

## EXECUTIVE SUMMARY

CropLife Australia is the peak body representing the plant science industry in Australia. Our response to the discussion paper 'A National Scheme for the Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals', outlines our proposals for a new regulatory framework for agricultural and veterinary chemicals.

We propose a three part regulatory scheme consisting of:

- Risk assessment and registration (APVMA)
- Control of Use (a new separate Commonwealth entity), and
- Recognition of industry self regulation.

This structure will enable the APVMA to focus on providing high quality and science based risk assessments and registrations. The new control of use entity will significantly reduce inconsistencies and minimise compliance costs. Recognition of industry programs will also minimise the compliance burden for governments.

Our submission also outlines proposals for a minor use scheme similar to those in the United States and Canada that would generate data for additional uses to be put onto labels for minor crops.

## RISK AND PRECUTION

### Regulating according to risk

CropLife believes that those activities and products that represent the highest risk to users, the environment, consumers and trade should be the major focus of regulatory attention.

Care must be taken to ensure that a reasonable and balanced approach to risk occurs. For example, a risk assessment process that is too conservative would preclude potentially beneficial products from being sold in Australia. A system that is too liberal may expose users, consumers, the environment and trade markets to unacceptable pesticide residues. Striking an appropriate balance require the APVMA to regulate according the risk.

### The Precautionary Principle

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 a chemical can be managed effectively. However a clear statement of the

precautionary principle means in an Australian regulatory environment would give clarity to the issue.

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

- The statement makes it clear that precaution 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 hypothetical risks are insufficient to trigger expensive regulatory responses.

### Total or aggregate risk, and risk from use

CropLife accepts that currently the APVMA cannot consider risks associated with the off-label or illegal use of a product and that this can affect the accuracy of the risk assessment conducted by the APVMA.

A more uniform approach to the control of use will be able to reduce the total risk from agricultural chemicals in Australia. Reductions in total risk are likely to accrue from greater clarity in the requirements for agricultural chemical users to manage risks in accordance with regulatory requirements, irrespective of their jurisdiction.

CropLife does not believe that risks from use should be managed by the APVMA. Instead the APVMA should focus on its role as the ultimate arbiter of risk for agricultural chemicals, and provide high quality and efficient risk assessments and registrations.

A new entity should manage risks from use and would be able to offer potentially significant reductions in risk through:

- Consistent national regulations on use;
- Consistent guidelines on training and accreditation requirements; and
- Increased registrations for minor uses to reduce the need for off label use.

### Comprehensive feedback loops

Proper feedback loops can provide valuable information and can enable more accurate risk assessments by the APVMA. Better feedback loops can also trigger other regulatory and administrative responses associated with adverse experiences. However, care needs to be taken to avoid disproportionate and excessive regulatory responses.

## Genetically modified crops

Regulation of GM crops should be commensurate with their risk. Control of use activities for GM crops should be conducted by qualified and skilled personnel. These are skills that are different to those required to regulate agricultural chemicals.

## A NEW MODEL

Several key principles must underpin a new model for agricultural chemical regulation. It must be:

- Effective
- Efficient
- Integrated
- Employ risk based regulation
- Harmonised
- Require competent users
- Employ effective feedback loops, and
- Funded equitably.

## Separate regulators

Separate regulators should be responsible for registration and assessment, and the control of use function. The functions, skills and key stakeholders are fundamentally different for each and each requires a different set of tools for effective regulation.

The two separate national entities would work collaboratively to reduce the total risk from agricultural chemicals.

To ensure national consistency and to facilitate this structure, regulatory authority for the control of use function should be conferred to the Commonwealth by all states and territories.

## Responsibilities of the new entity

The new control of use entity would be responsible for a wide range of functions associated with the responsible use of agricultural chemicals. It would administer programs such as the minor use initiative, adverse experience reporting and national residues monitoring. It would also be responsible for end-user compliance, and a cost benefit analysis should be conducted to assess the costs and benefits of this entity assuming all agricultural chemical compliance functions.

