CropLife AUSTRALIA

SUBMISSION IN RESPONSE TO

CONSULTATION REGULATION IMPACT STATEMENT

A NATIONAL SCHEME FOR ASSESSMENT, REGISTRATION AND CONTROL OF USE OF AGRICULTURAL AND VETERINARY CHEMICALS

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INTRODUCTION

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, formulators and registrants of crop protection and agro-biotechnology products. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $1.5 billion a year to the Australian economy and directly employs thousands of people across the country.

CropLife member companies spend more than $13 million a year on stewardship activities to ensure the safe use of their products on the environment and human health. CropLife ensures the responsible use of these products through its industry code of conduct and has set a benchmark for industry stewardship through programs such as ***drum****MUSTER*, ChemClear® and Agsafe Accreditation and Training.

CropLife welcomes measures designed to improve the effectiveness and efficiency of agricultural regulation in Australia. CropLife has long observed that the processes surrounding assessment and registration could be significantly improved to facilitate and encourage greater innovation in Australian agriculture.

In addition, the variety of approaches to regulation used by different jurisdictions has the potential to unnecessarily increase the risks associated with agricultural chemical use. Differences between states and territories with respect to allowed uses, training and accreditation for users and advisors, as well as restrictions on the agricultural chemical tools available in certain locations, each adds unnecessary compliance costs and confusion to farmers, other users and agricultural industries generally.

CropLife welcomes proposals to nationally harmonise rules and regulations regarding the assessment, registration and control of use of agricultural and veterinary chemical products, and looks forward to working with the government in ensuring that the best outcomes for the agricultural chemicals industry, farmers, consumers and the environment can be achieved. CropLife anticipates this will include a mix of regulatory and stewardship approaches that can deliver effective solutions at minimal cost to the Australian community.

EXECUTIVE SUMMARY

CropLife Australia (CropLife) recognises that inappropriate uses of agricultural chemical products can generate significant economic, social and environmental problems. In contrast, the benefits that can accrue from the responsible use of agricultural chemical products are proven, well established and significant. Between 30% and 50% of current Australian agricultural production is dependent upon the use of chemical products. Denying farmers access to these proven tools will result in significantly reduced yields, higher food prices and potentially greater environmental impacts as new lands are turned over to agricultural production, and less efficient production systems are adopted that do not assist in meeting global food security challenges.

An effective and efficient regulatory system must seek to balance the benefits associated with the responsible use of agricultural chemical products with the costs that may occur when products are used inappropriately or irresponsibly. This is the basis of Australia's risk based system for agricultural chemical regulation. Prior to approving an agricultural chemical product for use in Australia, the Australian Pesticides and Veterinary Medicines Authority (APVMA) must be satisfied it can be used in a manner that minimises the risk to users, consumers, the environment or trade. Without the APVMA being satisfied that such risks are acceptable, a product cannot be approved for use in Australia.

States and territories are subsequently responsible for controlling the risk associated with the use of agricultural chemical products. This includes measures to ensure that users are adequately and appropriately trained and accredited, that products are used in accordance with label directions or other rules and regulations, and that any special requirements to protect sensitive areas (such as Chemical Control Areas in Victoria and regulations to protect the Great Barrier Reef in Queensland) are followed.

The current risk based approach to agricultural chemical regulation, which seeks to minimise the risks to users, consumers and the environment while maintaining access to agricultural chemical products, and facilitating industry innovation in developing new products, should be maintained. While significant improvements to the way that this is achieved can be realised, this fundamental principle must be preserved in any new national system. Risk based regulations permit the most effective use of resources to manage the hazards associated with agricultural chemical products.

CropLife and its members have an established record of addressing environmental and regulatory issues through stewardship. Our ***drum****MUSTER,* ChemClear® and Accreditation and Training programs assist in the sustainable life cycle management of agricultural chemical products. Many of the options for further national regulation could be met through self-regulatory or co-regulatory measures implemented and operated by industry. Some proposed measures, such as training for users and advisors, could easily be implemented at minimal cost through adjustments to existing stewardship schemes.

Stewardship options, supported by minimal regulation must be fully considered as alternatives that potentially offer similar benefits to regulation at a much lower cost to industry, users and the community.

Overall, CropLife is concerned by a general lack of information regarding the comparative costs and benefits of potential options. While CropLife can assist with providing some information on the costs of certain options, it is not possible to provide firm positions and opinions about preferred options without a full consideration of their respective benefits and potential costs.

GOVERNANCE OPTIONS

CropLife continues to advocate that there must be an administrative separation between the pre-market risk assessment functions currently conducted by the APVMA, and the post-market compliance and enforcement functions currently performed by state and territory government agencies. Such an approach recognises the fundamental differences that occur between the pre- and post-market regulatory functions.

