



**SUBMISSION IN RESPONSE TO DISCUSSION
PAPER ON A NATIONAL SCHEME FOR
ASSESSMENT, REGISTRATION AND
CONTROL OF USE OF AGRICULTURAL AND
VETERINARY CHEMICALS**

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1. EXECUTIVE SUMMARY

CropLife Australia (CropLife) is the peak body representing the plant science industry in Australia. CropLife welcomes the opportunity to make this submission in response to the discussion paper on “*A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*” and to provide the views of CropLife members on the regulatory framework for agricultural chemicals.

CropLife believes several key principles should underlie a new national agricultural pesticides management framework. These include:

- Effectiveness;
- Efficiency;
- Integration;
- Risk based regulation;
- Harmonised national control of use legislation;
- Competent users;
- Effective monitoring and feedback loops; and
- Equitable funding arrangements.

CropLife proposes a new national agricultural pesticides management framework consisting of three parts:

- Risk assessment and registration – Australian Pesticides and Veterinary Medicines Authority (APVMA);
- Control of use – new separate Commonwealth Government entity to administer national legislation and responsible use programs; and
- Industry self regulation – existing industry schemes.

This structure will free the APVMA to focus on providing high quality, rigorous and scientifically based risk assessments. It will also set a clear structure for allocating responsibilities between the registration and risk assessment functions of the APVMA and the pesticide management and use responsibilities of the new national control of use entity. The structure will also enable the significant investment in stewardship initiatives that is made across several sectors of the Australian agricultural chemicals industry to be recognised and incorporated.

A national control of use entity will reduce inconsistencies between jurisdictions, minimise regulatory compliance costs, reduce the compliance burden for government and provide certainty to industry and users regarding the appropriate way to use agricultural chemicals. Together, these measures will reduce the risks associated with agricultural chemical use and generate benefits for consumer health, user safety, trade and the environment.

CropLife believes that the cost of the effective regulation of agricultural chemicals should be shared between all beneficiaries, including governments, users, consumers and the agricultural chemical industry. However, there are significant problems and difficulties that will need to be overcome to design a system that effectively targets users, and passes the additional costs of regulation on to consumers as a price signal. CropLife believes that industry should continue to fund the APVMA through a cost recovery scheme to cover the cost of product risk assessment and registration functions. Industry should also continue to fund self regulatory measures such as responsible use and waste management initiatives. However, in light of the difficulties in recovering costs state by state for a control of use scheme, a national scheme is proposed. CropLife believes the most effective and efficient solution would be for a national control of use scheme to be funded by the Commonwealth.

In addition, CropLife believes that effective compliance activities involve enabling and promoting compliance by users. For this reason CropLife supports the development of an Australian minor use program that would enable Australian farmers to have access to a sufficient toolkit of crop protection products in circumstances where there is little economic incentive for manufacturers and importers to register new uses for small markets. This will minimise the risks associated with the current reliance on off label uses and permits.

2. INTRODUCTION

CropLife welcomes the opportunity to contribute to the Council of Australian Government's development of "A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals". This submission provides the views of CropLife members on a chemicals regulatory framework, and while reference will be made in some instances to agricultural and veterinary chemicals, the views expressed are those of agricultural chemical manufacturers.

Australian farmers are among the most innovative and efficient farmers in the world. Farmers need to continue to innovate to meet the combined challenges of climate change, the global recession and food security. New crops, new pesticides and new pesticide uses are needed so farmers can continue to produce plentiful, affordable and nutritious food while battling pests, plant diseases and climatic conditions. It is essential that any risks from using these tools are efficiently managed so that the benefits from their use are maximised and costs minimised.

CropLife believes that the current review process examining the need for, and options to develop, a nationally harmonised system for the control of use of agricultural chemicals has the potential to significantly reduce risks associated with the improper use of those chemicals in Australia.

All agricultural chemicals are thoroughly reviewed in Australia by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and its advisory authorities before they are approved for use. All approvals for use come with a set of instructions (labels) that when followed, should result in no harm to users, crops, animals, environment, consumers or trade. Chemicals are also reviewed internationally to confirm their safety.

Misuse of agricultural chemicals can lead to drift, occupational exposure, residues and environmental contamination. The extent of these potential problems is not well known, but even one incident is too many. Effective resolution of many of the issues that CropLife has previously identified through numerous review processes could be significantly resolved through careful implementation of a national control of use scheme with corresponding complementary improvements to the APVMA.

The CropLife proposals included in this response to the discussion paper would unshackle agricultural innovation in Australia. They would give farmers and natural resource managers timely access to a broader range of softer, safer pesticides and uses. They would enable farmers and land managers to use more flexible, sustainable and productive solutions to pest and weed control challenges.

In responding to the discussion paper, CropLife examines elements of risk assessment and management, recommends improvements to the functions and scope of the APVMA, recommends options for a national control of use scheme and considers the options for funding different elements of the system, including the appropriateness of using cost recovery.

It is critical to note that CropLife's submission outlines a package of reforms that will deliver substantial benefits to Australian agriculture. CropLife's support for a separate national entity responsible for control of use is dependent upon that entity being funded by government. CropLife does not support shifting the financial burden of the control of use functions from government (where it currently lies) to industry.

Underpinning CropLife's recommendations and proposals is an effort to ensure the significant benefits that accrue to users of agricultural chemicals can be maximised while the risks to health, environment and trade are minimised and managed.

The term 'agvet chemicals' defined in the Introduction (Section 5) of the discussion paper should also include important products used to protect the environment (eg. from environmental weeds) and human health (eg. from mosquito borne diseases such as dengue fever and malaria).

CropLife Australia proposes a new model for regulation of pesticides that we believe will resolve most of the problems discussed in our previous submissions and improve the efficiency, efficacy, cost effectiveness and outcomes of the system in line with the COAG principles of good regulation.

3. RISK AND A PRECAUTIONARY APPROACH

CropLife believes that agricultural chemicals management must minimise the risk and maximise the benefits from agricultural chemical use. This requires a careful, logical and scientific assessment of the risk associated with agricultural chemicals at each stage of their life cycle. It also requires that those agricultural chemicals and activities that represent the highest risk should receive most regulatory scrutiny.

3.1. *Regulating according to risk*

As outlined in the discussion paper, the regulatory response to manage agricultural chemicals should focus on those activities and products that represent the highest risk. Initially, this requires a consideration of how risks should be assessed and who is responsible for determining what level of risk is appropriate. Traditionally, this role has been performed by the Australian Pesticides and Veterinary Medicines Authority (APVMA), however, the agency has been called upon to take a more precautionary approach when conducting its risk assessments.

A risk assessment process that is too conservative would preclude potentially beneficial agricultural chemical products from being sold on the Australian market. A system that adopts an excessively precautionary position could give greater weight to theoretical, unsubstantiated or irrelevant risks to justify additional, costly regulatory measures to avoid that risk. Such an approach may also result in some chemicals with risks that can be easily managed not being available to Australian farmers. Incentives for agricultural chemical innovation would be diminished with product registrants reducing investment in new products and new uses, depriving Australian industry of softer and safer chemicals with significant health, safety, environmental and trade benefits.

In contrast, a risk assessment approach that is too liberal may expose users, consumers and the environment to unacceptable agricultural chemical residues. Residues may also threaten export markets for Australian produce, with significant consequences for Australia's economy. In rare cases, crops may be damaged, causing significant losses to individual producers.

Efficiently balancing these competing objectives requires the APVMA and any new national control of use entity to regulate according to risk. Products and activities that entail potentially higher risks should receive the bulk of regulatory attention and assessment scrutiny. Products and activities with potentially lower risks should therefore receive lower regulatory and assessment scrutiny.

3.2. *The Precautionary Principle*

Some commentators have argued that the Commonwealth Government through the APVMA should adopt the 'precautionary principle' when assessing agricultural chemicals. They believe that under a precautionary approach agricultural chemicals should only be approved for use in Australia after they have been 'proven safe'. While there are many definitions of the precautionary approach, most state that in circumstances where there is a risk of serious or irreversible harm, then a lack of full scientific certainty should not preclude action to mitigate that risk. The principle is enshrined in Principle 15 of the 1992 Rio Declaration and states that:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The precautionary principle may be considered to be a statement of how risks and benefits might be balanced between competing interests. Australian anti-chemical activists misunderstand and misrepresent the principle in several ways that, if employed by regulators, would ultimately prove ineffectual and counterproductive.

Three key elements are regularly ignored by activist groups in calling for adoption of the precautionary principle. Strictly, the principle relates to serious and irreversible *environmental* degradation. It is not relevant to human health, worker safety or trade hazards that are also considered through the APVMA risk assessment process. While the logic behind the principle might be relevant, the origins and current applicability of the principle are in environmental risk assessment and not human health.

Secondly, measures should not be postponed on the basis of a lack of full scientific certainty. Full scientific certainty is an exceptionally high standard to meet, but the principle does require that at least some evidence of environmental harm is required. Untested hypotheses or plausible but unlikely theories are insufficient to meet the requirement for evidence of harm implied in this principle, especially when reliable, contradictory scientific data is available. In any event, where the APVMA determines there might be a significant risk that is not being managed effectively by current practices, it requires product registrants to actively generate any necessary additional data to assess the magnitude of that risk and to inform control measures.

Finally, measures to mitigate harm taken under the precautionary principle should be cost effective. Activist groups generally call for the precautionary principle to be applied in support of expensive regulatory actions such as prohibitions or bans, before even considering whether other management options may be more effective and efficient.

CropLife supports the precautionary approach currently applied in regulatory decision making for agricultural chemicals in Australia. Caution is required to ensure that risks associated with an agricultural chemical can be managed effectively. However, a clear statement of what a precautionary approach means in the context of the Australian regulatory system for agricultural chemicals is required.

CropLife would support a clear statement on precaution in Australia provided that:

- The statement makes it clear that a precautionary approach is different to ‘proving safety’; and
- The statement includes key elements of the original Rio Declaration, including that it relates to serious environmental harm, that mitigation measures must be cost effective and that while full scientific certainty is not necessary (or even achievable), mere hypothetical risks, in the absence of hard evidence, are insufficient to trigger expensive regulatory responses under a precautionary approach.

3.3. Total or aggregate risk

The discussion paper highlights that the APVMA conducts its risk assessments on a product by product basis. The discussion paper also highlights that this approach does not necessarily effectively take into account some elements of risk that may arise from the use of agricultural chemicals in Australia. In part, this is due to the APVMA not being able to consider the impact of off label uses of chemicals. The discussion paper also highlights that by failing to consider the potential impact of the total agricultural chemical load on the environment, the APVMA is failing to consider an important element of environmental risk.

CropLife does not accept this argument. Modern agricultural chemical products are often safer, softer and short lived, meaning they tend not to accumulate in the environment. Historic concerns regarding persistent products are therefore no longer relevant as they are well considered by registrants during product development, and assessed by registration authorities prior to products being released for sale and use.

CropLife supports the current approach for managing agricultural chemical risk on a product by product basis as this is considered to be the most effective and efficient way to consider the risks presented by the wide variety of registered products currently on the market. Due to the significant difficulties in obtaining greater information on use patterns after registration, using such information to refine assumptions made during risk assessment may prove ineffective, if not misleading. Instead, CropLife believes that risks from illegal use should be managed by a separate national control of use entity, leaving the APVMA to focus on science based risk assessment.

While improvements to the existing Adverse Experience Reporting Program (AERP) may increase the information available to the APVMA in considering its assessments, CropLife believes the risk assessment process for agricultural chemicals must continue to focus upon on label uses of chemical products. Information on off label uses may inform regulatory approaches to control of use, but are strictly not relevant to developing the risk profile of legally used agricultural chemical products. Illegal off label use is an issue for compliance and enforcement of control of use, not an issue that can be logically and reasonably considered during registration of a product.

As outlined in the discussion paper, there are two classes of risk associated with agricultural chemicals in Australia. The first of these is associated with the physical and chemical properties of the product itself. Risks associated with a product's toxicity, movement in the environment, persistence and residual effects all fall within this class. The risks that these factors present to human health, the environment and trade are all considered by the APVMA when conducting risk assessments of a product.

In addition to the risks inherent in the product, there is a second class of risk associated with the way that a product is used. While a product may be safe when used in accordance with the label directions approved by the APVMA, this does not always occur. Additional risks arise from users failing to comply with label instructions (either legally or illegally), by failing to use protective equipment, using the product on a non permitted crop or pest, or failing to comply with storage or disposal directions. The APVMA seeks to control this second aspect of total risk by specifying label instructions and requiring state and territory governments to enforce compliance with them. However, due to the variability in regulatory requirements existing throughout Australia, the assumption that states and territories effectively enforce compliance may be inaccurate.

The risk from the misuse of agricultural chemicals is not one that can be adequately quantified and considered by the APVMA. Instead, under current arrangements, each jurisdiction is responsible for managing this risk. As outlined in the discussion paper, differences in approaches to managing control of use have resulted in differing risk appetites and risk management strategies between jurisdictions.

CropLife considers a more uniform approach to control of use will generate significant net benefits for the Australian community. While some differences in approaches to risk will be sought by various interest groups to take into consideration particular regional sensitivities (for example, specific control of use regulations for Queensland farms designed to minimise the risk of pesticides entering the Great Barrier Reef Marine Park), consistent approaches to user risk are likely to result in a reduction of the total risk. With clear and comprehensive labels, together with proper monitoring and enforcement of control of use, there should be no need for further regionalisation of agricultural chemical regulation.

