Representing the Plant Science Industry

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19 December 2012

Committee Secretary
Senate Standing Committees on Rural and Regional Affairs and Transport
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Secretary

On behalf of CropLife Australia, I provide the attached submission to the Senate Standing Committees on Rural and Regional Affairs and Transport in respect to the *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012*.

CropLife welcomes the opportunity to present this submission to the Rural and Regional Affairs and Transport Committee inquiry to the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012. CropLife has for many years advocated for reform of agricultural chemicals regulation and has been actively engaged with the Government to assist it develop a package of reforms that deliver on commitments to reduce red tape and improve the efficiency of the agricultural chemicals regulator. Despite our considerable efforts, CropLife remains disappointed that the package of reforms introduced in the Bill:

- Do not remove or reduce any red tape;
- Introduce additional processes and procedures without any corresponding improvements in regulatory efficiency, or environmental or human health protection; and
- Increase the regulatory burden for agricultural chemical products resulting in fewer tools for users, more expensive products and less incentive to bring more modern technologies to the Australian market.

On top of failing to provide any genuine reform of agricultural chemical regulation to deliver greater efficiency, CropLife is disappointed with the inclusion of additional tests that reduce certainty for applicants and increase complexity within a regulatory system that is already excessively complex and difficult to navigate.

To assist the Committee, CropLife has attached with its submission its previous submissions in relation to this process. Many of the issues that we have sought to address at each stage of the process remain to be resolved.

CropLife looks forward to working with the Senate Committee to address the shortcomings associated with this Bill. Please do not hesitate to contact me or CropLife's Policy Manager – Crop Protection and Stewardship, Mr Ben Stapley, should you require clarification in respect to any aspect of this submission.

Yours sincerely

Matthew Cossey
Chief Executive Officer

CropLife AUSTRALIA

SUBMISSION TO

SENATE COMMITTEE ON RURAL AND REGIONAL AFFAIRS AND TRANSPORT

INQUIRY IN RESPECT TO

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL 2012

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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 agricultural biotechnology products. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are essential to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $1.5 billion per year to the Australian economy and directly employs thousands of people across the country.

CropLife and its members are committed to the stewardship of their products throughout their lifecycle and to ensuring that human health, environment and trade issues associated with agricultural chemical use in Australia are responsibly and sustainably managed. Our member companies spend more than $13 million a year on stewardship activities to ensure the safe and effective use of their products. CropLife ensures the responsible use of these products through its mandatory industry code of conduct and has set a benchmark for industry stewardship through programs such as ***drum****MUSTER*, ChemClear® and Agsafe Accreditation and Training. Our stewardship activities demonstrate our commitment to managing the impacts associated with container waste and unwanted chemicals.

The plant science industry's crop protection products include herbicides, insecticides and fungicides that are critical to maintaining and improving Australia's agricultural productivity to meet global food security challenges in coming decades. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority to ensure they present no unacceptable risk to users, consumers and the environment. Without access to these tools, farmers may potentially lose as much as 50 per cent of their annual production to pests, weeds and diseases.

Crop protection products must be used sparingly, carefully and responsibly. The responsible use of agricultural chemicals must be supported by a regulatory scheme that maximises the benefits associated with their responsible use, while minimising the costs from excessive, inappropriate and ineffective regulation. Farmers demand these products because of the benefits they provide to their businesses. While it is important for governments to provide for appropriate regulation of pesticides, any regulation must be mindful of the effects that poorly considered and excessive regulation will have through increasing production costs, discouraging investment and innovation and while not delivering any improvement in safety, health or environmental outcomes.

CropLife welcomes the opportunity to present this submission to the Rural and Regional Affairs and Transport Committee inquiry to the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012. CropLife has for many years advocated for reform of agricultural chemicals regulation and has been actively engaged with the Government to assist it develop a package of reforms that deliver on commitments to reduce red tape and improve the efficiency of the agricultural chemicals regulator. Despite our considerable efforts, CropLife remains disappointed that the package of reforms introduced in the Bill:

- Do not remove or reduce any red tape;
- Introduce additional processes and procedures without any corresponding improvements in regulatory efficiency, or environmental or human health protection; and
- Increase the regulatory burden for agricultural chemical products resulting in fewer tools for users, more expensive products and less incentive to bring more modern technologies to the Australian market.

On top of failing to provide any genuine reform of agricultural chemical regulation to deliver greater efficiency, CropLife is disappointed with the inclusion of additional tests that reduce certainty for applicants and increase complexity within a regulatory system that is already excessively complex and difficult to navigate.

