

SUBMISSION ON THE SENATE INQUIRY INTO THE STREAMLINING REGULATIONS BILL 2018



21 December 2018

1 INTRODUCTION

CropLife Australia is the national peak industry organisation representing the plant science sector in Australia. CropLife's members are the world leading innovators, developers, manufacturers and formulators of crop protection products and crop biotechnology innovations. The plant science industry, worth more than \$20 billion a year to Australian agricultural production, provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies key to the nation's farming productivity, profitability and sustainability.

The current regulatory system for agricultural chemicals in Australia is scientifically competent and technically proficient. CropLife's only concerns with this system relate to the Australian Pesticides and Veterinary Medicines Authority's (APVMA) ability to regulate agricultural chemicals efficiently, predictably and consistently.

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. An inefficient regulatory system means access to fewer crop protection tools for Australian farmers, facilitating faster development of resistance among target pests and thus diminishing the efficacy of remaining chemical options. The economic impact of weeds alone is estimated to be in excess of \$4 billion each year, with an impact on the environment that is similar in magnitude¹. It is imperative that the regulation of crop protection products in Australia is efficient and effective to ensure Australian farmers have access to the innovative tools the plant science industry provides. This will improve the ability of Australian farmers to be internationally competitive and productive.

Defined efficiency gains from legislative reforms introduced in 2014 have not yet been realised

The Australian National Audit Office's (ANAO) 2017 performance audit report on the implementation of pesticide and veterinary medicine regulatory reform highlights the serious failure of the reform processes to deliver real regulatory efficiencies².

The Department of Agriculture and Water Resources (the Department) imposed the previous government's 2014 reform package on the APVMA without realistic implementation timeframes or sufficient funding. These two factors directly contributed to the ANAO's poor assessment of the implementation processes by the APVMA. The ANAO's detailed and considered performance audit report confirms CropLife's long-standing call that urgent action is needed. The main findings of the report reflect industry's justified criticism of the Department and are best summed up on page eight of the report that, '*...overall, the regulatory burden on industry has not been reduced since the reforms were implemented.*'

Promising signs emerged in 2016, with the APVMA's timeframe performance for assessing pesticide applications within statutory timeframes reaching 82 per cent in the September quarter. These promising signs, however, were devastated during 2017, with the regulator achieving only 24 per cent of work within statutory timeframes for crop protection products in the June quarter.

¹ Australian Weeds Strategy – A national strategy for weed management in Australia. National Resource Management Ministerial Council (2006), Australian Government Department of the Environment and Water Resources, Canberra, ACT.

² Pesticide and Veterinary Medicine Regulatory Reform, Australian National Audit Office website, sourced 29 June 2017, <https://www.anao.gov.au/work/performance-audit/pesticide-and-veterinary-medicine-regulatory-reform>

Two years later, timeframe performance for approvals of crop protection products has finally returned to the level seen in the September 2016 quarter, at 80 per cent in the September 2018 quarter. Alarming, however, just 44 per cent of complex applications that would deliver Australian farmers with new, innovative crop protection products are being approved within timeframe. The APVMA's continued inability to finalise the more complex agricultural chemical applications within timeframe denies Australian farmers access to new and innovative products that the plant science industry provides. This further limits farmers' ability to improve productivity and compete internationally.

While the improvement in overall performance is welcomed, it is disappointing that timeframe performance remains below statutory obligations and has only just recovered to levels seen prior to the November 2016 announcement of the APVMA's relocation to Armidale.

2 FAILURE TO DELIVER REGULATORY EFFICIENCY

After the less than optimum outcomes of the 2014 reform package, the Department proposed additional legislative changes in the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017* (the Operational Efficiency Bill). Unfortunately, the proposed legislative changes presented in the Operational Efficiency Bill, currently with the Senate, are not the urgent reforms needed to streamline APVMA operations in respect to the organisation's transition to Armidale. Rather, they are necessary minor amendments to reduce regulatory burden and improve operational efficiency, and have still not been delivered, three years later than originally promised. Instead of focussing on developing the urgent and necessary reforms required to assist the APVMA during the transition to Armidale, and subsequent changes in operating structure, the Department has spent more than three years seeking to rectify the failures of the 2014 reform package.

Nevertheless, following public consultation, the Operational Efficiency Bill received not only industry-wide support, but also bipartisan support. This was until the government introduced an amendment to that Bill to deliver on its rushed and ill-considered announcement during the 2018 Federal Budget to reinstate the APVMA's Governing Board without any consultation. As a result, the Operational Efficiency Bill has not yet passed the Senate, further delaying the introduction of the proposed measures to rectify errors contained in the 2014 reform package.

Disappointingly, the proposed amendments contained within the *Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulations) Bill 2018* (the Bill) fail to deliver the urgent significant reforms required to improve the efficiency of the APVMA during its disruptive physical relocation.