Reductions in total risk are likely to accrue due to greater clarity in the requirements for agricultural chemical users to manage risks in accordance with regulatory provisions irrespective of their jurisdiction.

3.4. *The Arbiter of Risk*

The discussion paper outlines the large number of agencies that are involved in the risk assessment and registration of agricultural chemicals in Australia. At the national level, this includes the Department of Health and Ageing (DOHA), Food Standards Australia New Zealand (FSANZ) and the Department of the Environment, Water, Heritage and the Arts (DEWHA). Each of these agencies has their own appetite for risk, which may not necessarily be the same as that of the APVMA.

One major problem with the present framework is the over reliance on advice received from the Office of Chemical Safety (OCS) in DOHA and DEWHA. Instead of exercising its role as the arbiter of risk, the APVMA has tended to simply accept the views of OCS and DEWHA. This has resulted in OCS and DEWHA assuming the role of arbiter and the APVMA acting more as a clearing house.

CropLife believes that a consistent approach to risk is required to ensure high quality and effective science based risk assessments. While these risk assessments must be informed by data from registrants and scientific assessments by the relevant government departments, the final decision on whether an agricultural chemical can be used without unacceptable risk must remain with the APVMA. Only the APVMA has access to the complete set of information and data necessary to make a considered decision on the acceptable level of risk presented by a product.

In circumstances where an assessment of risk has a significant implication for another regulatory agency, the recently established COAG Standing Committee on Chemicals has the ability to be able to make a determination that can ensure there is an appropriate and consistent approach to risk.

3.5. Risks from use

CropLife does not believe that use risks, as opposed to product risks, should be managed by the APVMA. Instead, the greatest improvements to the APVMA could be achieved by making changes to enable it to focus on its core business of conducting high quality, science based risk assessments of agricultural chemical products. As outlined later in this submission, this requires the establishment of a separate national control of use entity alongside the APVMA to regulate user risks associated with agricultural chemical products.

CropLife does not consider that greater integration of assessment, authorisation and control of use functions in one agency would result in a corresponding reduction in total risk from agricultural chemicals. Instead, CropLife sees that there are significant efficiency benefits in having the APVMA maintain its role as a high quality and independent science based assessor of agricultural product risk.

Managing control of use risks requires distinctly different approaches to the strictly scientific risk assessments conducted by the APVMA. CropLife believes efficiency gains would accrue in circumstances where a new national control of use entity is able to employ the intrinsically different skill sets required to inform and develop policy on the appropriate training, accreditation and reporting requirements to be imposed on users of agricultural chemicals.

In addition to freeing the APVMA to focus on service delivery of high quality and timely risk assessments to product registrants, a new national control of use entity would be free to implement necessary agricultural chemical use policies and focus on providing high quality assistance to agricultural chemical users. The separation of policy making and standard setting functions between agencies would ensure that each is able to perform their core functions effectively and efficiently.

In conclusion, establishing a new national entity specifically to manage user risks from agricultural chemicals offers potentially significant reductions in risk through:

- Clear nationally consistent guidelines on the use of agricultural chemicals;
- Clear, nationally consistent guidelines on the training and accreditation requirements for users of chemicals; and
- Increased registrations for minor uses, thus reducing the motivation for, and the risks from, off label use.

3.6. Comprehensive feedback loops and monitoring

The objective of information feedback loops is to provide new information that either adds to, or confirms assumptions made at the time of the original risk assessment and to inform other compliance and administrative actions. Under the APVMA's current AERP, information on unexpected or damaging impacts from the use of agricultural chemicals can be provided to the regulator. Some commentators have suggested shortcomings in the AERP, citing the small number of reports generated for agricultural chemicals. While there are valid reasons for this, the small number of reports does not of itself indicate that the reporting scheme is flawed.

The current feedback systems for the APVMA are intended to be restricted to on label uses. As the AERP is used as a validation tool for the risk assessment process conducted by the APVMA, there is little utility for information on adverse effects that occur outside the use instructions approved by the APVMA in registering a product.

However, as outlined above, the total risk associated with agricultural chemical use in Australia incorporates user risks not taken into account by the APVMA. Currently, risks associated with inappropriate use are managed by the separate state and territory governments. Due to varied legislative approaches some jurisdictions have more robust approaches than others to actively manage these risks.

A more effective AERP would gather information that impacts the total risk associated with agricultural chemicals in Australia. This would include both on label and off label uses of agricultural chemicals. Adverse experiences from on label uses would be referred to the APVMA as currently occur. In addition, off label uses could be referred to a new national control of use entity. Where the off label use is illegal, this could inform monitoring, compliance and enforcement programs. If the off label use is considered legal, then this could inform the legal and regulatory framework, and potentially act as a trigger for regulatory changes to further reduce and manage agricultural chemical risks.

The APVMA's current Chemical Review Program provides a clear and robust framework for risk assessments to be reconsidered, taking into account new information and data from on label adverse experiences. While CropLife does not support mandatory adverse experience reporting, a comprehensive system enabling reporting into one nationally coordinated system would offer considerable benefits.

Adverse experience reporting could be used to trigger a range of administrative and regulatory responses. Responses could include targeted awareness raising programs for user groups found to be at particular risk from agricultural chemicals, increased training requirements for higher risk chemical applications, additional funding for minor uses for priority pest control problems, or identification that an adverse experience occurred due to inferior or inadequate application equipment maintenance.

In addition to the AERP, the National Residue Survey could also be used as a feedback loop. National Residue Survey reports are generally used to detect pesticide residues on agricultural products. Results could be used to reduce the risk from agricultural chemical products in two important ways:

1. Residue sampling of a crop might highlight that an agricultural chemical product has been used on a particular crop for which it is not registered. The outcome of this detection might trigger compliance and enforcement activity by the new national control of use entity to investigate the source of the contamination.
2. Residue sampling might identify that an approved pesticide has exceeded the Maximum Residue Limit for a particular crop. By identifying the issue, the new national control of use entity may be able to investigate whether the excess residue was caused by the grower applying the chemical incorrectly, or, if the chemical has been applied correctly, some of the assumptions made by the APVMA in conducting its risk assessments may need to be examined.

Other information sources could also be used to generate additional information on the ways that chemicals are used in Australia, such as water quality monitoring activities in Tasmanian waterways and the Great Barrier Reef Marine Park, with data generated enabling an examination of assumptions made during the risk assessment process. Feedback on impacts from occupational exposure might also be able to be referred through the same mechanism to inform a better risk assessment of worker safety.

Proper feedback loops can provide valuable information and can enable more accurate risk assessments and reviews to be conducted by the APVMA. Additionally, better feedback loops will also provide a clear mechanism for triggering other administrative and regulatory responses associated with adverse experiences. However, care in designing feedback loops needs to be taken to ensure that disproportionate and excessive regulatory responses do not occur.

3.7. Genetically Modified Crops

In the case of genetically modified (GM) crops, a number of agencies regulate risk. The Gene Technology Regulator is responsible for licensing any use of a GM organism in Australia and this license is based on a thorough risk assessment and risk management plan. GM plants that are resistant to insect attack have also been treated as insecticides under the National Registration Scheme and consequently the APVMA also regulates them in a similar way to how they regulate an agricultural chemical. The APVMA also regulates chemicals that are applied to herbicide tolerant crops.

A third Commonwealth regulator – Food Standards Australia New Zealand regulates food safety aspects of all GM crops that are intended for food use. In addition to these national assessments, most state governments have some power to block the commercialisation of a GM crop in Australia that has passed all of these safety assessments on the basis of marketing concerns.

CropLife agrees strongly that regulation should be commensurate with risk and notes that all GM crops that are approved by the OGTR are low risk. It is important that any control of use activities that are conducted for GM crops under a nationally harmonised scheme are performed by suitably qualified personnel. CropLife notes that the skills and knowledge required to regulate GM crops differs somewhat to those that are required to regulate agricultural chemicals.

4. A NEW MODEL FOR AGRICULTURAL CHEMICALS REGULATION

4.1. Principles

The Productivity Commission report on Chemicals and Plastics Regulation (July 2008) proposed a governance framework that enhanced national uniformity by addressing failures in policy development, chemical risk assessment, risk management standards setting and administration and enforcement. In responding to the Productivity Commission report recommendations, the Council of Australian Governments requested from PIMC a proposal for a single, national framework for consideration before mid 2010.

CropLife believes several key principles should underlie a new national agricultural pesticides management framework: These include

- Effectiveness: The proposed framework must effectively manage the total risk associated with agricultural chemicals in Australia. All components of risk should be comprehensively managed throughout the life cycle of the product.
- Efficiency: The framework should deliver an efficient regulatory scheme, imposing no greater cost on users, consumers, industry or government than is strictly necessary to deliver the desired outcome of a nationally consistent scheme. Ideally, the proposed framework should represent a lower economic cost than current arrangements.
- Integration: The new framework should be a seamless part of agricultural chemical regulation in Australia. Linkages with other interested agencies and key stakeholders should be integral to the system.
- Risk based regulation: Those activities and practices that represent the highest risk (whether to health, safety, trade or the environment) should be the main focus of regulatory attention.
- Harmonised national control of use legislation: The proposed framework must deliver legislation for control of use that is consistently applied across all Australian jurisdictions.
- Competent users: Agricultural chemicals should only be used by individuals who have the appropriate skills, training and expertise necessary to be able to manage the potential risks associated with agricultural chemicals. Higher risk activities should require higher levels of training.
- Effective monitoring and feedback loops: Effective feedback loops provide mechanisms for continual improvement of the regulatory approaches, support the sustainability of chemical regulation and should be incorporated into any new framework. There must be credible assessment of the frequency and severity of adverse events
- Equitable funding arrangements: Proposals to fund a nationally consistent scheme for agricultural chemical regulation should be equitable. This may include a mix of funding mechanisms including cost recovery where appropriate, but should not result in arrangements that unfairly allocate costs.

CropLife proposes a new national agricultural pesticides management framework consisting of three parts. These are:

- Risk assessment and registration;
- Control of use; and
- Industry self regulation.

Risk assessment and registration functions would continue to be performed by the APVMA. In addition, a new national control of use entity would be established to provide nationally consistent controls for agricultural chemical use in Australia. This national entity would also recognise industry self regulatory approaches to risk reduction, including Agsafe Accreditation and Training as well as **drumMUSTER** and ChemClear®.

CropLife's proposed framework aims to deliver a number of key outcomes along the supply chain:



4.2. Separate regulators for risk assessment and control of use functions

In accordance with CropLife's preferred framework for a nationally harmonised system for agricultural chemicals, separate regulators would exist for the risk assessment and registration, and control of use functions. CropLife believes that risk assessment and registration should continue to be provided by the APVMA, but a separate national control of use entity should be established to provide nationally consistent control of agricultural chemical use.

The APVMA is currently responsible for assessment and registration of pesticides. It also regulates label approval, product quality, chemical reviews and issues permits for minor use, emergency use and research. The APVMA has the expertise and experience to conduct these registration functions effectively, and CropLife believes the efficiency, timeliness and predictability of product registrations could be improved if the APVMA focussed on these functions and avoided control of use and associated public good activities.

Under this arrangement, the APVMA would continue to register products and assess label instructions to ensure that agricultural chemicals can be used effectively and safely. These functions require expertise in science and risk analysis. The APVMA would continue to liaise with other regulatory agencies with a key interest in pesticide regulation and product registrations, for example: poisons scheduling, the Office of Chemical Safety in the Department of Health and Ageing, the Department of the Environment, Water, Heritage and the Arts and Food Standards Australia New Zealand. The APVMA could also develop systems to ensure that their level of input into registration and compliance activities is commensurate with the expected level of risk of the products.

The functions, skills and key stakeholders for control of use are fundamentally different, and require a different set of regulatory tools and powers for effective regulation. Because of this CropLife believes that control of use must be managed by a separate government entity at the national level. It would administer control of use legislation, ensure user competencies, monitor use, encourage responsible use, coordinate with industry self regulation schemes and administer the minor use initiative. These functions require skills in administration, compliance and communication at a regional level.

The two national entities would work collaboratively to manage the total risk associated with the use of agricultural chemicals, but each would have a different focus. The APVMA would focus on pre-market risk assessment and registration, and the national control of use entity would focus on post registration management of agricultural chemicals throughout the remainder of their life cycle.

4.3. Regulatory power for control of use to be conferred to the Commonwealth

Given the widespread recognition throughout Australia of the need for harmonisation of control of use regulation and the failure to achieve this over 18 years, CropLife believes the best approach to achieve it is conferral of powers by state and territory governments to the Commonwealth. This approach has been successful in regulating the supply of agricultural chemicals under the Agvet Code. The disadvantages of other mechanisms for implementing national approaches were discussed in "*Chemicals and Plastics Regulation. Supplement to Research Report, January 2009*" published by the Productivity Commission.

Once the powers for control of use are transferred, the Commonwealth Government could draft national legislation and create an independent national authority or other government entity, as it did with the Agvet Code and the APVMA. A new national control of use entity would administer the national control of use legislation, regulate use and coordinate with industry programs for the benefit of users, the environment and ultimately consumers.

