



Representing *the best* of the plant science industry

**SUBMISSION TO SENATE RURAL AND REGIONAL AFFAIRS AND TRANSPORT
LEGISLATION COMMITTEE: AGRICULTURAL AND VETERINARY CHEMICALS
LEGISLATION AMENDMENT (AUSTRALIAN PESTICIDES AND VETERINARY
MEDICINES AUTHORITY BOARD AND OTHER IMPROVEMENTS) Bill [Provisions]**



10 October 2019

1 INTRODUCTION

CropLife Australia is the national peak industry organisation representing the agricultural chemical and plant biotechnology sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators 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 biotechnology products that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than \$20 billion a year to the Australian economy and directly employs thousands of people across the country. CropLife Australia is part of the International Federation of 91 national associations globally.

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 more internationally competitive, productive, profitable and environmentally sustainable.

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 then 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 when the APVMA began relocating to Armidale. The regulator achieved only 24 per cent of work within statutory timeframes for crop protection products in the June 2017 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 finally returned to the level seen prior to the announcement of the relocation of the APVMA to Armidale, at 80 per cent in the September 2018 quarter. Since then, however, overall timeframe performance has plateaued, at 85 per cent in the June 2019 quarter. As a result of significant operational improvements by the APVMA, the number of complex applications that would deliver Australian farmers with new, innovative crop protection products currently being approved within timeframe has improved from just 44 per cent in the September 2018 quarter to 66 per cent in the June 2019 quarter. Nevertheless, the APVMA's continued inability to finalise more than two-thirds of 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 and highlights the urgent need for meaningful reform to streamline the APVMA's functions.

To this end, the government recently committed to conducting a comprehensive review of the regulatory framework underpinning the National Registration Scheme for the agricultural and veterinary chemicals regulatory environment, with the review panel due to deliver its report to the Minister for Agriculture by February 2021. In conducting the review, an expert panel will consider the framework's aims, structure and operation and have regard to the regulatory roles and responsibilities at national, state and territory levels. By proposing to re-instate the APVMA's Governing Board, the government is inappropriately pre-empting the outcome of that review.

An APVMA Governing Board

Since relocation of the APVMA to Armidale was announced, CropLife has sought the urgent implementation of regulatory amendments to substantially streamline operations, enabling the APVMA to continue to effectively function while transitioning to Armidale. The cost of agricultural chemical regulation is already three times greater per product per annum in Australia than in the United States, despite the Australian market being a tenth of the size of the US market. It is therefore disappointing that the government has chosen to pursue the urgent implementation of an APVMA Governing Board, instead of regulatory reforms that are at least capable of delivering regulatory efficiency.

Despite our lack of support for the urgency and necessity of a Governing Board for the APVMA, CropLife provided the Department with specific criteria required for a Governing Board to be effective and protect the independent evidence- and science-based decision-making of the APVMA.

The direct and associated costs of a Board should be fully funded by government as an appropriate contribution to the effective operations of the Regulator. Without government funding, the cost of a Governing Board would be an additional direct cost to the farming sector, further limiting access to crucial crop protection products by farmers. The \$600,000 a year cost attributed to the APVMA Governing Board, as referenced in Senate Estimates³ in May 2018, is an exorbitant and unnecessary cost to what is already one of the world's most expensive agricultural chemical regulators for industry.

The APVMA has previously had a governance board. It was abolished in 2007 following recommendations made in the independent Review of Corporate Governance of Statutory Authorities and Office Holders. The agency now has a functioning governance structure, including an audit committee with external appointees. Any changes to this should only be implemented after proper and comprehensive assessment and consideration. It is clear and disappointing that the government hasn't properly considered other lower cost governance and management oversight measures.

³ Rural and Regional Affairs and Transport Legislation Committee Senate Estimates Hansard, Wednesday, 23 May 2018, page 95

CropLife and our members do not, in principle, oppose governance structures like a board of directors. What we do oppose is ill-considered politically motivated initiatives that impose significant costs on the farming sector without corresponding improvements.

On behalf of CropLife members and the entire Australian plant science industry, CropLife has repeatedly respectfully requested that the government withdraw from this Bill the provision that would establish an APVMA Governing Board. This will allow appropriate analysis and genuine industry and farmer consultation on the development of a governance arrangement that could add genuine value to the APVMA, rather than just an additional layer of costly administration and management.

2 FAILURE TO DELIVER REGULATORY EFFICIENCY

After the less than optimum outcomes of the 2014 reform package, the then Department of Agriculture and Water Resources (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 were not the urgent reforms needed to streamline APVMA operations in respect to the organisation's transition to Armidale.

Instead, they were 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, without any consultation, 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. As a result, the Operational Efficiency Bill failed to pass 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 Regulation) Bill 2018* (the Streamlining Regulation Bill) also failed to deliver the urgent significant reforms required to improve the efficiency of the APVMA during its disruptive physical relocation. The proposed measures contained in the Bill were predominantly administrative corrections, aimed at delivering minor internal efficiency improvements. Nevertheless, the Streamlining Regulation Bill received industry support when it was introduced to Parliament in October 2018. The Streamlining Regulation Bill was referred to the Rural and Regional Affairs and Transport Legislation Committee in November 2018, which recommended the Bill be passed. Disappointingly, the Streamlining Regulation Bill lapsed at dissolution on 11 April 2019.

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 was passed by the government prior to completion of the relocation in July 2019.

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 were missing from both recent Bills developed by the Department of Agriculture.