CropLife's position with respect to preferred governance models was detailed in our January 2010 submission *A National Scheme for the Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals* available at: http://www.croplifeaustralia.org.au/default.asp?V_DOC_ID=2295

The present Consultation Regulation Impact Statement (Consultation RIS) presents three governance options for regulating agricultural chemical products. These are:

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

   CropLife considers that the delivery of appropriate functions nationally, such as training, licensing and accreditation is likely to offer benefits to industry through:

   - Improving the portability of competencies, skill sets and accreditations between jurisdictions. Users who obtain the necessary competencies and accreditations would not be limited by jurisdictional boundaries, increasing competition for services.

   - Ensuring that users and growers are subject to one clear national standard when using agricultural chemicals. Irrespective of the jurisdiction in which users find themselves, users would have greater clarity regarding their obligations when using agricultural chemicals.

   - Minimising risks to users, consumers and the environment by ensuring that all users have obtained a level of competency appropriate to the risks that they will be expected to manage when using chemicals. This level of competency may vary depending on the risks. Similar risks in different jurisdictions would therefore require similar competencies to be obtained.

   This area is one where there is potential for cooperation between governments and industry. Industry stewardship schemes such as Agsafe's Accreditation and Training Scheme already assist regulators ensure that distribution and retail centres for agvet chemicals are meeting their legislative requirements under occupational health and safety, dangerous goods and major hazard facilities legislation. Similar arrangements should be explored before resorting to legislative solution.

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

   CropLife supports this proposal, noting that it is broadly consistent with the model developed and presented by CropLife in its January 2010 submission to the Product Safety and Integrity Committee (PSIC). This model:

   - Is likely to deliver the greatest level of consistency of agricultural chemical control of use regulation. It will prevent the 'regulatory drift' that inevitably occurs between jurisdictions as they seek to take account of their own local circumstances, or interpret agreed rules in novel and unanticipated ways.

   - Potentially offers greater flexibility and efficiency in resource allocation as resources can be directed to those areas and regions where compliance and enforcement effort is most required.

In recognition that states and territories have existing resources that could be deployed to deliver control of use services, these resources could be redeployed to provide control of use services for a national authority. This will ensure users are provided with appropriate advice from a national authority located within their region. The approach could be provided in much the same way as the current state based control of use functions where compliance officers are out-posted to regional areas from one central coordinating government agency. Like the APVMA, this new national body could be overseen by the Commonwealth, states and territories as partners with input from key stakeholder and user groups.

3. Maintain the APVMA's current assessment and registration role, with the Commonwealth, states and territories as partners overseeing the APVMA's policy and operational direction. Delivery of other regulatory functions, including training, licensing and control of use would be managed by states and territories under harmonised regulations.

   This approach is not supported. Over time, any harmonisation of regulation is likely to be lost as states and territories drift from an agreed, harmonised position. Any benefits that may be accrued will quickly be lost as companies are again forced to comply with differing sets of regulation.

ASSESSMENT AND REGISTRATION

CropLife notes that many of the options proposed in this section reflect policy proposals contained in Minister Ludwig's Policy Discussion Paper: Better Regulation of Agricultural and Veterinary Chemicals. As CropLife has already prepared its response to those proposals, they will not be reiterated in this submission. Rather, this submission will focus on those areas where clear proposals have been made that have not previously been addressed by CropLife, or where further views from the CropLife membership may prove beneficial to the ongoing policy development process.

CropLife's submissions to the Better Regulation of Agricultural and Veterinary Chemicals are available at: http://www.croplifeaustralia.org.au/default.asp?V_DOC_ID=2389

- *Assessment and use information*

  CropLife supports users of agricultural chemical products being given timely, up to date and relevant information that is critical to facilitate the safe use of a product. However, CropLife and its members are cognisant of the limitations of current labelling arrangements. New technologies may provide new solutions to ensuring that users have access to the latest information for the use of that product.

  While new technologies may be useful for obtaining the latest information, it cannot replace the requirement that up to date, relevant and reliable information be included on labels to ensure that adequate instructions are provided for users to be able to use and handle a product safely. Not all users have access to, or desire to use, modern information and communication technologies. For these individuals, the physically attached label will remain of prime importance.

  The Consultation RIS identifies three options to address these issues, namely:

  1. Develop a common approach to product efficacy across jurisdictions to limit label complexity and label approval effort.

     CropLife supports measures that would see a consistent approach to product efficacy across jurisdictions. Any measures that reduce and minimise label complexity are likely to result in better use outcomes. CropLife would welcome further information and discussion on the anticipated benefits associated with this option to ensure that they outweigh any implementation costs.