There is a range of administrative structures that could serve as an appropriate entity to administer the use of agricultural chemicals in Australia. A national entity could be constituted as a separate statutory authority, or it could be administered as part of a relevant Commonwealth Government department. Whatever structure is adopted, CropLife believes that to avoid any unnecessary duplication, it is critical that it have the authority to set national policies that promote the responsible and safe use of agricultural chemicals and the resources to effectively implement and enforce such policies.

4.4. **Responsible use programs**



Besides administering the national control of use legislation, the new national control of use entity would administer responsible use programs, such as the minor use initiative, national adverse experience monitoring and national residue monitoring. It would also set training and accreditation standards for users. It would assess information from the monitoring programs and determine whether any genuine adverse experiences or residue incidents were caused by on label or off label use. Where incidents result from on label use, the new entity would provide appropriate feedback to the APVMA, which would then decide whether to initiate a chemical review in order to amend labels or registrations. Where incidents result from off label use, the new entity would take any necessary action in compliance or user education.

4.5. **Compliance**

CropLife considers there are several options for the performance of compliance functions under the new framework.

The new entity's responsibilities for compliance and public affairs could start after the point of retail sale and would be risk based. Some monitoring, compliance and enforcement activities may be most efficiently conducted at a regional level (for example: regional awareness campaigns during high risk use periods). The new entity could outsource this work to state and territory governments under service level agreements funded through a cost sharing arrangement between the Commonwealth and state/territory governments. This should facilitate consistent approaches, performance and levels of activity nationwide. Care will need to be taken to ensure that services are delivered in rural and regional locations subject to clear performance criteria.

Alternatively, all compliance functions (including compliance functions currently performed by the APVMA to ensure products meet registration requirements) could be performed directly by the new entity. This would enable the APVMA to focus its efforts on providing high quality and timely risk assessments, registrations and reviews.

In recognition that there are many views on the ideal compliance mechanisms for effective agricultural chemical regulation, CropLife suggests that further investigation of the costs and benefits of the various options be conducted.

4.6. Industry self regulation



To ensure the new entity remains an efficient regulator, CropLife believes that it should recognise the significant investment in risk reducing stewardship programs already funded and delivered by industry. Additional regulatory measures should complement existing self regulatory schemes, rather than duplicate or conflict with them.

The agricultural chemical industry and broader agriculture sector make a large, ongoing contribution to responsible use and stewardship through several effective self regulation programs, notably Agsafe Accreditation and Training, **drumMUSTER**, ChemClear® and CropLife's Resistance Management Strategies for herbicides, insecticides and fungicides. CropLife members also engage in individual product stewardship activities. These include providing information to users, providing expert application services and creating records for farmers to meet regulatory requirements. Collectively, CropLife members contribute \$13 million each year to stewardship activities that reduce the risk from agricultural chemicals throughout their life cycle. Other parts of the crop protection sector contribute another \$3 million, totalling \$16 million from industry each year.

Current investment in stewardship activities by CropLife members is limited by the inefficiencies and disincentives associated with expensive and excessive regulation and a small Australian market for many agricultural chemical products. Resolving these issues will increase the incentive for registrants to develop and register new products and new uses of existing products. CropLife members would then be able to increase their investment in stewardship activities above current levels for the benefit of Australian agriculture.

Official Commonwealth Government recognition and endorsement of the schemes, and support of the minor use initiative, would assist in promoting responsible use. However, as participation in these industry schemes is not mandatory for all industry players, the Commonwealth Government may need to regulate non participants to ensure that they meet equivalent standards. The new entity could have a role in auditing and accreditation.

Other industry self regulation programs, such as the Aerial Agricultural Association of Australia's training courses and food supply chain quality assurance programs, should also be recognised and supported in principle by the Commonwealth Government.

Where appropriate, the new national control of use entity could play a role in coordinating and promoting these industry schemes. Its objective should be to raise the standards of those organisations and individuals that do not participate in these schemes to a similar level of competence. Care will need to be taken to ensure that the functions provided by the new entity do not duplicate those proposed in the National Stewardship Framework under the National Waste Policy released in November 2009.

4.7. Communication

Communication on use of pesticides is inconsistent and fragmented under the current control of use framework. Responsibility for communicating to stakeholders on issues related to agricultural chemicals is disjointed and inconsistent, with no clear line of responsibility between the APVMA and the various state and territory authorities. The result is that the APVMA is sometimes drawn into communication activities that are strictly the responsibility of state or territory governments.

The national control of use entity would be responsible for all communication on use of pesticides, including liaison with the community, public affairs and public education. Costs would be minimised by reducing duplication of functions between Commonwealth and state/territory levels and clear, consistent mechanisms could be provided to stakeholders and the community.

4.8. Policy

The new national control of use entity would be required to have some policy responsibilities. It would be responsible for drafting and informing policies required to manage the use of agricultural chemicals safely and sustainably. This function could be conducted under the current governance oversight of the Primary Industries Ministerial Council and the Product Safety and Integrity Committee. Where justified, this structure should also be flexible enough to accommodate region specific risks in chemical regulation.

Having one national control of use policy setting entity could generate significant economies of scale by reducing the resources required to conduct this function in all Australian jurisdictions.

4.9. Community engagement

A new national control of use entity must have adequate mechanisms for genuine community consultation. The discussion paper highlights that the APVMA's consultative mechanisms do not necessarily adequately capture community views or those of agricultural chemical users. The discussion paper also highlights that one of the reasons for this is the APVMA's focus on pre-market registration and risk assessment. As community interests are likely to span a broad range of issues associated with agricultural chemical use, and are unlikely to be limited to agricultural chemical risk assessment, the bulk of community consultation should be undertaken by the new entity.

Consultation need not occur through a committee as currently occurs in the APVMA. Other options for consulting with the broad range of community interests should also be investigated for potential efficiency and effectiveness benefits.

5. IMPROVEMENTS NEEDED IN ASSESSMENT AND REGISTRATION - APVMA



Under the current two part national agvet chemicals regulatory system, the functions of assessment, registration and label approval are the responsibility of the APVMA. The APVMA is also responsible for issuing permits for allowable uses of agricultural chemical products, ensuring product quality and compliance up to the point of retail sale. The control of use activities are carried out by the states and territories. Over time, the APVMA has engaged in activities that are largely concerned with product use, such as off target impacts, adverse experiences from misuse, community consultation and public education on use. The APVMA has also assumed some policy and public good activities that should be the responsibility of the Department of Agriculture, Fisheries and Forestry (DAFF), such as participation in international policy setting bodies, providing policy advice to other government agencies and Parliament.

While CropLife recognises that the current regulatory system needs improvement, we do not accept that giving the powers for regulation of control of use to the APVMA, through amendments to the Agvet Code, is the best way to achieve this. The functions, skills and beneficiaries are fundamentally different for assessment and control of use, and the diverse risks should be managed by two separate government entities, working collaboratively but separated in responsibilities by the point of retail sale of products. This would enable the APVMA to focus on its core business of assessment, registration and labelling of agvet chemicals and products, including development of conditions of use and product quality monitoring, whilst limiting risks to human and animal health, the environment and trade. These functions require expertise in science and risk analysis.

CropLife's main recommendations in relation to assessment and registration are discussed in this chapter. CropLife recommends that:

- The APVMA focus on its core business of assessment, registration and labelling;
- The Commonwealth Government establish a separate national entity to regulate control of use;
- The APVMA's assessment effort be commensurate with risk;
- The APVMA retain responsibility for assessing efficacy of products and risks to trade;
- The Commonwealth Government expand data protection provisions to encourage innovation;
- An agricultural chemical re-registration program not be implemented;
- Labelling system reforms be progressed;
- If the APVMA continues to be responsible for its existing compliance activities, they should be risk based, only focus on compliance with pre-market sale requirements, and include a broader range of compliance and enforcement powers.

5.1. Assessment efficiency

CropLife does not generally have major concerns about the scientific rigour of APVMA assessments. The main complaints of registrants are about timeliness, predictability and cost of registrations, and inconsistent compliance. However, there is a need for improved efficiency and CropLife acknowledges that increasing international collaboration between regulatory authorities will assist in improving timeliness, consistency and access to products. Many Australian farmers and environmental managers also lament the limited and slow access to some new pesticides that are available to overseas competitors, but are not registered in Australia due to a combination of deterrents including small market size, regulatory inefficiencies and inadequate data protection. A registration system that is efficient, provides adequate protection of intellectual property, and has adequate mechanisms and incentives to register small turnover uses and products would provide farmers the crop protection tools to enable them to be more responsive to changing agricultural, environmental or marketing conditions.

Given that total elapsed timeframes for assessment and registration of pesticides is a major problem for registrants, a useful benchmark for performance of the APVMA would be independent, transparent monitoring of compliance with statutory timeframes for applications. Of particular concern are delays in preliminary assessments ('screening'), which could be adjusted from a technical screening to a completeness check. It is yet to be seen whether the APVMA's recently introduced project management approach for large applications will result in reduced timeframes, but agreed time for an agreed data set would improve predictability of the timing of registration. However, the data requirements must be flexible so as to allow for different products and uses. Improved timeliness would enable registrants to better predict timing of getting products to market and avoid missing anticipated marketing opportunities for a particular growing season.

One registrant reported delays of over six months in excess of the standard registration timeframe in obtaining registration of a new chemical product. This delay cost the company an estimated A\$200 million in revenue as an entire season's sales for that product was lost.

To improve assessment efficiency, further work is needed to develop a system to align application assessment effort and cost with relative risk. Previous attempts to develop systems for appropriate assessment and regulation of low and high risk chemicals have failed or stalled. Collaborative work with industry on considering data waiver and reduced chemistry data requirements has also been delayed significantly.

Government policy in relation to the security of emails and other electronic communications has caused significant inefficiencies in the assessment and registration process. Despite requests from industry for electronic communication on routine registration matters, the APVMA is required by government policy to use the postal system, which greatly increases the time taken to register a product in situations where much liaison is required between the APVMA and the registrant. This can, and has in many cases, delayed getting products to market by many months.

Current data protection provisions in Australia are inadequate and in many cases, have failed to provide sufficient commercial incentive for development and registration of new chemicals and uses. The current incomplete intellectual property rights expose commercially sensitive research data to competitors without any means for compensation. Pesticide innovators require data protection to protect the research data they are required to submit to the APVMA during the registration process from use by their competitors for a set period of time. Data protection gives the innovators time to recoup the costs of their investment in research once their product is commercialised. While there is some data protection available in Australia, it is incomplete and does not cover the research data that is submitted for permits (including minor uses) and is inadequate for reconsiderations (chemical reviews).

CropLife and its predecessor organisation (Avicare Limited) has for over ten years been trying, in association with DAFF, to have legislation drafted to fix the gaps in the existing data protection provisions. Expanding the data protection provisions to cover new uses for existing pesticides, in conjunction with Commonwealth Government support for a minor use initiative, would largely resolve the minor use problem and eliminate most of the demand for off label uses of pesticides on specialty and minor crops (*refer Section 6.5 – Minor use*).

CropLife believes that under the proposed new framework for agricultural chemicals management, some of these issues can be significantly remediated. Under CropLife's proposed framework, the APVMA would be free to focus on providing high quality, science based risk assessments and registrations. The APVMA would no longer need to perform additional functions that are unrelated to this task. Resources that are currently dedicated to managing the Adverse Experience Reporting Program, community consultations, as well as some functions in informing policy development processes would be redirected to product registration and assessment.

5.2. **Re-registration programs are not needed**

A chemical re-registration program like that recently implemented by the EU is unwarranted and would impose an unnecessary and expensive regulatory burden on registrants

International conventions (for example, *The Stockholm Convention on Persistent Organic Pollutants*) address risks of existing chemicals and assess scientific data to determine any necessary actions on availability of specific chemicals. The APVMA monitors international and national pesticide information, standards and activities and reviews existing chemicals if it deems that new scientific data warrants a reconsideration of Australian registrations. Registrants also have a legislative obligation under the Agvet Code to report to the APVMA any new information that could potentially alter the outcome of a risk assessment on a product. The current APVMA Chemical Review Program reviews registrations when there is new information to justify it, and provides a clear and robust framework to reconsider risk assessments in the light of new data and significant adverse experience reports. However, improvements could be made to timeliness of reviews, data protection for new proprietary information supplied by registrants and transparency of the prioritisation process for Chemical Reviews.

A more equitable APVMA cost recovery model reflecting the true cost of maintaining product registrations would most likely lead to a reduction in the number of registrations for products that are not marketed or have very limited sales. Thus, cessation of the current cross subsidisation between products and companies would remove many of the unused product registrations that currently clog up the APVMA's registration system.

A requirement to re-register agricultural chemicals after a set time would create a large additional bureaucratic regulatory burden for little real benefit in risk analysis. Experience under the EU re-registration scheme has shown that where some products have not been re-registered and there is no alternative product for minor crops, farmer choice to control certain pests and diseases has become significantly limited. The EU has seen the loss of 276 of the 477 registered crop protection active ingredients since 1994 and only 149 active ingredients have been accepted for re-registration so far. In most of these cases, the chemical is lost despite it being able to be used in a safe manner. In order to meet new regulatory requirements, additional data must be generated and if a chemical is off-patent, 'free riders' would benefit from access to this data. This acts as a disincentive for innovative companies to generate this data. In other cases, the EU's hazard-based approach prevents re-registration of a chemical, despite extensive evidence that the chemical can be used safely provided certain precautions are taken.

