through researching and registering new use patterns (a demand/supply interaction). Whilst the Commission acknowledged the potential for public benefits to arise from investment in the minor use area, such potential benefits were largely

¹³ Holm, R. E., Baron, J. J. and Kunkel, D. L. 2007. Challenges faced by the IR-4 Programme and US specialty crop growers. *Bulletin OEPP/EPPO Bulletin* 37, p.204-208.

¹⁴ It is relevant to note that the US does not operate a permit system. As such all 'authorised' uses are on-label.

¹⁵ Incentivising the development of new 'soft' chemistries is often raised as a key issue by community groups.

dismissed as being difficult to quantify. In the APVMA's view this was something of a weakness of that analysis¹⁶. Nevertheless the Commission did indicate support for efforts to address minor use issues where they lead to a net public benefit. It also indicated support for a publicly funded program if justified by a comprehensive cost-benefit analysis that also took into account other policy options.

In this regard it is important to acknowledge that chemical access is critical for primary producers to efficiently produce quality agricultural commodities and to help ensure continuity of supply. A lack of availability creates incentive for off-label use, which as discussed above has potential to pose unquantified and unmitigated risk. As previously outlined chemical access for minor uses is a function of efficient regulatory frameworks and primary industries capacity to generate the data necessary to support the use patterns they require, whether publicly or privately funded. If the current review aims to address the minor use issue, as the Scoping Paper suggests it does, it seems critical that a comprehensive comparative analysis be conducted of:

- the costs associated with a level of public investment in the necessary research and development to facilitate chemical access for minor uses (which would have the effect of facilitating compliance and appropriate risk management); and
- the costs otherwise associated with providing the level of enforcement that would be necessary to eliminate off-label use (where it has the potential to pose risk) in order to manage risks and provide a level of surety that is consistent with the contemporary expectations of society.

Economic analyses conducted overseas (US) of the net national benefits from the investment of public funds into facilitating the coordination and development of data for minor use applications have demonstrated favourable returns in terms of net public benefit per dollar invested (Miller 2007)¹⁷. Favourable returns from investments in individual primary industry sectors have also

¹⁶ It should however be acknowledged that a detailed analysis as to the case for the public funding of minor use initiatives would have been somewhat of an extension from the Commission's terms of reference.

¹⁷ Miller, S. R. and Abdulkadri, A. 2008. The US Economic Impact of the IR-4 Ornamental Horticulture Project. Centre For Economic Analysis, Michigan State University. Available at <http://www.ir4.rutgers.edu/Other/AnnualReports/EconomicAnalyORHort.pdf>

been demonstrated (Miller *et.al.* 2008)¹⁸. Considered from the perspective of mitigating the potential social costs that may arise from unauthorised off-label chemical use, and in conjunction with other potential benefits, it would seem logical that similar net public benefits to those identified in the US may be realised in Australia.

¹⁸ Miller, S.R. 2007. National Economic Impact of the IR-4 Project. Centre For Economic Analysis, Michigan State University. Available at <http://www.ir4.rutgers.edu/Other/IR4EconomicImpact.pdf>

APPENDIX 1

COMPARISON OF HAZARD-BASED AND RISK-BASED LABELLING FRAMEWORKS