  2. Require that companies put all their market labels on a single, web-based database.

     CropLife considers that the consequences of such a proposal must be fully considered before this option is adopted. CropLife suggests that the benefits to farmers may not be as significant as originally intended and additional risks may be generated that create perverse outcomes.

     For example, a searchable database of labels that allows users to compare products might encourage greater off-label use of products. Users may compare apparently similar products and compare approved uses for each. This may result in users applying the label instructions and approved uses from one product when applying a different, competitive product. Such an approach not only has the potential to increase the risk associated with products by encouraging off-label use, but might also diminish incentives for registrants to develop new uses to put on labels through increased off-label use.

     Registrants generally prefer to have information associated with their products on their own websites. This affords a level of control over how information may be used, ensures that correct information is available and helps prevents off-label use from cross application of label instructions.

     CropLife also questions whether any benefits are likely to accrue over existing mechanisms for distributing labels, such as Infopest. Without a clear description of the objective that is sought to be achieved through implementation of this proposal and the benefits that are likely to accrue, the potential improvements in effectiveness or efficiency remain unknown.

     CropLife would welcome opportunities to work with regulators to develop mechanisms (not necessarily limited to labels) that facilitate the capacity of registrants to provide better information to users on how chemicals can be used, without encouraging greater off-label use.

3. Make no changes beyond those directly required by the Agricultural and Veterinary Chemicals Code Amendment Act 2010.

   Limiting changes to only those that are required under the Agricultural and Veterinary Chemical Code Amendment Act 2010 will not provide significantly greater benefit over and above that which is already in place. CropLife would seek greater reform to create improved benefits for users than would be provided if this option only were adopted.

   CropLife has recently examined the costs of redesigning labels to take into account new workplace chemical labelling requirements. Costs of designing, printing and applying new labels, along with the cost of training users on how to interpret new label directions and instructions, are estimated to exceed $100 million. Very clear benefits that exceed these significant costs would need to be demonstrated before proposals to require changes to printed labels could be entertained.

   Significant costs are incurred when users need to be trained to understand the information provided by new labels. Provided that this can be avoided, costs could be potentially much lower.

- *Facilitating registration of low risk products*

CropLife supports efforts to facilitate the registration of any product. However, care needs to be taken to identify those products that are genuinely of a reduced risk. Generally, an assessment of the level of risk is determined once the risk assessment has been conducted. Without that assessment, it is often not possible to determine the actual level of risk. All APVMA approved products, when used in accordance with label directions represent a low risk to users, consumers and the environment.

CropLife notes that the proposal seeks to develop a reduced risk/low risk program, which would have two elements. These are to:

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

The APVMA, irrespective of the product being assessed, must be satisfied that a product does not present an unacceptable risk to human health, environment or trade. CropLife could support the introduction of another assessment category by the APVMA to assess products that may appear to be low risk on the basis of characteristics specified in the Health Canada program. However, this presumption of low risk must be able to be recanted where closer examination demonstrates that a product might present a risk that needs to be fully assessed.

CropLife would welcome further information regarding the proposed financial implications associated with adopting a reduced risk program. CropLife would not support adoption of a program where products taking advantage of a reduced risk program are given fee and levy reductions if those reductions are the result of subsidisation from other applications. CropLife could not support a scheme that prioritised the assessment of 'low risk' product applications at the expense of conventional products.

Internationally, research and development of new agricultural chemical products is already moving towards adopting products that could be considered 'reduced risk' in response to market and consumer demands. Introduction of a 'reduced risk' scheme by the APVMA may simply be overtaken by events.

CropLife would not support adopting mechanisms that allow for the substitution of products. Substitution of lower risk products for higher risk products may be an ideal objective, but it may have significant perverse outcomes. Unlike other areas of chemical regulation, farmers require a comprehensive tool kit of chemicals to manage pests, weeds and diseases. Resistance management strategies require the use of different chemicals to remain effective. This does require periodically using chemicals that may have properties that present a greater hazard.

Substitution may be useful as part of an on-farm risk management scheme, when a user is selecting a chemical control scheme. In that case, a farmer may periodically substitute one chemical product with an alternative that presents a different hazard. This may occur when the atmospheric conditions for application mean that the risks of off-target movement may be greater for one product when compared to an alternative. Where both products are equally efficacious, substitution may be appropriate.

Substitution should not be used as justification to remove uses or cancel the registration of products. Ultimately, the substitution principle seeks to prioritise chemicals on the basis of their hazard, rather than their risk. Following the risk assessment process conducted by the APVMA, when used in accordance with established label directions, all approved products can be considered to be of acceptable risk. If a product presented an unacceptable risk to human health or the environment it would not be registered by the APVMA. Introduction of an additional substitution process to the risk assessment function will undermine the integrity of Australia's risk assessment approach to chemical regulation. It may also undermine the credibility of the APVMA as a chemical regulator.