5.3. **Labelling**

Despite repeated industry requests, necessary reforms of the labelling system have for several years stalled because of competing APVMA priorities. Information on labels is based on thorough scientific and risk assessment and is crucial for effective and safe use. Therefore, CropLife maintains that users should follow label directions because many users often do not have the expertise necessary to make their own assessment of risks to crops, health, the environment or trade. If users are required to follow label instructions, the information on labels must be clear, concise, consistent and current. The challenge is to balance the competing demands for completeness and conciseness.

CropLife recognises that, while labels must remain the primary mechanism for communicating how to use a product safely, they are not the only mechanism for communicating agricultural chemical product information.

Labels must also be consistent with, and complement Material Safety Data Sheets (MSDSs). Labels and MSDSs serve two different purposes. While labels provide all the information necessary for a user to use a product safely, MSDSs provide additional information on the physicochemical hazards presented by the product. MSDSs provide the necessary information to enable workers to be able to safely transport, handle and store agricultural chemicals before being used.

Under the proposed new framework for agricultural chemical regulation, the APVMA would retain the responsibility for approving labels. As indicated previously, by minimising the requirement for the APVMA to conduct activities not strictly related to the assessment and registration of chemicals, resources could be freed for necessary reforms in the labelling system to be implemented.

5.4. Compliance (products)

There is a widespread view held by registrants that APVMA compliance activities do not create a level playing field. Currently, the focus of the AgQA Scheme is on checking paperwork for active constituents, and the results show a high level of compliance with the APVMA standard. However, the APVMA conducts product testing for only a few active constituents each year, so there is industry concern about products not conforming to standards with respect to toxicologically, significant impurities and active constituent content.

Unregistered products are marketed openly, but the APVMA often takes only limited compliance action if there is no risk to health or the environment. The risk to the integrity of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) and confidence in the system is not currently required to be taken into account. The APVMA's governing legislation does not appropriately connect the matters that are defined in the assessment of chemical products for registration and the conditions that apply to such chemical products once registered. This means that the APVMA may be unable to take compliance action against a product supplied into the Australian market that is different to the product that is registered or against the people supplying those products. Further, the focus for regulatory action is on the supplier of the registered product, not the importer or manufacturer. There are also gaps in compliance where unregistered products containing pesticides are marketed for uses other than pest control (for example: 'plant growth promotants'). The APVMA's Review of the AgQA Scheme presents an opportunity to address these issues, but it has been substantially delayed.

In stark contrast to the principle of risk based regulation, the APVMA's compliance activities create additional costs for, and focus on, products and registrants of low risk. CropLife believes the APVMA's compliance priorities should be risk based.

Currently, the APVMA lacks the regulatory tools necessary to effectively enforce compliance. This restricts the ability of the APVMA to secure compliance with the law for products and active constituents. Since 2007, the APVMA's work on expanding the compliance tool kit has been stalled. Implementation of a new scheme for the effective management of all agricultural chemicals in Australia represents a significant opportunity to ensure the necessary compliance tools to effectively perform compliance functions are available to whatever entity is responsible for monitoring and promoting compliance.

5.5. Post registration monitoring

Current feedback loops to the APVMA are fragmented, incomplete and largely voluntary. Much of the feedback relates to use of chemicals and does not relate to product quality, registration or labelling. The APVMA's Adverse Experience Reporting Program (AERP) is a post registration quality assurance program, but it does not collect all the information on adverse experiences held by various agencies in the states and territories. This is due to the multitude and diversity of government agencies collecting this information in each jurisdiction, and also because reporting to the APVMA is not mandatory, except for registrants.

Whilst the APVMA defines adverse experiences as unintended or unexpected effects when a chemical product is used according to label directions, the Authority has recently expended considerable resources on promoting the Program, encouraging reports from the community and assessing information on misuse or off label use of chemicals (eg. spray drift). Whilst this information is useful, it relates to use rather than product quality and labelling. Some organisations have expressed concern that the number of adverse experience reports for agricultural chemicals is much fewer than for veterinary medicines, but there are valid reasons for this difference.

The AERP Vet Scheme was introduced before the AERP for agricultural chemicals, and many reports are of suspected adverse experiences when veterinarians administer veterinary medicines to single animals under clinical conditions. Many of the potential adverse experiences for agricultural chemicals are addressed by the chemical manufacturers through simple label modifications or other pre-emptive actions. The small number of reported adverse experiences for agricultural chemicals confirms that the registration system is basically effective and should not be seen as deficient reporting.

Residue monitoring in Australia is also fragmented, incomplete and only some programs are transparent. In addition to the National Residue Survey, some states conduct residue testing, as well as farmers and farmer organisations like the Australian Wine Research Institute, CBH and AUSVEG. There is little coordination or sharing of the results, and poor feedback into regulation and control of use. Unacceptable residues more often than not reflect poor agricultural practice and do not pose a risk to human or animal health. Unacceptable residues resulting from on label use should be dealt with by the APVMA, usually through label amendment. Residues resulting from off label use may trigger a range of administrative and regulatory responses depending on the specific circumstances of the use. This may include compliance action, awareness raising, changes to labels, investigation of user competencies or investigation of equipment.

The very small number of genuine adverse experiences and unacceptable residues attributable to on label use demonstrates that the APVMA's registration system is effective. As feedback on adverse experiences and residues mostly relates to misuse, the monitoring and feedback programs would best fit under the proposed national control of use entity, as long as there is appropriate feedback to the APVMA when incidents relate to product quality, registration or labelling.

CropLife recommends that as post registration monitoring functions should cover adverse experiences that relate to on label and off label applications of agricultural chemicals, and could require responses other than label changes or an examination of assumptions made during the risk assessment process, this function should initially be performed by the national control of use entity. Where an incident occurs that requires the attention of the APVMA, the incident report could then be forwarded to the APVMA for corrective action. The national entity would also be able to respond to issues in ways that the APVMA could not.

5.6. *Minor use permits*

Issuing permits for minor uses, research or emergency uses is an important part of the APVMA's assessment and authorisation role. CropLife supports the role of the APVMA in issuing these permits, which should be an adjunct to a more comprehensive minor use program. This would significantly reduce the load on APVMA resources currently tied up in issuing hundreds of minor use permits every year. In 2008-09, the APVMA finalised 512 permits, 75% within the statutory timeframe. CropLife recommends that the Commonwealth Government provide modest support for a minor use program (*refer Section 6.5 – Minor use*). This program, together with appropriate data protection, would facilitate registrants putting more minor uses onto product labels and allow the APVMA to focus more on registration.

One example of the urgent need for a minor use program is the lack of any herbicides registered in Australia to control the environmental weed, *Hymenachne* that is spreading in north-eastern waterways. About ten herbicides are available for control of this serious weed in the US but the market in Australia is too small for companies to register these products for use in Australia. Environmental managers are frustrated by the lack of access to these herbicides and the difficulties of obtaining multiple temporary permits for different jurisdictions.

5.7. *Regulatory overlap in health and safety*

CropLife notes the discussion paper highlights that its scope does not extend to areas of regulatory overlap such as with the occupational health and safety (OH&S) labelling of agricultural chemicals. While CropLife accepts that these issues are beyond the current scope, CropLife maintains its position that the APVMA should continue to be the primary regulator of agricultural chemicals in Australia.

CropLife believes that to maximise the benefits from agricultural chemicals, while minimising the risks, great care needs to be taken to ensure the information provided to users is accurate and relevant. Adding information that is not necessarily relevant to the safe and responsible use of a product forces users to make judgements about what information is relevant and needs to be followed, and what information should be ignored.

Requiring users to make these decisions increases the risk that farmers will misuse products, or make incorrect product use choices. When approving product labels, the APVMA takes great care to ensure that users are given label directions that are accurate, legible and enable users to safely use the product. Additional information that is not required for the safe use of a product undermines the effectiveness of all instructions on the label.

CropLife believes the APVMA must continue to be the primary arbiter of agricultural chemical product risk in Australia. Other government agencies with significant interests in the responsible and safe management of agricultural chemicals (such as agriculture, environment, health, worker safety and food safety departments) should continue to work cooperatively to ensure common issues are addressed strategically and logically with minimal regulatory burden placed on Australian businesses.

To that end, CropLife believes the APVMA has sufficient expertise and powers to be able to effectively manage risks and issues identified by interested agencies. Given these circumstances, all agencies with an interest in agricultural chemical regulation should use existing APVMA processes before imposing additional regulatory requirements on agricultural chemical products.

5.8. APVMA responsiveness

The APVMA is generally very receptive to suggested improvements expressed by stakeholders and is consultative in its approach. However, registrants are frustrated by slow progress in resolving many of the problems due to competing priorities in the APVMA. A renewed APVMA focus on core business should result in quicker resolution of the issues that are important to registrants in achieving timely registration of products. The potential resultant improvements in timeliness and cost of registrations would restore confidence in the assessment, registration, labelling and compliance processes and facilitate timely access to pesticides.

6. IMPROVEMENTS NEEDED IN CONTROL OF USE

CropLife's main recommendations in relation to control of use are discussed in this chapter. CropLife recommends that:

- The Commonwealth Government establish a separate national entity to regulate control of use;
- National control of use legislation is enacted incorporating mandatory competencies, record keeping for pesticide applications, licensing for all commercial operators, neighbour notification for high risk uses and prohibition of off label uses except under permit;
- All users of agricultural chemicals maintain competencies at a level that corresponds to the risk of their use;
- The Commonwealth Government establish a program to generate necessary data to support minor use registrations on labels;
- A national adverse experience reporting program be established that can respond to on label and off label uses of agricultural chemicals;
- A national residues monitoring program be established to replace the current state and territory programs;
- Industry self regulatory programs be recognised;
- Compliance programs should include a range of activities including communication, education, training and monitoring. Enforcement should only be used as a last resort; and
- A national communication program be administered by the new control of use entity.

6.1. *Control of use activities*

The principal control of use activities are:

- Administering relevant legislation, codes of practice and guidelines;
- Oversight of competencies for training, accreditation, licensing; and
- Monitoring, surveillance and compliance.

These activities require many different skills from the core skills the APVMA requires in science and risk analysis to conduct chemical assessments and registrations.

6.2. *Current problems*

Each jurisdiction has its own primary legislation for control of use, which differs significantly between states and territories and is administered by different government departments in each jurisdiction (for example: Primary Industries in Victoria, Industry and Investment in New South Wales, Health in Western Australia, Employment, Economic Development and Innovation in Queensland, Resources in the Northern Territory).

The regulation of agricultural and veterinary chemical use is further complicated by other relevant legislation under agriculture/primary industries, OH&S, health, environment, transport, food and other legislation at state, territory and Commonwealth levels. This multiplicity of legislation has caused confusion and unnecessary regulatory burdens on pesticide manufacturers and the users of their products. The impacts of these regulatory burdens are borne by farmers and their customers, agribusiness, the pesticides industry and government entities at all levels.

CropLife outlined many of the problems with the current regulatory framework in its submission to the Productivity Commission's Study of Chemicals and Plastics Regulation¹ and gave many examples. Problems with the current state and territory control of use regulations include off label uses, complexity, duplication, inconsistency, contradiction, gaps (minor use, data protection, national monitoring) and compliance. Different jurisdictions and different agencies have different approaches and levels of risk management. Jurisdictions also differ in their resource levels for auditing and compliance activities, but there is a common perception that current resourcing levels are insufficient to ensure responsible use.

¹ Submission in Response to Productivity Commission Study of Chemicals and Plastics Regulation. CropLife Australia Limited, 12 October 2007

An example of inconsistent control of use approaches is found in the Sunraysia areas of north-western Victoria and south-western New South Wales, where herbicide spray drift between different agricultural enterprises has been a problem. Victoria has addressed the problem of herbicide damage to sensitive horticultural crops by imposing certain restrictions on spray applications within Agricultural Chemical Control Areas. On the other hand, New South Wales has no such restrictions on spraying volatile herbicides on broadacre crops just across the Murray River, so spray drift can occur across the state border.

In amenity horticulture, flower growers have ongoing problems with limited access to appropriate pesticides because of the huge diversity of plants grown and the small size of each segment of the industry. It is very difficult for such a fragmented industry to obtain registrations or permits for the many different uses of pesticides that they need. The problem is even greater for herbs and spices, where no pesticides are legally available for use in many situations, but off label uses may lead to residues in produce for which no Maximum Residue Limits (MRLs) have been set.

Most jurisdictions allow pesticides to be used at below label rates and do not require mandatory user competency levels. These regulatory inconsistencies allow unwitting and inappropriate application of herbicides that can cause resistance development². Herbicide resistance is a rapidly growing problem in Australia that could threaten the efficacy and sustainability of some herbicides, and even undermine the minimum till cropping systems that are vital to reduce soil erosion, soil moisture loss, carbon emissions and fuel use.

6.3. Control of use legislation

Constant efforts since 1995 to harmonise control of use between jurisdictions have failed to achieve satisfactory consistency. The Productivity Commission report on Chemicals and Plastics Regulation (July 2008, pp. 221-222) summarised the various unsuccessful attempts to harmonise state and territory control of use regulations. To illustrate the complexity of legislation in Australia, two tables summarising some of the use controls for agricultural chemical products in each state and territory were attached (Attachments 2 and 3) to CropLife's submission to the Productivity Commission's Study of Chemicals and Plastics Regulation³. State governments are naturally defensive of their respective approaches.