The new entity would also be responsible for community consultation and communication functions. These are critical to ensuring adequate community consultation on agricultural chemicals issues occurs.

The new entity must also have adequate capacity to set policies relevant to its functions.

## Industry self regulation

Industry's self regulatory programs (including **drumMUSTER**, ChemClear® and Agsafe Accreditation and Training) are already effective at minimising the risks from agricultural chemicals. To ensure that the new system is efficient, these should be recognised by government.

Where appropriate, the new control of use entity could also play a role in coordinating and promoting these industry schemes. Its objective would be to raise the standards of organisations and individuals not participating in these schemes to a similar level of competence.

## IMPROVEMENTS IN REGISTRATION AND ASSESSMENT

### Efficiency

CropLife has few concerns regarding the scientific rigour of APVMA assessments, however, CropLife is concerned with timeliness aspects of the APVMA's current performance.

Under CropLife's proposed new model, the APVMA would be free to focus on providing high quality, science-based risk assessments and registrations. The APVMA's other current functions would be transferred to the new control of use entity.

### Re-registration

CropLife does not support re-registration programs. They provide little real benefit in risk assessment but impose a significant additional regulatory burden on registrants. The APVMA's current powers to commence a chemical review whenever new data indicates that this is required, is a superior approach.

Re-registration programs in Europe have resulted in a loss of nearly 60% of all registered active ingredients since 1994.

### Labelling

Labels are the key mechanism for communicating information on the safe use of agricultural chemicals to users. The APVMA should retain authority for approving labels, but reinvigorate activities to reform the regulatory process for approving labels.

Other Commonwealth agencies should refrain from creating additional label requirements that have the potential to harm worker safety by adding unnecessary and confusing information.

## Compliance and monitoring

The APVMA's current approach to compliance tends to focus on compliance by existing registrants while unregistered products are openly marketed. This creates additional costs for products and registrants of low risk when compared to the higher risk of unknown and unregistered products.

CropLife believes that whatever entity is given responsibility for compliance activities, it must be given the necessary tools to effectively perform all compliance functions.

The APVMA's current monitoring and feedback loops are fragmented and incomplete. CropLife supports establishing a new national adverse experience reporting system to coordinate and collect adverse experience information from the various existing state based systems. This new system should be administered by the new control of use entity with close links to the APVMA to forward instances of adverse effects resulting from on-label use.

## IMPROVEMENTS IN CONTROL OF USE

CropLife supports development of national legislation to harmonise control of use across all jurisdictions. Currently, each jurisdiction has its own primary legislation for control of use. Rules differ significantly between states and territories. This can cause confusion among users and unnecessary regulatory burdens on registrants.

Differences occur in off-label uses, training requirements, liability for misuse, record keeping and neighbour notification.

CropLife does not support off-label uses of chemicals. While CropLife understands that there are some benefits to users from allowing agricultural chemicals to be used off-label, CropLife is concerned that this approach requires users to manage health, environmental and trade risks that they may not be well equipped to handle.

Allowing off-label use also undermines the valuable data protection given to registrants who innovate and scientifically evaluate and register specific uses at significant cost.

Nationally consistent rules for off-label uses of chemicals will not only reduce the risk from these uses, but provide a significant incentive for registrants to continue to innovate and supply the market with new, safer and softer products.

## 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.

CropLife recommends that the new control of use entity establish a scheme where agricultural chemicals are used by people with appropriate competencies. This means that activities that involve higher risks would require higher level competencies. The scheme could be complemented by industry accreditation schemes for advisors on product use.

## Minor use

A new minor use program administered by a new control of use entity and modelled on similar schemes operating in the United States and Canada would be of significant benefit to agricultural chemical users in Australia. Currently, many crops and markets are too small to justify the investment required by registrants to develop the data needed for a new use.

This results in a lack of available pesticides for small and emerging industries, and a strong temptation for growers to use products in unapproved patterns.