For example, products that are approved as 'low risk' on the basis of a very low intrinsic hazard might not be as effective as established products. This could lead to a more significant and rapid development of resistant pests and weeds. A rapid loss of efficacy would undermine the APVMA's credibility as a regulator for registering products that quickly become ineffective. In the absence of substitution, resistance management strategies would largely control this risk through the use of a wide variety of chemical tools, all of which could be considered to present an acceptable risk following APVMA assessment and registration.

While CropLife has not considered the likely costs and benefits of this proposal, we consider there are likely to be significant costs associated with introduction of a substitution program that would not be outweighed through any reduction in risk.

- *Facilitating access for minor uses*

CropLife has previously submitted its views with respect to how to facilitate inclusion of minor uses on labels where there is limited economic incentive for registrants to develop the necessary data. This forces users to rely on permit applications that burden both the regulator with a large number of applications, and permit applicants (users) that need to periodically prepare and submit permit applications.

Reliance on permits and other off-label access to chemicals is an unsatisfactory solution to the problem of insufficient incentive to add uses to labels. CropLife's 2010 submission provided significant detail about the problem, and proposed measures that would substantially assist the issue (http://www.croplifeaustralia.org.au/default.asp?V_DOC_ID=2295).

CropLife has also worked with minor use industries to develop a *Submission on Reforms to Deliver Sustainable Minor Use Crop Protection Solutions for Australia's Agricultural Industries* (*Sustainable Minor Use Submission*)(March 2011).

Significantly, it recommends a new platform for the delivery of a sustainable and effective approach through a single, national regulatory framework.

The proposed reforms contained within the *Sustainable Minor Use Submission* allow Australian agricultural industries to work with other stakeholders on a commodity and national scale, to identify and develop meaningful pest, weed and disease minor use priorities, reduced risk products, risk reduction strategies and ultimately, effective, targeted crop specific Integrated Pest Management (IPM) programs. These will, in turn, provide cost effective and meaningful guidance to minor use agricultural sector organisations and to Horticulture Australia Limited, Grains Research and Development Corporation and the Rural Industries Research and Development Corporation on funding priorities for IPM, biosecurity and other areas of sustainable crop protection policy. Significantly, it combines minor use with a new initiative on risk reduction, which is a first for Australia. In so doing, the proposal as outlined in the recommendations below, addresses the key objectives contained in the preamble to the Agricultural and Veterinary Chemicals Act 1994. These recognise the importance of protecting the health and safety of human beings, animals and the environment as essential to the well being of society and the demands of ecologically sustainable development in a regulatory system.

The proposal also meets the required policy outcomes for three key elements of the proposed national policy framework for assessment, registration and control of use of Agvet chemicals approved on 10 August 2010.

The *Sustainable Minor Use Submission* proposals will:

- Effectively manage risks while minimising costs for business;
- Ensure that users in all jurisdictions have the same rights of access to agricultural chemicals (unless regional risk management measures require otherwise);
- Provide that Australia has an internationally competitive scheme that does not unduly restrict access to new and existing agricultural chemicals;
- Ensure that agricultural chemicals will be registered and available for use on as wide a range of pests, weeds and diseases as possible; and
- Ensure that access to chemicals is available for minor industries and minor uses in larger industries.

CropLife is disappointed that the Consultation RIS does not address some of the key issues associated with minor uses of agricultural chemicals. Registrants require a nationally harmonised use framework to facilitate the sort of investment needed to get minor uses onto labels.

CropLife is also disappointed that the general issue regarding the lack of resources available for research is not addressed. While registrants, research and development corporations and grower organisations can assist, this does not cover the entire agricultural industry. Investment is required to assist the development of agricultural industries sustainably through the provision of risk assessed chemical control options. While improvements in data protection are welcome and supported. and may contribute to increasing the number of uses on labels, this measure is unlikely to comprehensively address the core problem faced by minor users of chemicals.

- *Access to high-risk chemicals*

CropLife strongly supports measures that ensure only those individuals that have the necessary skills, knowledge and experience have access to high risk chemical products. State schemes that provide access to restricted chemical products (RCPs) following attainment of a set of competencies are supported. Further, these approaches to obtaining access to RCPs should be nationally consistent. The significant human health hazards that RCPs present to individuals exposed to them occurs irrespective of the jurisdiction in which the RCP is accessed.

The Consultation RIS seeks to implement a coordinated national program for control of access to, and use of high risk chemical products.

CropLife supports this objective, provided that a consistent requirement for access to these chemicals is obtained across all jurisdictions. Development of appropriate competencies should be determined by the appropriate control of use agency, rather than the APVMA. CropLife does not support adding functions to the APVMA that are not related to its core business of the risk assessment and registration of agricultural chemical products.