The main differences in control of use between jurisdictions concern off label uses, Restricted Chemical Products, training requirements, record keeping, neighbour notification and liability for misuse. Victoria, and to a limited extent South Australia, allow off label use of chemicals that are not on a restricted list, providing the user complies with specific restraints and prohibitions. The Victorian system allows uses without a permit at lower rates or frequencies, for unspecified pests, or for different crop and pest combinations than specified on the label. Western Australia has enacted, but not yet implemented, legislation to allow similar off label uses. Victoria allows chemical products to be used on crops and in situations where they are not approved by the APVMA and contrary to the intent of the approved product label, subject to certain restrictions and conditions.

This essentially ignores the detailed research and risk assessment that is required to register a pesticide and its uses, and thereby threatens to undermine the national pesticide assessment and registration system. Allowing off label uses gives Victorian farmers a competitive advantage as they can use pesticides on minor crops or in situations that farmers in other jurisdictions are not legally able to do. This is an unsatisfactory way around the minor use problem. If the minor use initiative (*refer Section 6.5 – Minor use*) is implemented, more uses would be registered on labels and there would be less demand for off label uses, especially for minor crops. Some other jurisdictions (for example: South Australia) allow off label uses without a permit for pest controls registered in another Australian jurisdiction.

² Neve, P. and Powles, S. (2005). High survival frequency at low herbicide use rates in populations of *Lolium rigidium* result in rapid evolution of herbicide resistance. *Heredity* 95:485-492

³ Submission in Response to Productivity Commission Study of Chemicals and Plastics Regulation. CropLife Australia Limited, 12 October 2007

The Victorian Government describes its approach as performance outcome based, but places the responsibility for managing public health and environmental risk squarely on the shoulders of the user. It relies on monitoring of residues and adverse experiences, which at best are limited and fragmented. Residue monitoring in Victoria only covers a few selected crops through the National Residue Survey, the Victorian Produce Monitoring Program (26 and 11 crops respectively). FreshTest and supermarket quality assurance programs also exist but these results are not available to governments. Use of pesticides against pests not specified on the label may require additional or later applications that could lead to unacceptable residues in produce. Similarly application of pesticides to crops not specified on the label could cause residue violations because trials have not been conducted on those crops and no MRLs have been set.

The Victorian Government has argued that their residue testing indicates users are able to manage agricultural chemical use, as testing to date has not shown any systemic residue problems for Victorian produce. Unfortunately, the argument is flawed.

As the Victorian approach to agricultural chemical use leaves a potentially very wide range of agricultural chemicals that could be used on any particular produce, it is impossible to be sure that the residue tests are being conducted for the correct pesticide. Residues of chemicals may be present, but not detected as any residue testing program must necessarily focus on a few chemicals that are most likely to be present, and the scope for a wider range of chemicals on any crop is greater under the Victorian system.

Off label uses also undermine data protection given to registrants who innovate and scientifically evaluate and register specific uses at considerable cost. Off label uses are anti-competitive because products are used in situations for which the registrant has not conducted the expensive research trials required for registration of those uses. Off label use reduces the incentive for manufacturers to put minor uses onto labels, and potentially raises problems of liability if misuse of the product causes harm.

Label directions for pesticide use are the result of extensive and expensive scientific research by the manufacturer, and rigorous evaluation by the APVMA to ensure safe and effective use. Allowing users to disregard parts of the label in some situations devalues the label and risks encouraging a culture of negligence towards directions. Users are likely to be confused about which label statements are mandatory in each situation and jurisdiction. Users and registrants may ultimately lose confidence in the National Registration Scheme for Agricultural and Veterinary Chemicals.

Licensing requirements and fees for commercial pesticide applicators vary between jurisdictions, with no mutual recognition, so this poses an additional financial burden on operators who work across state borders. Even the definition of commercial pesticide users differs between jurisdictions, meaning only contract sprayers and urban pest controllers in some jurisdictions, but including all applicators (except in domestic and home garden situations) in Western Australia. The Western Australian definition includes farmers, as well as private and government employees. Aerial spray contractors generally have to meet much more stringent pesticide use regulations than contract ground spray applicators, even though many of the risks are the same.

It is often claimed that state governments need flexibility to make regulations that are jurisdiction specific to accommodate unique environments, climate or different community expectations, but little evidence is supplied to justify this. As the discussion paper points out, differences in pesticide use needs are more likely to be based on regional agricultural differences and not jurisdictional boundaries.

Current labelling already takes into account some regional and crop differences between jurisdictions, and a national control of use regulatory system could allow sufficient flexibility to accommodate genuine differences based on objective science and risk analysis. Evidence is lacking to justify the claim that real differences exist between jurisdictional communities in their attitudes to risk. Differences in control of use regulations should only be based on actual differences in risk, not on political or non scientific pressure, or to seek a competitive trade advantage over other states. Under national control of use legislation, some flexibility to respond to regional or state issues could be accommodated through outsourcing of post sale compliance activities to jurisdictions through service level agreements.

6.4. Competencies, accreditation and training



Ensuring that agricultural chemical products are handled by appropriately qualified and skilled people is critical to reducing the total risk from their use. Current state based systems vary widely with respect to who is required to be trained, what training is necessary and the need for retraining. Some jurisdictions (such as the Northern Territory) only require training for commercial operators while others require some level of training for all users of agricultural chemicals.

Wherever agricultural chemicals are used in Australia, misuse can have serious impacts. For example, volatile esters of some agricultural chemicals if applied when temperatures are high can evaporate and resettle many kilometres from the original application, with potentially harmful consequences. Agricultural chemicals that are applied shortly before heavy rainfall can run off into streams and rivers. Cattle grazing on previously treated pastures can ingest detectable levels of pesticide residues with potentially significant impacts for entire Australian domestic and export industries.

Proper training and accreditation can significantly mitigate these risks. CropLife believes that all users of agricultural chemicals must undertake training commensurate to the level of risk associated with their activities. Users of agricultural chemicals who merely apply chemicals under direct supervision of a manager would only require basic training to ensure they are able to understand the risk from their activities, the measures needed to manage those risks and how to use the appropriate personal protective equipment. In NSW, these activities require an AQTF Level 2 competency, and this would seem appropriate for the level of risk presented by this activity.

Users who make higher level risk management decisions with respect to using agricultural chemicals would be required to be trained at a higher level to ensure they are able to effectively make those decisions. Decisions regarding how to set up spray equipment to minimise drift risks, as well as decisions on what chemical to use in particular circumstances, would require training at this level. Training at the AQTF Level 3/Level 4 competency standard, as currently conducted by the *ChemCert* and *SmartTrain* programs, could be appropriate for the level of risk associated with these activities.

User competencies could be complemented by industry programs that accredit agricultural chemicals advisors. Schemes such as *AgCredited*, administered by the Australian Institute of Agricultural Science and Technology can assist agricultural chemical users in ensuring advice that they receive on agricultural chemical use is accurate and of high quality.

Whatever schemes are put in place, it should be remembered that extensive industry programs are already in place designed to manage the risks from agricultural chemicals. Programs such as *Agsafe Accreditation and Training*, which ensures that chemicals are safely and responsibly transported, handled and stored prior to supply to the end user, *Spraysafe*, which ensures that aerial spray applicators are appropriately trained, along with some product specific stewardship programs by product registrants, are all useful in minimising the risks associated with chemical use. Regulatory responses for accreditation and training schemes should recognise and incorporate current industry schemes as much as possible to minimise the impact of any new regulation.

6.5. Minor use

A minor use is a low volume use of a pesticide. Typically manufacturers will spend around \$100,000 generating the regulatory data required to register each use for a pesticide. As the markets for minor uses are small, it does not make commercial sense for manufacturers to invest in registering these uses. As a result, there is a severe lack of pesticides that are legally available to most minor uses in Australia.

6.5.1. The extent of the problem

The current process for registering minor uses is not meeting the needs of Australian specialty crop producers. The minor use permit system was established in recognition of this situation, but it should be noted that a permit is not a registration. The differences and the issues created by these differences will be discussed under *Section 6.5.2 – Issues with the permit system*.

One indication of the extent of the minor use issue in Australia is the number of minor use permits that are assessed by the APVMA each year. However, this may well be only the tip of the iceberg with an unknown number of industries lacking the resources and knowledge to apply for permits.

At the *Minor Use 07 – Future Directions* forum, Mr Roger Toffolon, Manager of Chemical and Biological Risk at New South Wales Department of Primary Industries, stated that at any time between 1999 and 2007 there were around 500 permit applications awaiting assessment. Between 150 and 200 of these were processed each quarter. Typically there are around 1,000 active permits for agricultural chemicals and these permits need to be renewed every few years, placing an additional burden on regulators.

The table below shows the relative distribution of these minor use permits amongst different agricultural sectors.

Table 1: Relative proportion of APVMA permit applications⁴

Agricultural Sector	Proportion of minor use permit applications
Vegetable	27%
Fruit and nuts	25%
Non crop	16%
Broad acre	12%
Forestry	6%
Other	14%

The main sector affected by minor use is horticulture and in 2007 just over half the number of active APVMA minor use permit applications were in fruit and nut crops, and vegetables. Horticulture Australia recognises the extent of the minor use problem with annual investments in minor use research of around \$1 million raised by a levy on growers that is matched dollar for dollar by the Commonwealth Government. However, most small and emerging horticultural industries are not covered by the Horticulture Australia levy and these industries lack the resources and structures necessary to successfully progress their own permit applications.

⁴ Norden, A. (2007) APVMA (Presentation at Global Minor Use Summit) Rome, December 2007. Available at [http://ir4.rutgers.edu/Other/FoodUseWorkshop/Australia\(Alan%20Norden\).pdf](http://ir4.rutgers.edu/Other/FoodUseWorkshop/Australia(Alan%20Norden).pdf)

A lack of legitimate pest and weed control solutions presents a strong temptation for growers to use chemicals in unapproved patterns – also referred to as off label use. A significant proportion of fruit and vegetable production occurs in peri urban environments that provide fresh food to large Australian cities. In peri urban regions the risks of off label usage are magnified by the proximity of the urban population. Better management of these risks would deliver benefits to all sectors of the community through better environmental risk management and the continued provision of reasonably priced, high quality fresh fruits and vegetables.

Table 1 indicates that 12% of minor use permits are granted for broad acre industries, which are the backbone of Australia’s agricultural exports. This reflects the shortage of agricultural chemicals for minor uses in major crops and a developing market for niche broadacre crops. Minor uses in major crops occur when pests are sporadic or limited in distribution. The lack of early controls can result in the pest problem quickly increasing and causing major disruptions to agricultural production. For this reason, the Grains Research and Development Corporation has also been an investor in minor use research.

It is also worth noting that non crop uses comprise 16% of minor use permit applications. These are typically for environmental purposes such as controlling noxious weeds or invasive pests.

The statistics on why a permit is being sought provide additional information on the extent of the problem.

Table 2: Justification for minor use permit applications⁵

Justification	Proportion of applications
No registered product available	52%
Registered product unsuitable	31%
Use changes	12%
Quarantine	5%

Table 2 indicates that 83% of all permit applications result because the applicant has no useful legal option for addressing their pest problem. In other words, around 830 of the 1,000 minor use permits reflect a crop protection need that is not being effectively addressed by existing products. As noted earlier, this may only be the tip of the iceberg.

6.5.2. Issues with the permit system

Whilst the permit system provides some access to crop protection products for specialty industries, there is a number of reasons why registration of these uses is preferable.

Grower groups attempting to access chemicals under the permit system must first familiarise themselves with the regulatory requirements and the proper way to generate regulatory data. Often experiments on the behaviour of the agricultural chemical are required and specialty growers must also lead the development of this information. This process causes growers to invest large amounts of time in order to gain and maintain a minor use permit, despite the fact that they are seeking only a small number of additional uses. The process also leads to duplication of effort and education, as growers seeking similar products in similar industries develop the necessary skills and information to obtain a permit. The process of educating growers is particularly challenging when growers come from non English speaking backgrounds, as is the case with several communities in peri-urban regions.

⁵ Norden (2007) *Ibid.*

CropLife agrees with the discussion paper that there is significant cross subsidisation of minor use permit assessment costs within the current fee structure of the APVMA and notes this as another drawback of the current system.

Under the current minor use permit system there is uncertainty around the product warranty and liability issues from both a grower's and a registrant's perspective.

The fact that permits are time limited and often restricted to certain jurisdictions can also create issues for specialty crop growers. In some cases, specialty industries comprise only a handful of growers and there is no ability to fund an industry group with the resources required to renew a permit application. This is especially problematic when the industry is required to generate additional data in order to renew the permit. Due to these organisational issues, permits can be unintentionally allowed to lapse. Alternatively, the APVMA may decide not to reissue the permit, following a failure of the industry to generate required additional data during the life of the original permit.

Often a minor use permit is granted following extrapolation of data from a similar use in a similar crop. While this extrapolation is useful in addressing some needs, one issue with this process is that it limits the ability of new industries to innovate, as every use must be closely related to an existing pattern of use. A novel approach that cannot be compared to an existing registered use is likely to require additional data generation that in many cases is unfeasible for an emerging industry. Consequently there is an over-reliance on older chemistries and use patterns.