Government investment (estimated by CropLife to be \$4million annually) to help generate this data will not only reduce the risk from off-label uses of agricultural chemicals, but also create additional potential for these minor and emerging industries to become major income earners for Australia.

## Industry self-regulation

The agricultural chemical industry has initiated and successfully managed several self regulatory schemes (including *drumMUSTER*, ChemClear® and Agsafe Accreditation and Training). CropLife Australia members must also comply with the Agsafe Code of Conduct, the CropLife Code of Conduct, and the *International Code of Conduct in the Distribution and Use of Pesticides*.

While these programs have been successful in lifting the standards of agricultural chemical management within the industry, not all manufacturers, registrants and users participate. Official Commonwealth and State/Territory Government recognition and endorsement of these schemes would assist in promoting responsible use. Non-participants may need regulation to encourage similar standards.

## Compliance

Any new national entity will require a comprehensive suite of compliance tools that must include:

- awareness raising functions
- identifying training and competency requirements
- effective monitoring and reporting schemes
- ability to refer relevant issues to the APVMA, and
- dedicated regionally based staff.

This comprehensive suite of tools will enable the new entity to significantly reduce both intentional and unintentional non-compliance. This will reduce the enforcement burden on government.

CropLife considers that it is important the new entity not merely enforce compliance with regulation, but actively promote compliance with a range of measures.

## **COST RECOVERY**

Currently, the APVMA is funded through a mix of fees and levies on registrants. These resources fund almost all the APVMA's activities, including registration and assessment functions. CropLife recommends that the APVMA should not be given responsibility for control of use, and that this must be performed by a new entity that is adequately resourced by government to effectively perform its functions.

### Control of use requires government funding

In accordance with the Commonwealth's cost recovery guidelines, cost recovery should only be applied where it is effective, efficient and consistent with the Government's regulatory and policy objectives. For the control of use function, cost recovery is ineffective and will result in several undesirable consequences.

### Registrants' responsibility

Registrants of agricultural chemical products have responsibility to provide to the market products that can be used safely. Pre-market registration and assessment conducted by the APVMA takes into account their human health, trade and environmental risks. The costs of this assessment take into account the final price of the product. Arguments that environmental effects are negative externalities are incorrect.

In contrast, registrants are responsible for impacts that occur from the unexpected actions of third parties.

## Costs cannot be recovered from users

It is the users of agricultural chemicals that generate the need for control of use legislation. Users are also critical in reducing risks from use. Finally, users benefit most from *use* of agricultural chemicals (registrants benefit from their *sale*).

Australian farmers are also price takers, rather than price setters. Prices for their produce are set by international markets, and increases in their costs will not be able to be passed on to consumers. The price signal sought by cost recovery will be lost, resulting in a system that is neither efficient nor effective.

## Cost cannot be recovered from existing levies

Using existing levies to fund cost recovery activities would result in undesirable cross-subsidisation where higher risk products have their regulatory cost subsidised by lower risk products.

Further, arguments that cost recovery results in a more sustainable model are flawed as the use of agricultural chemicals is both seasonal and heavily dependent on climate conditions. While some activities will reduce with lower chemical use, many others (including administration, monitoring and feedback loops) will not.

Reliance on variable cost recovery does not result in financial certainty for the new entity.

## Cost recovery is inconsistent with policy objectives

Recovering costs by increasing product levies will increase the incentive for counterfeit and illegal products to be directly imported into Australia. This consequence is inconsistent with the Government's policy objective.

In Europe, detections of counterfeit products are increasing with the majority originating in China. Australia's proximity to, and strong trade links with China means that we face a real risk from counterfeit products. In these circumstances, cost recovery from existing products is strongly opposed.

## Cost recovery for registration and assessment

CropLife supports cost recovery as an effective and efficient mechanism for registration and risk assessment activities. However, the expansion of the APVMA onto areas properly the responsibility of government has resulted in significant undesirable cost shifting from government to industry.