CropLife is particularly disappointed that a range of measures that could have been introduced to increase the efficiency of the regulatory scheme have not been implemented. CropLife also remains concerned that several measures included in the package of reforms will not deliver any benefits in managing agricultural chemical risks. While CropLife does recognise that some of the measures in the Bill will be of benefit to applicants and registrants, there is a significant risk that those benefits will be more than countered by the additional regulatory burden imposed by this Bill.

The lack of any serious analysis of the costs and benefits of this package of amendments remains concerning to CropLife. A transparent and accountable assessment of the costs and benefits of the reforms is urgently required.

DISCONNECT BETWEEN STATED PROBLEMS AND PROPOSED REFORMS

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is a globally respected, scientifically and technically sound regulator of agricultural chemicals. It is actively engaged in programs of the Organisation for Economic Co-operation and Development to share assessment of new agricultural chemicals through international partnerships with the United States', Canadian and United Kingdom pesticide regulators. Its expertise and scientific credibility are well recognised within Australia, throughout the Asia-Pacific and globally. While the APVMA regularly produces risk assessments and registrations that are scientifically sound, it generally does so inefficiently. This has been well recognised through a number of Australian reports into regulatory efficiency in the chemicals sector and is even confirmed by the regulation impact statement used to justify these reforms.

It remains disappointing that the well-recognised need for greater regulatory efficiency has been undermined by misinformed and misdirected attempts to introduce additional administrative processes. These new processes do not address any regulatory gap. They will not result in improved health or environmental outcomes. They will only add additional unnecessary cost to an already burdensome and expensive registration system.

Current laws provide the APVMA with wide-ranging powers to control, regulate, restrict and cancel particular uses of agricultural chemicals in circumstances where there is evidence that current use patterns may be having detrimental impacts. Indeed, registrants and approval holders themselves are presently required (under section 161 of the current Act) to provide to the APVMA any information they have that may indicate a particular product represents an unacceptable risk.

Without a clear understanding of the costs and benefits that will accrue from implementation of the proposed reforms, CropLife is concerned that more regulation will result in significant additional costs on a key agricultural supply industry without generating any benefit associated with that cost.

CropLife's own investigations indicate that the potential ongoing costs from additional regulation are likely to be significant and any benefit either small or non-existent.

CropLife strongly recommends that a cost and benefit analysis must be conducted to identify the net impact of these reforms, not only on the agricultural chemical industry, but also on key agricultural industries that rely on modern crop protection tools to remain competitive and productive.

IMPLEMENTATION AND TRANSITIONAL MEASURES ARE INSUFFICIENT

Current proposed implementation dates are unrealistic, leaving insufficient time for the regulator to prepare necessary guidance material and documentation in advance of key reforms commencing. Current APVMA plans suggest that necessary supporting documentation such as the risk compendium, variation instruments and key guidance materials will not be completed until the end of 2014.

The agricultural chemical industry is now preparing applications and submissions for assessment by the APVMA after July 2013. It can take many months to prepare all the necessary paperwork for applications and to conduct all the required research and trial data to support a particular use pattern. Applicants are doing this without any certainty as to how their applications will be assessed by the regulator.

Implementation of new requirements must be delayed while necessary supporting material is developed to allow applicants to produce applications they can be assured meet all the new requirements of the reformed application and registration system.

CropLife also does not support transitional arrangements that are ignorant of the realities of the timeframe necessary to assess a chemical product. Current proposals to transition applications made prior to the implementation of the new system after only one year are insufficient. The on-clock time for a Category 1 application is currently 15 months, however, average elapsed times for a decision on an application exceed three years. Transitional arrangements should allow applications made under the current system to be determined in accordance with existing rules. The proposed transitional arrangements do not facilitate this.

WHAT'S WRONG WITH THE BILL

While some of CropLife's concerns raised in response to earlier drafts of the Agricultural and Veterinary Chemicals Legislation Amendment Bill have been addressed, several significant concerns raised by CropLife remain. These include:

- **Re-approval and re-registration**

  Current measures contained within the Bill to introduce a re-approval and re-registration system are expensive, unfair and will not deliver any better protection of workers, consumers or the environment. The additional regulatory process imposes significant added cost for no benefit.

- **Inconsistent data protection provisions**

  Despite assurances that protection for data submitted to the APVMA would be extended to ten years, the protection for data submitted as part of a reconsideration remains at eight years.