It is beyond time that the Department and the APVMA deliver tangible ongoing improvements to the regulation of agricultural chemicals in Australia. Without this, the regulatory inefficiencies will continue leading to hundreds of millions of dollars in lost productivity every year.

There have been many parliamentary, departmental and regulatory reviews and inquiries into the APVMA's regulatory reform processes over the last few years. CropLife and our members have constructively engaged in all previous reform agendas and proposed specific and targeted initiatives to improve the system. The importance of this regulator maintaining its technical competencies whilst significantly improving efficiencies is crucial to the plant science industry and the nation's farming sector. It's time for the development and implementation of real reform that delivers genuine improvements to the regulator's efficiency, which have been outlined by industry over many years.

The competency and capacity of the Department's senior management responsible for this policy area must be seriously questioned. Industry has invested significant time and resources over the years towards developing rational, well-considered and reasonable reform measures. These efforts have been rendered futile by the Department's inability to deliver the tangible benefits and efficiency gains such reforms would bring. The Australian agricultural sector, its supporting industries and the Australian community more broadly, demand a significantly greater level of professionalism and competence from the senior executive of the Department.

3 UNDERWHELMING REFORM PROPOSALS

The proposed additional legislative changes presented in the Bill again fail to deliver the urgent and targeted reform required to streamline APVMA regulatory functions that will assist the APVMA during its transition to Armidale. The proposed measures contained in the Bill are predominantly administrative corrections, aimed at delivering minor internal efficiency improvements. Not one proposal is expected to deliver tangible efficiency gains for industry and expedite the availability of new and innovative critical crop protection tools to Australian farmers. The Bill comes at a historic low-point in industry confidence in the Department's capability to deliver effective and implementable regulatory reform.

The Department's astounding lack of urgency and competency at delivering these reforms has culminated in the delivery of a tranche of underwhelming reform proposals, none of which will deliver any perceivable, immediate efficiency gains to the regulation of agricultural chemicals in Australia. At this rate, these reform options will be implemented after the APVMA relocates to Armidale and therefore well after they are desperately needed.

CropLife has, for more than 18 months, sought the urgent implementation of well-considered regulatory reform to address the expected significant resource and capability losses of experienced regulatory scientists at the APVMA during its transition to Armidale. Despite constructively engaging in numerous reform consultation processes with the Department, not a single piece of legislative reform has been passed by government.

CropLife and our members developed a range of specific and detailed urgent regulatory and legislative reform proposals, which were submitted to the Department for consideration in July 2017. Unfortunately, the key proposals that would deliver genuine regulatory efficiency and therefore assist in the transition to Armidale remain missing from recent Bills developed by the Department.

Despite the Bill failing to deliver reform that will deliver genuine regulatory efficiency, it does contain necessary technical corrections and minor adjustments to the legislation and there is no reason why it should not be passed.

4 MISSING REFORMS

The proposed measures put forward by CropLife would allow the APVMA to efficiently register products during the current capability crisis and ensure Australian agricultural productivity remains competitive. Disappointingly, the Bill has either excluded or amended all CropLife's proposed measures.

CropLife has strongly advocated for the introduction of an Agricultural Benefit Test, similar to the risk/benefit argument required in New Zealand, to limit the number of applications received and assessed by the APVMA. Where there is no benefit to Australian agricultural productivity, the regulator need not expend limited resources on registering another product where there are already many similar products registered and available to the market.

Increased utilisation of international regulatory information reduces the reassessment of regulatory information, thereby leading to regulatory efficiencies. While the APVMA has improved their use of international data and assessments via operational improvements, CropLife proposed the introduction of an interim international recognition registration system. In specific situations where the proposed use pattern is the same, interim international recognition registration would enable Australian farmers to access new and innovative products based on the product's registration by a respected overseas regulator, with only necessary Australian-specific assessments conducted by the APVMA. This would allow the APVMA to efficiently register products during the current capability crisis and ensure Australian agricultural productivity remains competitive.

The introduction of provisional registration would enable Australian farmers' access to new and innovative crop protection products, while outstanding lower regulatory risk requirements are completed. Small delays in registration can result in use windows being missed and new technology not being available for that season, which can be as much as a year in some circumstances. A modified version of CropLife's provisional registration proposal was originally included in the Department's consultation on the Bill. Disappointingly, the provisional registration proposal was amended to such an extent that it would have a net-negative impact on the APVMA's operational efficiency and could not be supported.

These proposed legislative reform measures would achieve the Department's intention of improving farmers' access to key crop protection tools that only their international counterparts currently enjoy, while improving the internal operational efficiency of the APVMA and allowing them to focus on achieving their core business goals. It is disappointing to CropLife and our members, as well as to Australian agriculture more broadly, that these proposals have not been included in the Bill.