Access to agricultural chemicals must be restricted to those that hold an AQF Level 3 competency. This would be the minimal level of competency for using restricted chemical products. Where other risks require special skills or knowledge by the user for a product to be used safely, higher competency standards may also be applied. Previously, PSIC had for many years sought to develop a list of higher risk chemical products that would require greater competency to be used. A similar body, or an appropriate delegated authority, could be used to identify and implement additional necessary competencies. The national agency for training, licensing and accreditation identified in Section 5, Option 1 of the Consultation RIS would be an ideal body to conduct this activity.

Consideration should also be given to employing self-regulatory and co-regulatory measures to meet this objective. Agsafe's existing Accreditation and Training program is well placed to implement this measure efficiently and effectively. The current program could be modified to adopt additional functions while minimising further costs for governments (and therefore industry). The likely costs and benefits will be dependent on the governance options chosen, but CropLife would be willing to work with the Government to ensure that all options, not solely regulatory ones, are examined when seeking to achieve this option.

- *The Precautionary Principle*

Should the government wish to expressly incorporate a precautionary approach into agricultural chemical legislation, care must be taken to ensure there is a clear statement of what policy objective such incorporation would be expected to achieve. As the Consultation RIS notes, the APVMA already takes a conservative and cautionary approach to the risk assessment and registration of agricultural chemicals that in many ways would fulfil and potentially exceed, the requirements of a precautionary approach.

An express adoption of the precautionary principle has been promoted in several submissions as requiring that registrants should bear the responsibility for 'proving the safety' of agricultural chemicals.

These submissions misunderstand that the precautionary principle is not solely about 'proving safety'. Most constructions of the precautionary principle recognise that a certain magnitude of harm is required to trigger precautionary action and recognise that there are economic costs that must be considered before taking action. Misguided efforts to coopt the precautionary principle as merely a requirement for registrants to 'prove safety' misunderstand that risk assessments conducted by the APVMA do not seek to achieve zero risk, as there is always some level of uncertainty when dealing with complex natural systems and environments. Further, it completely misunderstands that applicants do need to demonstrate with high quality data that the use of their product will not present any unacceptable risks to human health, the environment or trade.

A strict interpretation of precaution is unlikely to be consistent with the stated policy objectives to provide Australia with a scheme that does not unduly restrict access to new and existing agricultural chemicals.

Applicants are already required to demonstrate the safety of their products before registration.

If it were to be adopted, a clear statement of precaution would need to be provided, with a clear understanding of what the implications would be. A precautionary approach (similar to that adopted by the European Commission) that only considers the intrinsic hazards of a chemical product without considering the assessed risk from approved use patterns should not be accepted. While not necessarily supporting inclusion of a precautionary principle in the absence of a close consideration of the likely impact upon the current regulatory scheme (the likely impact will be dependent upon the interpretation of precaution adopted) CropLife would prefer a flexible interpretation.

A flexible interpretation of the precautionary principle would allow the regulator to consider a broader range of mitigation options beyond that which would be possible under a strict interpretation. It would allow the regulator to ensure that all elements of the proposal, including the need to establish that there is a threat of serious and irreversible damage, and that response measures be cost effective, are addressed.

PERMISSIBLE USES

CropLife supports mechanisms that will provide farmers with the tools they need to grow safe, healthy and nutritious food. However, like all uses of agricultural chemicals, permissible uses of crops must be carefully considered to ensure that they do not expose consumers or the environment to unacceptable risks.

CropLife supports the existing risk assessment processes for agricultural chemical products. These processes remain the best mechanism to ensure that all the risks associated with the permissible applications of agricultural chemicals can be safely and responsibly managed. Permissible uses seek to identify a range of situations where agricultural chemicals may be used in a way that is not strictly described upon the label.

Allowing chemicals to be used in a manner other than that described on a label has potential liability implications for registrants should the use result in an adverse impact. Further, allowing permissible uses diminishes the value of the data protection that is critical to encouraging innovation, research and development necessary to add new products onto labels.

- *General access categories and permits*

  Option 1 seeks to identify a series of situations where agricultural chemicals may be used in ways that are generally regarded as safe. Such situations might include:

  - Using a chemical at a rate lower than that specified on the label;
  - Using a chemical at a frequency less than that specified on a label; and
  - Using a chemical to control a different pest to that specified on a label.

  CropLife is concerned that some of these suggestions may have deleterious impacts upon industry stewardship activities, such as resistance management strategies. These strategies ensure that chemical products are able to remain effective against target pests for as long as possible. Maintaining this effectiveness precludes the need to increase application rates at later dates to achieve an acceptable level of control.