- **APVMA capacity to issue permits without the consent of a registrant**

  Allowing the APVMA to, on its own initiative, issue permits to use a product in a manner inconsistent with label instructions must only be exercised with the consent of the registrant. Registrants bear significant liability for the performance of their product and should not be forced to assume additional reputational and product risk because of decisions made by the regulator. While CropLife supports this initiative as an important mechanism to support potential introduction of a minor use program in the future, appropriate controls must be implemented to give registrants appropriate control over the use of their products.

- **Re-approval and re-registration periods based on hazard rather than risk**

  Selecting a re-approval or re-registration period that varies because of the hazard of the active constituent can lead to perverse outcomes. Products that present similar risks may be subject to different reconsideration periods simply because they use different active constituents. Despite no real difference in risk, the regulatory burden may be double for some products when compared to its marketplace competitors.

- **Introducing inappropriate and unclear concepts and language**

  New concepts such as 'unmanageable risks' and poorly defined requirements around 'undue hazards' are vague, unnecessary and are likely to build in additional uncertainty into the registration and approval processes. CropLife has advocated particular amendments to ensure that these amendments are consistent with the APVMA's regulatory approach to managing the risks of agricultural chemical products.

Indeed, the operation of key elements of the Bill are likely to hinder the introduction of innovative new products. It is claimed the Bill and associated measures will deliver increased transparency and predictability for applicants, primarily through the APVMA developing "*an overarching risk-based compendium*" that will "improve *transparency by detailing all relevant guidelines, standards and methods which would guide regulatory decisions*".

On the basis of the Government's belief that the risk-based compendium will deliver applicants with predictability as to the exact data and information the APVMA will require to assess a certain

application, the proposed Bill substantially constrains the manner with which, and the timeframes within which, applicants can engage with the APVMA to provide additional information in support of their application (under a Section 159 request). The Bill and associated regulations may require the APVMA to refuse an application if an applicant is unable to provide this additional information within the short timeframe specified in the regulations.

Croplife does not share the Government's view that the risk-based compendium will be able to provide registrants with full predictability of the APVMA's exact data and information requirements for individual applications. CropLife is particularly concerned that these changes will diminish applicants' ability to successfully register innovative new active constituents in Australia. In reality, the potential specific risks associated with a new active ingredient registration or other complex application are not always fully characterised at the time the application is lodged. Under the current system registrants have the opportunity to constructively engage with the APVMA to understand what data and information the regulator requires to reach a decision on an application, and to provide such information. Under the proposed changes, an applicant will only have a short window of time to answer an additional data request from the APVMA (proposed to be 5 months for a Category 1 application under the proposed regulations), and if the information cannot be provided, their application could be rejected.

These changes will substantially increase the business risk facing an applicant considering introducing new chemistry into the Australian market. In cases where the risk compendium is not definitive as to the information required by the APVMA, applicants will not have sufficient time to generate additional data required to address the APVMA's request, and therefore have their application rejected. Given the reputational consequences of having an application for a brand new molecule rejected in a developed market such as Australia, this aspect of the Bill will reduce the willingness of Croplife members to bring new, innovative molecules into the Australian market, ultimately to the detriment of Australian agriculture.

CropLife remains disappointed that the benefits of the reform process are significantly undermined by measures that are not targeted at the core problems of regulatory efficiency, and are ignorant of the practical effect on the APVMA's approval process. Amendments that will result in further hindrance to the approval and registration of new products must be removed from the Bill.

WHAT REFORMS ARE MISSING?

Genuine efficiency reforms that should be part of the reform process include:

- **Reducing the scope of products assessed by the APVMA**

  Dairy sanitisers, swimming pool chemicals and cleaners may not be most appropriately regulated by the APVMA and may be more appropriately controlled by another agency, if necessary. Removing these products from the APVMA's regulatory scheme will allow the Authority to focus its resources on its core business of assessing, approving and registering agricultural and veterinary active constituents and products.

- **Clarifying obligation regarding the export of agricultural chemicals exported under permit**

  Currently, some agricultural chemical products are required to have an APVMA issued permit to be exported from Australian manufacturing sites. Permitted products are treated as being 'registered' for the purposes of the Agvet Code and are therefore potentially subject to a sales levy. As the APVMA has only a very limited role in the compliance obligations related to products that are exported for use in other countries, collecting a sales levy is unnecessary. Specific amendments to ensure that products that are exported do not draw a sales levy should be introduced through this process.