A more strategic approach to minor use authorisations would be centrally coordinated and government funded to reduce duplication in both research and education and increase efficiency. A strategic approach would also allow proactive planning for minor use authorisations, rather than the reactive approach of applying for a permit when a pest is already a problem. It would also remove issues relating to cross subsidisation. The registration of these uses would allow the resources that are required to assess and reassess permits to be redeployed. Furthermore, industries that are baffled by the current system would not have to learn all the regulatory requirements as they do currently and this would allow these industries to direct these resources to production.

6.5.3. *There is the potential for emerging industries to become major income earners for Australia.*

Some of Australia's current major industries have been developed from crops that were minor or non-existent in 1950. These include cotton, mushroom, lupin, sunflower, broccoli, soybean, melon, canola, triticale, avocado, macadamia, chickpea, mango, kiwifruit and almond⁶.

Over the past 15 years, there has been strong growth in the processed Asian foods market. Between 1991 and 2006 the market size has increased from 2.7 million consumers to an estimated 3.5 million consumers, which is an average growth rate of 1.6% per annum. Furthermore, the market value has increased from A\$1 billion in 1994 to A\$2.4 billion in 2008, which is an average growth rate of over 7% per annum.⁷ Australia's close proximity to several Asian markets raises the possibility of further export oriented growth, however, this is currently being constrained by export market requirements such as appropriate MRLs or the need for certain quarantine treatments.

⁶ RIRDC (2004) *The New Crop Industries Handbook*. Available at:
<https://rirdc.infoservices.com.au/downloads/04-125.pdf>

⁷ RIRDC (2009) *Processed Asian Foods in Australia — An update*. Available at:
<https://rirdc.infoservices.com.au/downloads/09-162.pdf>

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

Under an integrated national system that included a publicly supported minor use registration program, some temporary permit approvals may still be necessary so that short term needs can be addressed while registration data is generated. Such a need is likely to diminish over time as registrations of additional use patterns provide specialty crop growers with a greater number of legal options.

Off label uses that have not been assessed by a regulatory agency are not supported by CropLife.

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

The Victorian Approach to minor use

The Victorian approach gives specialty crop farmers a lot of flexibility but little information about appropriate use patterns. Under the Victorian approach, any person who chooses to use a crop protection chemical in an off label manner must take responsibility for efficacy, residues and OH&S considerations. In some cases, farmers conduct expensive residue tests individually so that they are certain they do not exceed residue limits. This appears to be unnecessarily duplicative when compared to the APVMA assessing these risks and providing advice on how to manage them. There is also a redundancy of effort with each farmer individually facing the difficulty of conducting an assessment of this type, often without a complete data set.

CropLife believes a central approach that generates registration information for farmers would address the information gap that creates the motivation for the Victorian approach. Risks would be better managed, efficiencies improved and farmers would be able to focus on food production rather than regulatory matters.

National Specialty Crops Program

CropLife's preferred approach to the minor use issue is to establish a national registration program for minor uses based on the approach taken in the United States and Canada.

The US IR-4 Project has nearly 50 years of experience in generating registration data for minor uses. The priorities for registration are determined by the specialty industries themselves through an annual workshop that also involves agricultural researchers and extension staff. Minor uses chosen as priorities at this workshop are researched and appropriate regulatory data generated. This data is then provided to the Environmental Protection Authority for assessment and registration. A program based on this model has also been operating in Canada since 2003.

Possibly the biggest advantage of this approach is that it provides the necessary funding to generate regulatory data for minor uses, primarily through government funding. CropLife understands that an investment of A\$4 million per annum by the Commonwealth Government would be sufficient to allow an Australian research program that could gather and prioritise minor use needs and fund the research required to register these uses.

A modest investment of this nature would generate regulatory data for hundreds of minor uses each year. It is also likely that this investment will stimulate additional investment from state governments, grower groups and registrants. A specialty crops program will address the root cause of the minor use issue – namely that there is no commercial incentive or ability for other groups to fund this research leading to an information gap. The lack of this data leads to all the other problems associated with the minor use issue and the generation of such data removes any doubt about the safety and effectiveness of different crop protection treatments.

The data generated by the US and Canadian government funded programs is of international quality, which is often not the case with data generated for permits in Australia. Both the US and Canadian programs require that all data is generated according to the standards of Good Laboratory Practice, which is important in terms of gaining registrations and in data sharing exercises with other countries that may lead to tolerances in export markets.

A national specialty crops registration program would also realise a range of other efficiencies. In countries that have a national program, growers are not required to understand the complexities of regulatory data generation, simply their priority pest problems. The registration of uses for entire crop groups rather than individual crops reduces duplication and ensures maximum return on public investment. Crop group registrations are prioritised and consequently there is a large incentive for grower groups to coordinate their requests and identify important strategic pests in a proactive manner. CropLife supports registration of uses for crop groups both by the APVMA and by a National Specialty Crops Program.

The establishment of a similar program in Australia would allow data exchange with the Canadian and US programs, potentially realising further significant efficiencies. It is also worth noting that the EU is currently establishing a similar program, so opportunities for data exchange may increase over time.

CropLife strongly supports the establishment of a publicly supported national registration program for minor uses as the only long term solution to the minor use issue in Australia.

Other approaches to increase minor use registrations

Another method for increasing the number of minor use registrations is to utilise recent multi lateral registration assessments to increase the market size – thus making some minor uses into major uses. Australia, the US, Canada and the EU have all participated in a number of joint registration assessments in recent years, and some completed registrations have included significant numbers of minor uses. This method also benefits from data generated by the US IR-4 Program and the Canadian Minor Use Pesticide Program.

A related process is data sharing, where two countries swap regulatory data for a particular use. To date, Australia has had limited ability to participate in such processes due to a lack of registration data for specialty crop uses.

Another option involves the establishment of crop groups that share similarities in production method or biology. An example of a crop group is 'Tropical Fruit – inedible peel'. In this example, it then becomes possible to establish a legal use pattern for all tropical fruits with inedible peels by generating the necessary data in a range of representative crops. This increases the market size, which can then prompt registrants to fund data generation. In programs where public funding is used to generate regulatory data, crop groups provide a cost effective way of registering uses for a wide variety of crops.

Reducing data requirements for minor uses is another approach that can decrease registration costs and in theory this can make the registration of such a use economically attractive for a registrant. However, in practice many registrants are reluctant to register uses with reduced data requirements due to concerns about liability exposure if an unexpected complication arises with the use.

6.5.6. Increased enforcement

The discussion paper suggests increased control of use enforcement as one way to address the minor use issue. CropLife does not believe such an approach would be economical or effective.

Currently, there is already significant enforcement of MRLs through residue monitoring conducted by major food retailers. Growers who repeatedly infringe these limits lose these retailers as customers and this situation acts as a considerable incentive for growers to meet existing residue limits whenever they can.

The cost of conducting residue sampling across hundreds of specialty crops in multiple locations would quickly exceed the cost of generating regulatory data for these uses. If residue violations were detected at certain points in the supply chain it could be very difficult and time consuming to track these violations to the individual farmer. Without an admission of guilt it may actually be impossible to prove who was responsible for the residue violation, as the treatment may have occurred after the produce left the farm.

Another major issue with increased enforcement to prevent illegal uses is that in many cases producers are faced with the choice of losing their crop or using a chemical in an unapproved way. It is likely that there would remain significant incentives for farmers to continue off label uses in these situations, even if government enforcement of residue limits was increased significantly.

CropLife agrees with the suggestion in the discussion paper that it would be cheaper to fund a national minor use program. It would also be much more effective in preventing unauthorised uses by giving farmers appropriate legal options to protect their crops.

6.6. Monitoring



Although much of the current feedback, through the APVMA's Adverse Experience Reporting Program (AERP) and various residue monitoring programs, relates to use of chemicals, insufficient information is available to assess the effectiveness of the current control of use framework on a national scale. Even where the APVMA receives and evaluates reports of adverse incidents, it does not have the power to take action on control of use issues, except reporting back to states and territories through its Registration Liaison Committee or the Product Safety and Integrity Committee.

Reporting adverse experiences to the APVMA under the AERP Ag is voluntary, except for registrants, and much data collected by various agencies in the states is not collated nationally. Adverse experience data collected by poisons information centres, hospitals, environment agencies, state government departments and local councils is generally not submitted to the APVMA. In Western Australia, pesticide incidents can be reported to many different agencies (Departments of Health, Agriculture, Environment, Fisheries, Conservation and Land Management, Community and Employment Protection, Worksafe, Water Corporation and local government Environment Health Officers) and there is resistance to state wide collation of data or national reporting requirements. Even if a member of the public wanted to report a pesticide incident, it would be unclear where the report should be lodged.

Australia has a plethora of residue monitoring programs, each with different scope and objectives. In addition to the National Residue Survey, Australian Total Diet Study and FreshTest, state and territory governments, commodity groups and supermarket chains have their own programs. In addition, the Australian Quarantine and Inspection Service tests agricultural exports and imported food products. Some monitoring programs are confidential and some target specific commodities.

For example, in their most recently published annual surveys, the National Residue Survey targeted 26 plant and 22 animal products for random testing, and the Victorian Produce Monitoring Program targeted 11 fresh horticultural products. Available results generally show that over 99.5% of produce has no chemical residues above acceptable limits, and the few cases where unacceptable residues were detected reflected poor agricultural practice but not a risk to human or animal health. Unacceptable residues are traced back and investigated by relevant authorities and corrective action taken where necessary. However, there is no national collation of the data from the various monitoring programs, and thus no coordinated mechanism to assess and improve the effectiveness of the current control of use framework on a national scale.

The APVMA's risk assessments are based on the assumption that all pesticide use is according to product labels, but the different jurisdictional approaches to control of use invalidate this assumption. Current feedback suggests that the APVMA registration system is effective in ensuring pesticide products on the market are effective and safe if used according to the label. However, most of the few known adverse experiences relate to inadvertent or intentional misuse, not product quality. This suggests the need for improved user competencies, monitoring and compliance activities after the point of retail sale. As the beneficiaries of improved use are the users, the environment and ultimately the consumer, then pesticide registrants should not pay for control of use. Without effective feedback on actual use and outcomes, it is impossible to measure externalities and achieve minimal risk.

To effectively monitor pesticide use, strategic, transparent, national adverse experience and residue programs are needed. Registrants would continue to report significant adverse experiences resulting from on label uses. At the very least, these two programs would establish standard protocols for data collection, coordinate the evaluation of reports from the various jurisdictions and agencies, collect, collate and analyse data, establish and maintain a national database(s), and provide feedback on genuine adverse incidents to the relevant regulatory body to take appropriate action according to whether the incidents were due to on label or off label use. In cases where significant adverse experiences result from on label use, the national control of use entity would not re-examine the assumptions made in APVMA risk assessments, but would inform the APVMA, who may consider the information as part of a formal review process. In cases of adverse experiences that result from off label or misuse, the national control of use entity could take appropriate action to reduce the risk of recurrence. A new national residue monitoring scheme to replace the current state and territory programs could be more comprehensive, focussed, efficient and accessible, and therefore provide better feedback on pesticide use.

6.7. Industry self regulation



The chemical industry has initiated and successfully managed several self regulation programs as part of its commitment to supply chain stewardship, responsible manufacture and responsible use.

CropLife Australia member companies must comply with the CropLife Australia Code of Conduct, The Agsafe Code of Conduct and the FAO International Code of Conduct on the Distribution and Use of Pesticides. Members must also participate in the Agsafe Accreditation and Training program, and the waste reduction programs of **drumMUSTER** and ChemClear®.

CropLife has also developed industry guidelines, such as pesticide Resistance Management Strategies, and the Container Design and Performance Guidelines for Liquid Animal Health and Crop Protection Products. Members provide agronomic advice, particularly on effective and responsible use to farmers (including spray drift risk management, eg. CottonMap). Through these self regulation programs and contributions to policy development, CropLife members contribute many millions of dollars towards responsible manufacture and use, in addition to their major contributions to the APVMA through its cost recovery mechanisms.

Other industry and user self regulation programs were discussed above, such as *ChemCert*, *SmartTrain*, the Aerial Agricultural Association of Australia's *Spraysafe* training courses, and industry, commodity group and food supply chain quality assurance programs.

Whilst these self regulation programs are successful, they do not cover the whole pesticide or agriculture industries. Official Commonwealth Government recognition and endorsement of these schemes would assist in promoting responsible use, but non-participants may need regulation to meet equivalent standards. The Commonwealth Government could also play a role in coordination and auditing.

6.8. Compliance (use)

Current legislative instruments for control of use differ widely between jurisdictions. Not only do the jurisdictions have different approaches, but the legislation is administered by various agencies with differing attitudes to agriculture and risk.

In the interests of consistency, equity, clarity and efficiency, CropLife advocates national legislation that would mandate competencies, record keeping for applications, licensing for all commercial operators, neighbour notification for high risk uses and prohibition of off label uses except under APVMA issued permit. Compliance and enforcement activities after the point of retail sale should be risk based and may be most efficiently conducted at a regional level, perhaps through outsourcing. The model preferred by CropLife would be for the national control of use entity to outsource compliance and enforcement activities to jurisdictional governments under service level agreements with clear performance criteria for service delivery.