  Application rates for products are not set at the maximum level allowed while not presenting unacceptable risks. Rather, they are set at the minimum level necessary to assure effective control of target pests. Applying chemicals at rates below those directed on labels would result in a situation where efficacy is lost, resistance has developed, and chemicals are applied without any commensurate benefit to the user.

  CropLife has similar concerns with respect to proposals to permit the use of chemicals to control pests that are not specified on product labels. To permit this type of use significantly undermines the value of data protection held by registrants of competitive products that specifically target that pest. If there are no competitive products, CropLife would be concerned with respect to how efficacy can be assured when products are applied to different pest species. Use of chemicals where no benefit accrues to the user should be discouraged at all times.

  CropLife questions whether there are legitimate reasons under implementation of IPM strategies to permit lower application rates.

  Option 2 proposes to enhance the efficiency of assessments for minor use permits. While options for improving the regulatory processes for approving permits for minor uses are supported, this approach misses the point. Currently, the APVMA is swamped with large numbers of permit applications because the current registration system does not facilitate getting minor uses onto labels. The problems associated with the permit system are a symptom of the shortcomings of the APVMA in being able to encourage investment by registrants (either independently, or in collaboration with grower organisations) to develop data to get uses onto labels.

While it is likely that there will always be some need for permits to be available in emergency situations, the current over reliance on permits to address the shortcomings of the regulatory system for minor uses is unsustainable. Comprehensive measures to address the problems associated with minor use are needed to address the minor use issue as opposed to continuing to rely on the permit system to deal with a problem that it was neither intended, nor well suited, to resolve.

- *Permissible uses for crops*

CropLife does not support off-label uses of agricultural chemicals for major crops. In addition to the reasons outlined at the beginning of this section, off-label uses for crops presents significant additional trade risks that would need to be effectively managed.

Users are often not able to manage the risks associated with such off-label use and the potential consequences are very significant, and extend well beyond the user. Excessive residues of agricultural chemicals can lead to loss of overseas export markets for entire crops. A risk of this sort will require extensive monitoring by regulators to ensure pesticide tolerances are not exceeded. Given the range of potential crop and pesticide combinations, the cost of maintaining an effective monitoring program is likely to be significant.

While the regulator may specify that a grower must take responsibility for ensuring that where they use a chemical off-label that there are no detectible residues present, users are rarely able to discern when this occurs.

Agronomists and advisors should not be permitted to provide advice that is contrary to that provided on the label. Regulators need to support and protect the integrity of label instructions. This is the key risk communication mechanism between registrants and users. The instructions to users are not merely guidance for how a product might be used, they are legally binding directions that require users to use products in a pre-determined and risk assessed manner.

Even where crops are not destined for export markets, off-label pesticide use on major crops has the potential to affect the potential human health exposures for consumers. This seriously undermines the risk basis of agricultural chemical regulation by the APVMA.

Again, the proposals for off-label uses of chemicals in crops are merely a symptom of the broader issues preventing innovation by registrants of agricultural chemicals. Addressing these core issues is likely to have greater positive impact upon availability of chemicals for users without the corresponding increased risks associated with off-label uses.

- *Management of the chemical portfolio*

CropLife has already provided extensive comments with respect to proposals to implement a re-registration system in Australia. While CropLife will not reiterate its concerns in this submission, our opposition is based on the facts that:

- Older chemical products registered by state agencies prior to the establishment of the National Registration Scheme have been reassessed to ensure that they remain safe to use;
- It will not generate reductions in risk to users, consumers or the environment and will impose significant costs that will ultimately be borne by farmers;
- A re-registration scheme is likely to result in useful chemicals that have been used with no environmental or health concerns being withdrawn because of the economic costs of supporting a product through a re-registration process;
- A re-registration process will diminish the economic return on investment for new chemical products, meaning that farmers will miss out on access to new innovative products; and
- There is no policy problem that has been identified that would be resolved by implementation of a re-registration scheme.

CropLife suggests that the Productivity Commission's recommendation for the APVMA to efficiently manage the aggregate risk of agvet chemicals was not a reference to implementation of a chemical reapplication or re-registration scheme. While currently there are limited tools available for regulators to assess the aggregate risk, international efforts to identify potential risks within the chemical portfolio are proceeding and may in the future provide useful tools.

- *Supplier compliance – importers, manufacturers and retailers/distributors*

CropLife supports proposals to provide the APVMA with a complete, modern set of compliance powers. CropLife has previously observed that the APVMA's compliance tools do not permit the Authority to tailor its enforcement responses to the range of offences that fall within its jurisdiction. Ensuring that the range of compliance tools available to the APVMA reflect is functions as a risk assessor of agricultural chemical products, the compliance tools could be expanded.