- **Mechanisms to facilitate participation by all registrants and/or approval holders in generating data for active constituents and registered products that are placed under review**

  As discussed elsewhere in this submission, this includes mechanisms to encourage all approval holders and product registrants to participate in data generation activities at an early stage of the chemical review process by removing the incentive to delay decisions to generate additional data.

- **Disbanding the APVMA Advisory Board**

  Currently, this Board serves no useful purpose yet drains APVMA resources through providing sitting fees and secretariat services. Its removal would free those resources to be redirected towards core APVMA functions.

Other reforms may need additional consideration but may ultimately be implemented as part of a concerted effort to improve the efficacy and effectiveness of the Australian regulatory system. Such reforms may include:

- **Implementing an expanded scheme for classes of products of low regulatory concern**

  While this may require some further consultation with affected industries, CropLife would welcome a discussion on whether certain criteria could be established to facilitate the registration of products that would not unreasonably be expected to generate unacceptable risks to users, consumers or the environment. Again, successful implementation of a reform of this type would enable the APVMA to focus its resources on its core business of assessing, approving and registering innovative agricultural chemicals and formulated products.

- **Implementing a program to actively support minor uses for agricultural chemicals**

  While not strictly an efficiency reform, a program of this type will be critical to address some of the consequences from the proposed reforms. At any one time, the APVMA may be processing as many as 1,000 permits for minor uses. This puts a significant strain on scarce APVMA resources. A minor use program dedicated to developing data necessary to support getting new uses onto product labels would minimise the need for permits to be regularly renewed.

- **Providing for the APVMA to consider the net environmental impact associated with the removal of an agricultural chemical**

  In some circumstances, cancellation of an active constituent approval or of a chemical product may have adverse environmental consequences. In some very limited circumstances this could be used to justify some use patterns to ensure the protection of Australian ecosystems.

- **Ensuring consistency among regulators with respect to workplace safety risks**

  New national workplace legislation requires agricultural chemical users to conduct workplace risk assessments. The Government should consider whether changes to the APVMA's systems could be made to ensure that the Authority's assessments continue to provide benefits to users.

- **Providing for the APVMA to competitively source health and environmental risk assessments**

  Currently, these assessments are only conducted by the Department of Sustainability, Environment, Water, Population and Communities and the Department of Health and Ageing. Often these departments use contractors to conduct the risk assessments. Allowing the APVMA to directly contract with risk assessment providers could potentially save significant resources.

Each of these reforms represents an opportunity to reduce the red tape imposed on registrants of agricultural chemical products. Their successful implementation would increase the APVMA's efficiency and capability to deliver high quality risk assessments and registrations in a timely manner. All of these suggestions have previously been presented to the Government. It is therefore disappointing that these potential reforms have been overlooked in favour of others (such as the continuation application scheme) that will increase the industry's regulatory burdens without any evidence of improved protection for human health and the environment.

CONCLUSIONS

CropLife is committed to the safe and responsible use of agricultural chemicals in Australia. However, continual unnecessary increases in the regulatory burden on applicants, registrants and approval holders escalates the total administrative and regulatory costs of the registration system, which is likely to result in a loss of safe and useful products. Unless amendments to the Bill are made to deliver some real reductions in regulation, CropLife must conclude that the promise of cutting red tape and of a more efficient and effective regulator is merely a cover for a political policy agenda that will harm Australian agricultural producers and consumers, and not deliver any improvement in health, safety or environmental outcomes.

CropLife has engaged at every stage of consultation on development of this reform package, and with the Government directly. Our objective has been to seek to ensure that any changes to the system for managing agricultural chemicals deliver genuine improvements in efficiency, and that any additional regulatory burden is fully justified and targeted at a clearly expressed problem. For the information and consideration of the Committee, CropLife has attached these submissions.

Attachments:

A. Submission in response to Policy Discussion Paper 'Better Regulation of Agricultural and Veterinary Chemicals' (20 December 2010)

B. Supplementary submission in response to Policy Discussion Paper 'Better Regulation of Agricultural and Veterinary Chemicals – anticipated costs from implementation of a reconsideration scheme (3 February 2011)

C. Exposure Draft – Agricultural and Veterinary Chemicals Legislation Amendment Bill (29 February 2012)

D. Second Exposure Draft – Agricultural and Veterinary Chemicals Legislation Amendment Bill (22 October 2012)

E. Review of APVMA Cost Recovery Discussion Paper prepared for CropLife Australia (16 February 2012)

F. Review of APVMA Cost Recovery Discussion Paper Addendum prepared for CropLife Australia (14 June 2012)