Any new national entity will need an appropriate suite of regulatory and administrative tools. A comprehensive suite of tools will facilitate a significant reduction in the compliance burden on government, enabling a corresponding reduction in the duplication of compliance resources in jurisdictions.

A comprehensive suite of tools will include:

- Awareness raising functions to ensure users are aware of their responsibilities to manage and apply agricultural chemicals responsibly;
- Identifying competencies and training requirements for users to ensure they have the necessary knowledge and skills required to safely and effectively use agricultural chemicals;
- Establishing mechanisms (such as an accreditation scheme) to enable users to identify individuals that can provide expert and professional agronomic advice;
- An effective monitoring and reporting scheme that can identify and distinguish between intentional non compliance and other activities that might result in adverse chemical impacts, but require a different and lesser regulatory response;
- The ability to refer issues to the APVMA in circumstances where management of a potential issue might require changes to label directions; and
- Dedicated staff based in regional locations (where the majority of products are used) and focussed on agvet chemical control of use. These could be employed by jurisdictional governments, under cost sharing arrangements, specifically to implement and enforce control of use policy.

By having a comprehensive suite of agricultural chemical management tools, the national control of use entity will be able to significantly reduce unintentional non compliance. The national entity would be charged with promoting the safe and responsible use of agricultural chemicals. Its tools would be deployed to minimise the need for compliance and enforcement. Successfully used, these tools would significantly reduce the cost of regulatory compliance by adopting a holistic approach to promoting the responsible use of agricultural chemicals.

6.9. Communication

Communication on use of pesticides is fragmented under the existing control of use framework. A national approach to control of use could provide more consistent and accessible information to users, the public and other stakeholders. The Commonwealth Government should fund community consultation on control of use, public affairs and general public education on agricultural chemicals.

7. COST RECOVERY

In Chapter 4 of this submission, CropLife supports the development of a new national entity responsible for agricultural chemical control of use. As noted in the discussion paper, the move to a single national framework will require consideration of how this function could be funded.

Currently, the APVMA is funded through a mix of fees and levies on registrants of agricultural chemical products. These resources fund almost all of the APVMA's activities, including the registration and risk assessment functions. At the Commonwealth level, creating and administering another, separate entity to regulate control of use of agricultural chemicals will require additional resources. Several options exist for meeting these budgetary requirements including:

- Government funding from general (taxation) revenue;
- Cost recovery from product registrants by increasing and extending current cost recovery arrangements; and
- Cost recovery from agricultural chemical users.

As outlined elsewhere in this submission, CropLife does not believe that responsibility for control of use should be given to the APVMA. To date, the APVMA's functions have gradually increased into areas that CropLife believes should strictly be the responsibility of a government department. This has resulted in a significant cross subsidisation of government activities by agricultural chemical registrants. If the APVMA were to be given responsibility for managing a national control of use regime, CropLife believes that this would result in an undesirable shifting of costs for the control of use function from governments to registrants.

Even if the Commonwealth Government chose initially to fund a control of use function within the APVMA, there would be a perverse incentive to allow the level of cross-subsidisation from the registration activities to grow, allowing the government to gradually reduce its funding of control of use activities. Such a cross-subsidisation is particularly inefficient as it leaves both the control of use function and the registration and assessment function under resourced. For this and other reasons, CropLife strongly opposes the control of use function being conducted by the APVMA.

7.1. Cost recovery should not be applied for control of use

In accordance with the Commonwealth Government's cost recovery guidelines, CropLife believes cost recovery should only be applied in circumstances where it is effective and efficient, and consistent with the Government's regulatory and policy objectives. After considering the issues, CropLife believes cost recovery for control of use functions does not meet any of these objectives. In contrast to the registration and assessment of agricultural chemical products, cost recovery for control of use is likely to be ineffective and result in several undesirable consequences.

The Productivity Commission highlighted that should responsibility for end-use control of agricultural chemicals be conferred to the Commonwealth, this would give the Commonwealth the legal authority to raise the necessary funds to support that regulatory objective.

7.2. Control of use functions are appropriate for government funding

CropLife, along with other stakeholders, has previously argued that many of the functions performed by the APVMA have public good characteristics that are not directly linked to product registrants. CropLife recognises that there is an alternative view, outlined by the Productivity Commission that indicates that control of use regulation is better seen as a reduction in the negative externalities of pesticides. Consequently, increases in pesticide purchase costs would result in a price signal being provided to users that better reflects the true costs of pesticide use. While potentially consistent with government policy, there are several logical and practical difficulties with applying cost recovery to an extended control of use regime.

CropLife does not accept that there are negative externalities associated with the legal use of agricultural chemicals. Potential risks to the environment, worker safety, consumers and trade are all considered during registration and assessment. These costs are incorporated into the price of the product, removing any negative externalities. However there are externalities associated with the inappropriate and illegal use of agricultural chemicals.

7.3. Registrants' responsibility

CropLife considers it is the responsibility of manufacturers and suppliers of agricultural chemical products to ensure they have provided chemical products that can be used safely without any negative impacts on human health, trade or the environment. These are not externalities as they are adequately accounted for through the registration process that assesses the level of risk presented by each product.

In contrast, there are several externalities that are associated with the use, as opposed to the manufacture and registration, of agricultural chemical products.

While agricultural product registrants have a responsibility to provide agricultural chemicals that can be used safely, registrants cannot be held accountable for externalities that only accrue due to the actions of third parties.

For example, in some situations improperly applied agricultural chemicals may drift onto neighbouring sensitive sites. Spray drift is a complicated and complex issue that is affected by a broad range of factors including weather conditions, spray droplet size, the product being applied and the application equipment used. To minimise the risk from spray drift, chemical labels can direct users on the precautions that they must take to ensure agricultural chemical products do not damage human health or the environment. These risks have thus been incorporated into the current regulatory scheme through the APVMA approved product label and are not externalities. However, in circumstances where a user either disregards label use directions, or is permitted by local legislation to use a product in a manner not specified on a label but which does generate drift, then negative externalities can accrue.

It is important to recognise that in the example given above, negative externalities only accrue as a function of the activities of the user, not the product registrant.

7.4. Difficulties in recovering costs from users

CropLife accepts that the identifiable group that creates the need for regulation should pay for it. However, the need for regulation is not only created by agricultural chemical product registrants. All users of agricultural chemicals (including farmers, natural resource managers and civic maintenance workers) have a critical role in reducing the risks associated with these products. The potential for negative externalities to occur from the misuse of chemical products by users generates the need for effective and efficient control of use regulation. As the objective of a national control of use scheme is to avoid the negative consequences that arise as a result of misuse of agricultural chemical products, principles of equity would suggest that a contribution from chemical users towards the cost of regulation might be appropriate.

Users of agricultural chemical products generate the need for control of use legislation and it is users that receive the benefit from the use of these products (registrants and suppliers receive their benefit from the *sale* of these products, not necessarily from their use). Despite this, cost recovery principles may require the most effective and efficient way to recover the cost of the new control of use regulatory scheme may be to increase and extend the current levies on agricultural chemical products. The result of this would be to increase the cost of these chemical products, which would then be incorporated into the price of farm produce that better reflects the true cost of their production. Unfortunately, this idealistic approach does not work in Australia. Australian farmers are price takers rather than price setters. Over 60% of Australian agricultural produce is exported. Instead of being able to incorporate the additional cost from more expensive agricultural chemical products, the price that farmers receive from their produce is set by the world commodity prices. Given Australia's relatively open domestic market, even production for the domestic market is heavily influenced by world commodity prices.

As a consequence, any price signal sought to be given by increasing the cost of agricultural chemicals is likely to be lost as it will not result in prices for farm produce increasing by a corresponding amount. Costs would end up being absorbed by all farmers, effectively reducing the competitiveness of Australian agriculture. This would undermine other government policy objectives that aim to increase the competitiveness of Australian food production.

CropLife does note that it is not all users that create the need for regulation. Many farmers in Australia are very careful to ensure they comply with all label instructions when applying agricultural chemical products in recognition of the significant economic, environmental and safety benefits that accrue from doing so. In contrast, users that are unable or unwilling to comply with label instructions or approved permits significantly increase risks from agricultural chemical use and create the need for regulation. However, CropLife agrees with the discussion paper that considers that it is likely to be very difficult, expensive and inefficient to design a cost recovery system that is able to distinguish between high risk and low risk users and generate incentives for users to voluntarily reduce their risk level. Failure to do so will mean that low risk users will subsidise higher risk activities through a control of use scheme.

For these reasons, CropLife believes that cost recovery for control of use regulation is likely to be neither efficient nor effective. Price signals to reflect the true costs of administering control of use regulations will not be passed to consumers. Rather, the result has the potential to lead to some perverse outcomes, including significant cross subsidisation of higher risk users by lower risk users, and significant reductions in the productivity and competitiveness of Australian agricultural industries.

Without being able to pass on the additional cost of farm inputs, Australian farm production will be less internationally competitive. Australian agricultural produce, grown with the benefit of an advanced and comprehensive regulatory regime controlling the use of agricultural chemicals, may be replaced with imported produce grown under less strict regulatory regimes. Imported produce, in some circumstances, may have increased human health risks to consumers due to excessive chemical residues or contaminants. This was recently observed when some imported food products were found to be contaminated with melamine.

7.5. Cost recovery for control of use should not occur from levies on existing products

CropLife will strongly oppose any proposal to fund control of use activities through imposing additional levies on agricultural chemical products. In addition to merely adding to the input costs of agricultural producers without any ability to pass those costs onto consumers, there will be other undesirable consequences from additional levies.

In the agricultural chemicals industry, many popular chemicals have succeeded because they are easy to use and effective against a broad range of target pests. The relatively low risk that these products pose to human health, trade and the environment means that they can be safely used and applied in a wide variety of circumstances with only basic personal protective equipment required.

In contrast, higher risk chemicals often require more specialised personal protective equipment along with greater care and skill in application. This is in addition to higher risk chemicals often being registered for fewer uses. Their higher risk results in fewer circumstances where the product can be used safely. If cost recovery were applied broadly across all chemical products, lower risk chemicals would significantly cross-subsidise the control of use activities necessary for higher risk chemical products.

The alternative to a flat rate across all chemical products would be to have a sliding scale for levies where higher risk agricultural chemical products have a higher rate of levy in comparison to lower risk agricultural chemicals. Unfortunately, this approach is still problematic as it will result in logical and practical difficulties in identifying products and activities with higher risk.

It should also be remembered that there are significant positive benefits from agricultural chemical use. The responsible use of agricultural chemicals enables Australian farmers to produce abundant, affordable and healthy food sustainably. The availability of cheap and healthy produce has significant human health benefits for Australian consumers and the viability of agricultural industries that underpin the economies of many regional communities.

The use of herbicides can also generate environmental benefits associated with farming practices. The introduction of no till farming practices reliant on the use of herbicides has improved soil biodiversity, reduced carbon emissions by eliminating the need for tillage, as well as reducing soil erosion and sediment run off into streams and rivers.

Agricultural chemicals are not only used in farming. They can be used by natural resource managers, including government agencies, to control invasive pests, weeds and diseases in national parks, or by civic authorities to control pests, weeds and disease vectors. These benefits are broad based and benefit the entire Australian community. CropLife and other stakeholders have previously argued that as control of use regulation is primarily for the benefit of the whole Australian community, the activity should be government funded.

The discussion paper does consider that there may be significant benefits in terms of sustainability of funding if cost recovery was adopted. The paper argues that government funding will always be subject to government budgetary pressure, increasing the risk that the resources necessary for an effective and efficient control of use regime will be reduced to meet higher priority funding commitments. The paper suggests that cost recovery can provide a regular and reliable stream of funding that is much less likely to be reallocated by the government. CropLife is concerned that this approach is based on the assumption that agricultural activity, and consequently, agricultural chemical use is relatively constant from year to year. Unfortunately this is not the case.

Australian agricultural regions are subject to enormous variability from season to season. Australian agriculture is also frequently subject to long periods of serious drought that can have disastrous impacts on agricultural productivity. As the production and sale of agricultural chemical products in Australia is usually largely dependent upon the productivity of the agricultural sector as a whole, levies imposed upon agricultural chemicals will to a large extent, be dependent upon climatic factors. An income stream that varies significantly from year to year will make forward planning of any control of use activities particularly difficult, with little capacity to anticipate available resources beyond a few months.

Funding that varies significantly from year to year is not a sound basis for long term strategic planning and may lead to other problems with administration, such as excessive levels of staff turnover with consequent losses of corporate knowledge and increased recruitment costs, as well as difficulties in planning and budgeting.

From a sustainability perspective, variable income levels might be identified as an efficiency gain as levels of resourcing vary in accordance with the size of the regulatory task. While some regulatory activities might reduce during periods where chemical use declines, other activities may not reduce at all. Activities associated with accreditation and training are not likely to reduce as significantly and require ongoing administration by any control of use entity. Similarly, activities relating to the control of environmental pests with agricultural chemicals may actually increase at the same time as decreases in agricultural production.

Due to the difficulties in applying cost recovery for control of use effectively and efficiently, CropLife recommends that the most effective and efficient solution for resourcing control of use regulation is through government funding. Control of use functions are already government funded by each state and territory. Given that significant efficiencies should be achieved through having one national administering agency, CropLife believes that nationalisation will result in the most efficient outcome for governments as well.