Basing the compliance tools upon guidance established by the Attorney-General's Department, and modelled on existing tools employed by other chemical regulators such as the Therapeutic Goods Administration and the National Industrial Chemicals Notification and Assessment Scheme, is appropriate.

The APVMA's compliance functions with respect to retailers and distributors should remain limited. While the APVMA must retain the appropriate tools, industry stewardship programs, as well as significant regulatory attention from other regulators (such as the Australian Competition and Consumer Commission and Safe Work Australia) mean that there is limited need for the APVMA to extend its functions into the retail sector.

CONTROL OF USE

CropLife supports national approaches to control of use. Irrespective of the governance options chosen, nationally consistent approaches to control of use will benefit industries in meeting their obligations to safely use and handle agricultural chemicals.

Jurisdictional differences in regulations controlling the safe and responsible handling of chemicals are generally not justified. While some states believe that jurisdictional changes are required to take into account the special climatic or environmental circumstances, this ignores the fact that growing regions are not bounded by state borders.

Where regional conditions require that special measures be put in place to protect a sensitive environment (such as growing regions adjacent to the Great Barrier Reef) the existing registration scheme can take these risks into account. Current permissible uses of 2,4-D in Western Australia reflects this capacity.
Nationally consistent approaches to control of use are needed to protect the integrity of the risk assessments conducted by the APVMA. Accurate risk assessments on a product are confounded when different states allow chemicals to be used off-label by users with different levels of training. As directed by the Productivity Commission, a national system must at the very least, involve 'uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.'

- *Monitoring, Auditing and Surveillance*

  The Consultation RIS proposes to establish a national program for monitoring residues of agvet chemicals and contaminants in agricultural commodities and the environment, integrated with effective auditing and surveillance.

  Significant monitoring and surveillance already occurs through much of Australia for environmental impacts of agricultural chemicals. Monitoring in Queensland and Tasmania regularly demonstrates that where agricultural chemicals are detected, they are well below any level that could be considered to present an unacceptable risk. In addition, the National Residue Survey regularly demonstrates that agricultural chemical residues rarely exceed Maximum Residue Levels.

  Collectively, the current publicly available monitoring data would indicate that most farmers and users are able to use the majority of chemicals without any adverse impacts on human health or the environment.

  CropLife is concerned that there is no clear statement of the mix of residue monitoring activities that are anticipated should this proposal be adopted. A comprehensive system of environmental monitoring is likely to be prohibitively expensive. While costs may be minimised by adopting a risk based approach, the significant costs of monitoring and testing samples may potentially significantly exceed any benefits in terms of enhanced compliance or reduced environmental risk. Without a clear proposal and a discussion of the likely costs and benefits that would accrue, CropLife could not support implementation of a comprehensive monitoring system.

  However, an approach that uses the results of existing monitoring programs to inform risk-based compliance functions may generate benefits that outweigh costs. Greater assessment of the likely costs and benefits of the various monitoring options should be considered as this option develops further.

  CropLife would welcome greater detail and further consultations with respect to proposals for effective auditing and surveillance to ensure that the benefits associated with any auditing and surveillance scheme are not exceeded by corresponding costs.

- *Record keeping*

  CropLife supports record keeping as an important part of the responsible use of chemicals. Care needs to be taken to ensure that the regulatory burden is minimised. Many users of agricultural chemicals already keep records of use for other reasons, or under the requirements of other regulatory schemes.

  Careful design of record keeping requirements can significantly reduce the regulatory burden resulting from compliance. For example, under any new record keeping requirements, existing requirements should be recognised. Users must not be required to keep additional records where these records duplicate ones already kept under other regulatory or stewardship schemes. Further, regulators should not require users to keep records of information that is freely and publicly available. Finally, users should only be required to keep the minimal record necessary to allow the regulator to meet the policy objective sought through a record keeping process.

  Ultimately, record keeping should only be used to help identify problems associated with agricultural chemical use. Record keeping should not include mandatory reporting of agricultural chemical use.

TRAINING AND LICENSING

CropLife supports proposals to implement nationally consistent competencies for all users of agricultural chemicals. As the misuse of agricultural chemicals might have impacts at long ranges from the point of application, all users must have the skills, knowledge and expertise necessary to manage the potential risks that arise from using agricultural chemicals.

The risks from use arise irrespective of whether a chemical is being used by a fee for service operator or a farmer. Similar measures must be in place for all users to enable safe use.

Currently, differences in training and licensing regimes can lead to confusing requirements for users that operate across state and territory borders, and can hinder the transferability of competencies and licences between states, increasing costs for businesses.

CropLife considers that an effective training regime must reflect the risks that users are likely to face. This should result in a graduated scheme where users that apply chemicals under direct supervision undertake basic training to ensure they can understand, read and comply with the label directions.