5 CONCLUSION

Agricultural chemicals are cost effective, efficient, essential and sustainable tools for farmers to use to control pests, weeds and diseases. They represent a core input for modern farming systems. A streamlined, effective regulator capable of delivering timely risk assessments, approvals and registrations is essential for Australian agriculture. Any meaningful regulatory reform proposals should focus on improving the efficiency, predictability and consistency of the APVMA.

CropLife is deeply concerned that the previous government's 2014 reform package, imposed on the APVMA without realistic implementation timeframes or sufficient funding, has not delivered any quantifiable ongoing efficiency dividend, three years after implementation.

Disappointingly, the proposed legislative changes presented in the Bill still fail to deliver the urgent, targeted reforms that the APVMA desperately needs to improve operational efficiency and reduce regulatory burden during the considerable disruption of relocation to Armidale. The disruption of the physical relocation of the APVMA is likely to be felt for a number of years, despite the APVMA's commendable efforts to overhaul its internal procedures. Consequently, substantial reform is still urgently required to assist the APVMA during this very challenging period.

The Bill consists of mainly administrative corrections, which at best will deliver minor internal efficiency improvements. To assist in developing meaningful legislative reform amendments that would enable the APVMA to meet their legislative requirements and conduct their core business during its relocation, CropLife provided the Department with a range of proposals for consideration in July 2017. Few of these measures have been included in the Bill. Those that were included have been amended to a point at which they are unlikely to achieve the intended outcome of the original proposal.

Despite our frustration with the slow process and lack of proper implementation of previous legislative reforms, CropLife remains committed to continuing to work with the Department and the APVMA to create a more efficient regulator. The focus of any future reforms should be on ensuring the APVMA is capable of delivering more timely risk assessments, approvals and registrations, while maintaining the existing primacy for the protection of human health and safety and the environment.

The cost burden of the APVMA falls on the regulated entities – the developers, manufacturers and registrants of innovative crop protection products – through a cost recovery process. Delays and inefficiencies result in unnecessary costs to crucial agricultural input products. These costs end up on the farm gate. The importance of this regulator maintaining its technical competencies whilst significantly improving efficiencies is crucial to the plant science industry and the nation's farming sector.

Urgent action is needed and the importance of having the implementation of future specific and targeted reforms appropriately funded by government with well-considered and appropriate timeframes cannot be underestimated. While the Bill fails to deliver reform that will deliver genuine regulatory efficiency, it does contain necessary technical corrections and minor adjustments to the legislation and there is no reason why it should not be passed.

APPENDIX 1: THE PLANT SCIENCE INDUSTRY

CropLife member companies are the innovators, developers, manufacturers and formulators of chemical and biological crop protection products, and agricultural biotechnologies for plant breeding, such as genetically modified crops.

The plant science industry's crop protection products include fungicides, herbicides and insecticides critical to maintaining and improving Australia's agricultural productivity to meet future global food security challenges. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure they present no unacceptable risk to users, consumers, the environment and the trade of agricultural produce.

In 1995 it took the assessment of 52,500 compounds to develop one effective crop protection chemical active constituent. It now requires the assessment of more than 140,000 compounds and expenditure of more than \$400 million over an 11-year period to bring just one successful crop protection product to the market. More than one-third of this cost directly relates to compliance with regulation and registration requirements. Without access to these tools, farmers could lose as much as 50 per cent of their annual production to pests, weeds and diseases. A Deloitte Access Economics report released in 2018, '*Economic activity attributable to crop protection products*', estimates that up to \$20.6 billion of Australian agricultural output (or 73 per cent of the total value of crop production) is attributable to the use of crop protection products.³

Consumer safety is CropLife and our members' highest priority. We recognise the importance of gaining and maintaining community trust in our role in the food production supply chain. CropLife and its members are committed to the stewardship of their products throughout their lifecycle. Significant investment in stewardship activities ensures there are no unacceptable human health risks associated with agricultural chemical use in Australia and that any environment and trade issues are responsibly and sustainably managed. 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 **drumMUSTER**, ChemClear® and safety training programs run by CropLife's wholly-owned stewardship and safety organisation, Agsafe.

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. Access to fewer crop protection tools would facilitate faster development of resistance among targeted pests, diminishing the efficacy of remaining chemical options. The economic impact of weeds alone is estimated to be over \$4 billion each year, with an impact on the environment that is similar in magnitude⁴.

The current regulatory system for agricultural chemicals in Australia is scientifically competent, technically proficient and globally recognised. CropLife's only concerns with the current system relate to the APVMA's ability to regulate agricultural chemicals more efficiently. It is imperative that the regulation of crop protection products in Australia is efficient and effective to ensure Australian farmers have access to the innovative tools the plant science industry provides. This will improve the ability of Australian farmers to be internationally competitive and productive.

³ https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf

⁴ Australian Weeds Strategy – A national strategy for weed management in Australia. National Resource Management Ministerial Council (2006), Australian Government Department of the Environment and Water Resources, Canberra, ACT.