The government has now merged the Operational Efficiency Bill and the Streamlining Regulation Bill into the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019* (the Bill), after removing one provision from the Streamlining Regulation Bill that would have provided an accreditation scheme for external assessors. CropLife is extremely disappointed that the government has chosen to ignore calls from industry to remove the provision to implement an APVMA Governing Board and engage in meaningful consultation to determine the most appropriate governance structure for the APVMA, and that instead, the new Bill contains this poorly thought out proposal.

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 the 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. Without this, regulatory inefficiencies will continue leading to hundreds of millions of dollars in lost productivity every year.

3 RE-INTRODUCTION OF APVMA GOVERNING BOARD IS NOT SUPPORTED

In its original form, the Operational Efficiency Bill 2017 passed the House of Representatives on 12 February 2018, more than 18 months ago, with the support of the plant science industry and farming sector organisations. The Operational Efficiency Bill in its original form also received bi-partisan support. The government subsequently sought to amend its own Operational Efficiency Bill in the Senate to introduce an ill-considered and expensive Governing Board for the APVMA. This amendment was undertaken without proper consultation or consideration of the impact on industry and Australian farmers and without due consideration of the feasibility of alternative, lower cost and more effective options.

The APVMA's previous governance board was abolished in 2007, following recommendations made in the independent Review of Corporate Governance of Statutory Authorities and Office Holders (the Uhrig Review).⁴ This review recommended that statutory authorities only implement governance boards where they can be given the full power to act. Considering the APVMA's function as a globally respected, scientifically and technically sound independent regulator of agricultural chemicals and veterinary medicines, it would be wholly inappropriate for any board to make or influence normal regulatory and registration decisions. The original amendment to the Operational Efficiency Bill had to be significantly revised since originally presented to rectify major errors, highlighting the rushed and ill-considered approach taken by government.

Any governing board should be skills-based, responsible for setting the strategic direction and overseeing the financial and operational performance of the APVMA. As stipulated by the Uhrig Review, the Board must not have the power to make or influence the normal regulatory and registration decisions of the APVMA. As originally presented, however, the amendment provided no protection for the independent, science- and evidence-based regulatory decision-making undertaken by the APVMA. This would have enabled APVMA regulatory decisions to be potentially influenced by political agendas and campaigns by activist organisations. For this reason, it is no surprise that the amendment was, and still is not supported by the plant science, animal medicine or farming sectors.

The APVMA currently has a functioning governance structure, including an audit committee with external appointees, and changes should only be implemented after proper and comprehensive assessment and consideration. Adding an additional layer of bureaucracy also comes at the significant cost of \$600,000 per year, a cost that will ultimately be borne by Australian farmers. The government is only funding the nominal first year costs, which means its ongoing costs will ultimately fall to Australia's farmers, who should not be expected to foot the bill – especially at a time when so many are doing it tough, due to extreme drought conditions.

⁴ <https://www.finance.gov.au/sites/default/files/Uhrig-Report.pdf>

4 CONCLUSION

Agricultural chemicals are cost-effective, efficient, essential and sustainable tools for farmers 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 resulting from the considerable disruption of relocation to Armidale. The disruption resulting from 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. The Bill does, however, contain necessary technical corrections and minor adjustments to the legislation. CropLife is frustrated that the untimely, poorly considered proposal to re-instate the APVMA's Governing Board has resulted in the delay in having these other, non-controversial measures introduced.

Despite our frustration with the slow process, the lack of proper implementation of previous legislative reforms and the government's determination to re-instate the APVMA's Governing Board without adequate consideration or consultation, CropLife remains committed to continuing to work with the Department of Agriculture and the APVMA to create a more efficient regulator. CropLife's chief concern with the Bill is that appropriate analysis and genuine industry and farmer consultation on the development of a governance arrangement that could add genuine value to the APVMA, rather than just an additional layer of costly administration and management, has not occurred.

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. Any additional costs associated with the registration of crucial agricultural and veterinary chemical products would ultimately be borne by farmers. Without government funding, the additional \$600,000 a year cost required to maintain an APVMA Governing Board will undoubtedly end up at the farm gate. The government's commitment to fund just the nominal first year costs ensures that Australian farmers will be expected to foot this exorbitant and unnecessary cost for three years before a review to determine whether the re-introduction of the Board has led to any conceivable efficiency gains to the APVMA's operations has been completed.

The APVMA's Governing Board was abolished following the Uhrig Review's 2003 recommendation that statutory authorities only implement governance boards where they can be given the full power to act. Having acknowledged that such a board would, under no circumstances have the power to make or influence the normal regulatory and registration decisions of the APVMA, the government's intended purpose for re-instating the APVMA Governing Board is unclear. The proposal to re-instate the Board inappropriately pre-empts the outcomes of the recently announced review of the regulatory framework underpinning the National Registration Scheme for the agricultural and veterinary chemicals regulatory environment. Any consideration of significantly altering the governance structure of the APVMA should be deferred until this report has been delivered.

On behalf of CropLife members and the entire Australian plant science industry, CropLife will continue to respectfully request that the Government withdraw from this Bill the provision that would re-establish an APVMA Governing Board.

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.⁵

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 ensuring human health and safety, and the responsible and sustainable management of the environment and trade issues associated with agricultural chemical use in Australia. Our member companies contribute millions of dollars each 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 **drumMUSTER**, ChemClear® and Agsafe Accreditation and Training. Our stewardship activities demonstrate our commitment to managing the impacts associated with container waste and unwanted chemicals.

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 magnitude⁶.

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.

⁵ https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf

⁶ 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.