- *Fee for reward users*

  The Consultation RIS proposes that the Government will develop and adopt a national licensing scheme for all fee-for-reward users of agvet chemicals, which would embrace dual business/operator and/or business only licensing.

  Given the lack of detail regarding the likely costs and benefits associated with this activity, it is difficult for CropLife to provide a firm opinion with respect to this option. Further, CropLife would welcome discussions with governments to consider whether co-regulatory and self-regulatory measures could be developed that meet the objectives for a nationally consistent user licensing scheme.

- *Farmers and other occupational users*

  The Consultation RIS proposes two alternative options for training and licensing requirements for farmers and occupational users of chemicals. These are:

  - Establish a nationally agreed power to set competency requirements for users, with those requirements to be based on risk and to be consistent with the levels assumed in the assessment and registration process; or
  - Adopt a national licensing scheme for ‘commercial users’ of agvet chemicals, which could embrace dual business/operator and/or business only licensing.

CropLife recommends that superior chemical use outcomes are likely to be achieved by requiring all users that apply chemicals to complete necessary competencies. This would include operators that operate as part of a business.

Licensing ensures that users have the skills, knowledge and experience necessary to manage the risks that they come across when using chemicals. For all users, the level of competency required will need to reflect the level of risk that they are expected to manage. Individuals operating under supervision as part of a business may only require a lower level of competency to ensure that they understand information on labels and how to comply with label directions.

Other users and business operators that make risk management decisions regarding how agricultural chemicals should be applied to minimise the risk of drift, off target movement, or residue impacts should be required to demonstrate higher competency levels. This is consistent with recommendations to match the regulatory burden to the degree of risk. Higher risk activities should therefore only be allowed following a demonstration of higher level competencies.

- *Sales personnel and advisors*

CropLife does not accept that recommendations for off-label use by sales personnel or advisors can play an important part in the effectiveness and safety of agricultural chemicals. Rather, CropLife is of the view that off-label use presents a significant threat to the safe and effective use of chemicals because:

- It undermines the risk assessment conducted by the APVMA when registering a product;
- Advisors and sales personnel are not able to fully assess the risks when making off-label recommendations, potentially resulting in unanticipated or adverse outcomes;
- Consequences of adverse experiences may not be limited to the farmer or grower relying on any advice provided; and
- It undermines the incentive for registrants to develop the data to support registration of new uses on labels.

CropLife supports proposals to ensure that sales personnel and advisors are appropriately trained to provide useful and valuable advice to farmers to meet their pest management needs. However, that should not extend to providing advice that users should use a product in ways that expose users, consumers, the environment or trade to unacceptable risks.

The Consultation RIS identifies two options for accrediting sales personnel and advisors. These are to:

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

2. Recognise an industry developed scheme that trains and accredits advisors and sales persons to ensure that they are competent.

CropLife supports Option 2 as likely to generate similar benefits but at considerably lower cost than a regulated scheme. Certain aspects related to training of sales staff within Agsafe accredited premises already occurs. CropLife would be willing to work with governments to further develop self-regulatory and co-regulatory measures that will address this issue.

Formal recognition by regulators would be required, and supported, to ensure that advisors do not recommend uses of chemicals that involve unacceptable levels of risk.

CropLife would welcome further discussion regarding the likely costs and benefits resulting from implementing an accreditation scheme for advisors.

CONCLUSION

Development of a national scheme for the regulation of agricultural chemicals presents a rare opportunity to comprehensively assess the entire regulatory scheme for agricultural chemicals. CropLife welcomes all opportunities for consultation with governments as proposals are developed. It is critical that the outcome of this process, along with other parallel processes examining the best way to regulate agricultural chemicals, must be progressed carefully and thoughtfully. Registrants, users and community groups need to be fully seized of the costs and benefits associated with each option presented to be able to provide useful and considered feedback to the government.

CropLife expects that further consultations with affected industries and community groups will be required as the costs and benefits of each option are identified. Cost information in particular will be critical to determining what options are likely to deliver the best outcomes for all stakeholders at the lowest cost. While some proposed options may appear to offer benefits in terms on reduced risk or increased efficiency, they may not be adopted in circumstance where their cost far exceeds the likely benefit.
The options contained in the Consultation RIS at this stage require further consideration and discussion of likely costs and benefits. Where appropriate, options for industry self-regulation and co-regulation must also be considered.

It is important that Commonwealth, state and territory governments maintain their commitments to developing a nationally harmonised approach to agricultural chemicals. However, the potential impact upon Australian agriculture of implementing measures that are expensive and ineffective does require that options are carefully considered. It would not be acceptable to waste the current, significant opportunity to address key regulatory issues by failing to follow appropriate consultation and policy development processes.