7.6. Cost recovery is inconsistent with the government's policy objectives

The Commonwealth Government's cost recovery guidelines state that cost recovery should not be applied in circumstances where its application will result in outcomes that are inconsistent with the government's policy objectives.

CropLife notes that implementation of a cost recovery scheme for the control of use of agricultural chemicals will result in impacts that are inconsistent with the Commonwealth's policy objectives. If cost recovery is imposed as an additional levy on existing pesticide products, this will result in a corresponding increase in the price of agricultural chemicals for growers and other users.

Increasing the costs to users will increase the incentive for individuals to directly import chemicals from overseas markets that may not meet Australian quality and labelling standards. Increased prices also increase the incentive for manufacturers of counterfeit products to seek to bring them to Australia. The risk from these activities is that products may not comply with Australian quality, safety or labelling requirements and present an unacceptable risk to human health, the environment and trade.

To date, CropLife has only anecdotal evidence that counterfeit products are being imported into Australia. However, the European Crop Protection Association (ECPA) has reported that instances of counterfeit and fake pesticides are growing in Europe. ECPA reports that the majority of counterfeit and fake agricultural chemical products originate in China. ECPA considers a strong national regulatory regime that promotes and supports the use of legitimate agricultural chemicals is critical to minimising the threat from counterfeit and fake products.⁸

In Australia, our proximity to, and strong trade links with China mean we face a real threat from counterfeit products. Imposing a cost recovery scheme that increases the costs of agricultural chemical products in circumstances where these costs cannot be passed on to consumers will increase the likelihood that users will turn to counterfeit products. In these circumstances, implementation of cost recovery for control of use functions is inconsistent with the Commonwealth's policy objectives.

Any control of use scheme should be established to support and enable the safe, legal and responsible use of agricultural chemicals. CropLife would not support cost recovery arrangements that increase the size of the compliance task for any control of use entity by increasing the risk of illegal agricultural chemical imports with the corresponding increases to health, safety, the environment and trade.

7.7. Cost recovery for registration and assessment activities

CropLife supports cost recovery as an effective and efficient mechanism for funding the APVMA's registration and risk assessment activities. However, as discussed throughout this submission, CropLife is concerned that the expansion of the APVMA into policy development and advisory activities has resulted in industry effectively funding activities that should be government funded.

In 2009, the APVMA issued a Cost Recovery Impact Statement (CRIS) that proposed several changes to the APVMA's cost recovery scheme. CropLife feels that some of the proposals contained within that CRIS will significantly reduce the equity and efficiency of cost recovery by the APVMA. Some targeted changes to the APVMA's proposals would result in a much more effectively targeted cost recovery scheme. For example:

- Neither registrants nor farmers are able to accommodate rising application fees while still recovering from the global recession and facing ongoing drought conditions;

⁸ ECPA (2008) *Counterfeit Pesticides Across Europe – 2008*. Available at: http://www.ecpa.be/files/ecpa/documentslive/9/17853_Counterfeit%20Pesticides%20across%20Europe%20-%20Facts-Consequences%20and%20Actions%20needed.pdf

- The current fee/levy structure causes 5% of registered products to heavily subsidise the remaining 95%. This distortion would be exacerbated by the proposed fee increases and magnify the disincentive preventing industry from bringing new and innovative products to Australia; and
- Raising fees to reduce reliance on a levy that can vary from year to year might increase budgetary certainty, but to do so without reducing the levy results in a double impost on industry that cannot be absorbed.

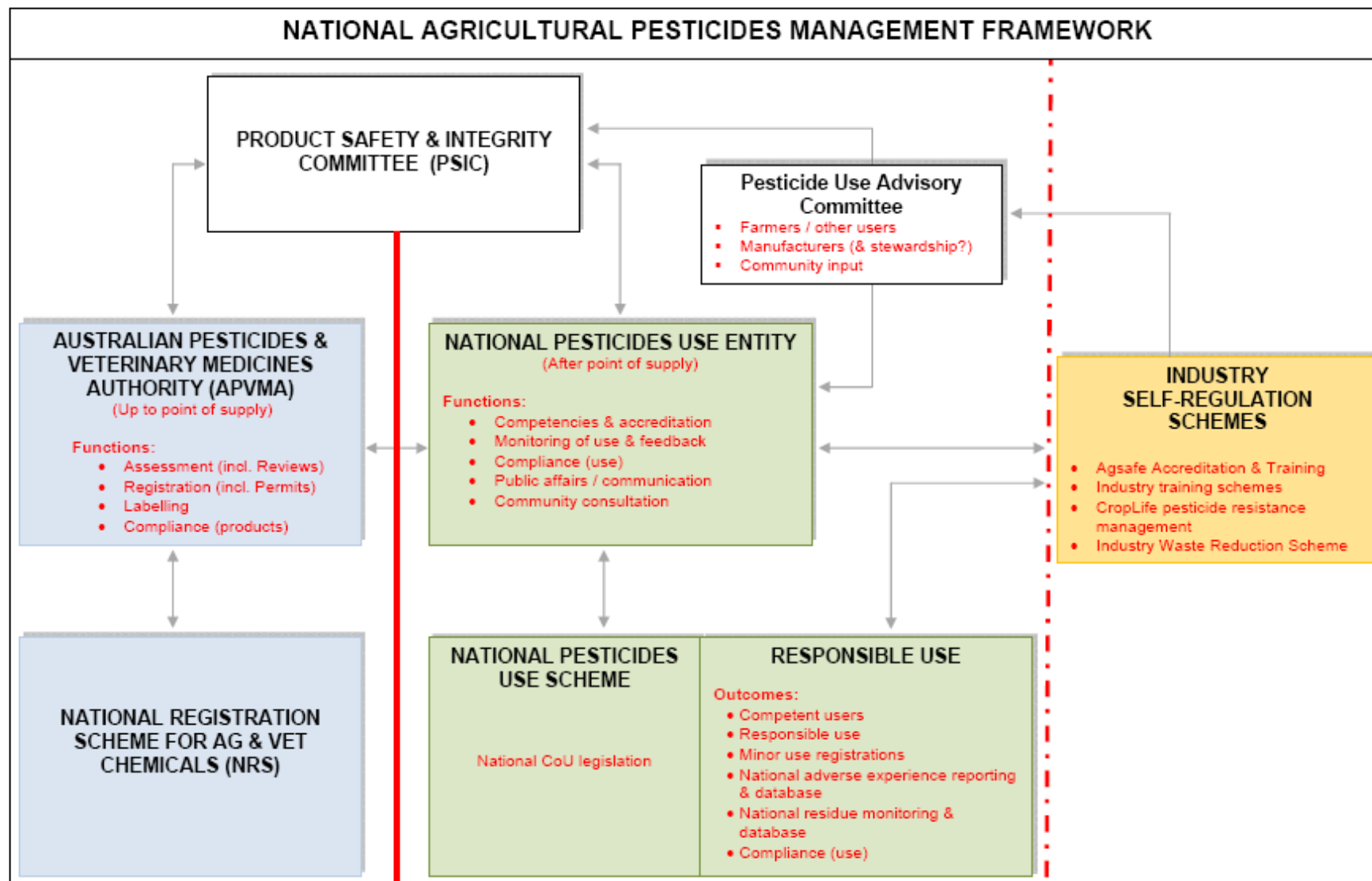
Further details of CropLife's preferred cost recovery arrangements for registration and assessment activities can be found in CropLife's submission to the APVMA's CRIS.

ATTACHMENTS

Attachment 1: National Agricultural Pesticides Management Framework

Attachment 2: Questions from discussion paper with references to answers in submission.

ATTACHMENT 1



ATTACHMENT 2
QUESTIONS FROM DISCUSSION PAPER WITH REFERENCES TO ANSWER IN SUBMISSION

Q1	<p>In either the current state and territory control of use or APVMA responsibilities for agvet chemicals are there any gaps, overlaps or unnecessary inclusions and, if so, what are they?</p> <p><u>Gaps:</u> Feedback loops Minor use registration program Data protection Accreditation</p> <p><u>Overlaps:</u> Occupational health and safety MRLs Licensing</p>	<p>3.6, 5.5 6.5 5.1 6.4</p> <p>5.7 6.2, 6.3</p>
Q2	<p>How effective are the current registration arrangements for facilitating adequate chemical access for minor uses?</p>	<p>5.6, 6.5</p>
Q3	<p>What particular costs or benefits would arise from a greater integration of assessment, authorisation and control of use for agvet chemicals?</p>	<p>4.2, 4.3</p>
Q4	<p>What do you take the precautionary principle to mean? What are the potential costs and benefits that could arise from adoption of a more precautionary approach in circumstances where lack of full scientific certainty exists in agvet chemical assessment, registration or control of use?</p>	<p>3.2</p>
Q5	<p>How responsibly and effectively does the APVMA appear to take up information provided by industry or signatories to the National Registration Scheme?</p>	<p>5.8</p>
Q6	<p>How could information be more effectively provided by industry or signatories to the National Registration Scheme and how could it be better integrated into the APVMA's regulatory activities?</p>	<p>3.6</p>
Q7	<p>What would be the advantages/disadvantages of adopting an assessment process for new chemicals based on an agreed time for an agreed data set?</p>	<p>5.1</p>
Q8	<p>What are the most important ways in which the efficiency of the APVMA's assessment process could be enhanced?</p>	<p>5.1, 5.3, 5.5</p>
Q9	<p>How close is the alignment between chemical/product risk and effort in the assessment process and how best could it be enhanced?</p>	<p>3.3, 3.4</p>
Q10	<p>What is the benchmark against which the performance of the APVMA should be assessed?</p>	<p>5.1</p>
Q11	<p>What is the evidence that assessment would be more efficiently performed without the APVMA being required to carry out either efficacy or trade assessment? How would the risks that are currently managed through APVMA assessment of efficacy or trade risk be adequately managed in the absence of that responsibility?</p>	<p>5.1</p>
Q12	<p>What would be the advantages and disadvantages of introducing a requirement for reregistration of agvet chemicals?</p>	<p>5.2</p>

ATTACHMENT 2 - QUESTIONS FROM DISCUSSION PAPER WITH REFERENCES TO ANSWER IN SUBMISSION (CONT.)

Q13	Is there a case to be made for revision of the APVMA's compliance powers and if so, what improvements are needed?	5.4, 6.8
Q14	Is there evidence to suggest that there would be net benefits from government budgetary support of applications for minor use permits?	6.5
Q15	What role, if any, could off label access for chemicals for minor use play in an integrated system?	6.3
Q16	What are alternative systems for minor use and specialty crops/animals?	6.5
Q17	What is the evidence that a particular approach to control of use is/is not effective and efficient: <ul style="list-style-type: none">• in agricultural use, or;• in urban amenity horticulture or sectors such as management of golf courses and other sporting venues, or;• in pest and weed control?	6.2
Q18	Is there a need for flexibility of control of use to respond to local or regional issues, and how could such flexible arrangements be delivered by a single national regulator, if at all?	6.3
Q19	What is the evidence that government penalties are more effective than industry incentives in achieving compliance with chemical use rules?	
Q20	To what extent is there a need for a balance to be determined between government compliance action and industry mechanisms?	3.3, 4.4, 6.7
Q21	What evidence is there that training is effective in improving agvet chemical use?	6.4
Q22	Should there be a required level of training for access to agvet chemicals and if so, what should be the basis for establishing that requirement (e.g. level of training and scope of operation, such as commercial operator or private landholder)?	6.4
Q23	Under what conditions should a single national regulator be expected to deliver assessment authorisation and control of use services effectively and efficiently and, if so, would there be a need for flexibility at a regional level?	4.2, 6.3
Q24	Is there a harmonised mode of governance that would provide for control of use by state agencies that was effective, efficient, integrated with assessment and authorisation and consistent across jurisdictions: <ul style="list-style-type: none">• from the models considered in section 11, or• alternatives not mentioned here?	4
Q25	With respect to permit applications, regional knowledge and access to local advice what would be some of the disadvantages and advantages of control of use by either: <ul style="list-style-type: none">• a single national authority, or;• harmonised provision by state agencies?	6.3, 4.2
Q26	What other key principles need to be considered in assessing the case for or against cost recovery?	7
Q27	What other arguments are there in support of government funding of control of use regulation, particularly monitoring compliance, investigation and enforcement?	7.2

ATTACHMENT 2 - QUESTIONS FROM DISCUSSION PAPER WITH REFERENCES TO ANSWER IN SUBMISSION (CONT.)

Q28	What is the view of stakeholders regarding the arguments made for cost recovery of monitoring compliance, investigation and enforcement, particularly: <ul style="list-style-type: none">• cost recovery would not be inconsistent with the Government's policy objectives;• the regulated industry is a beneficiary of the regulatory activities; and• the users of agvet chemicals create the need for the regulatory activity.	7
Q29	What is the potential impact of cost recovery of control of use regulation on: <ul style="list-style-type: none">• manufacturers, if it results in higher regulatory fees; and• the users of agvet chemicals if it results in higher prices for agvet chemicals?	7.4
Q30	What are the potential risks that an increase in the cost of agvet chemicals will result in higher levels of improper usage?	7.6