CropLife AUSTRALIA

*Representing **the best** of the plant science industry*

SUBMISSION ON THE REVIEW OF AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT ACT 2013

29 March 2019

1 INTRODUCTION

CropLife Australia is the national peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife makes this submission on behalf of our member companies who are the innovators, developers, manufacturers and formulators of chemical and biological crop protection products, and agricultural biotechnologies for plant breeding.

CropLife welcomes the opportunity to participate in the review of the operation of the amendments to legislation made by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Amendment Act).

While recognising that the Australian Pesticide and Veterinary Medicine Authority (APVMA) is scientifically competent and technically proficient, and the associated legislative and regulatory frameworks are robust, CropLife continues to be concerned with the structural and operational inefficiencies for agricultural chemical regulation in Australia. Furthermore, concerns remain with the ability of the APVMA to continue to improve its operational efficiency compared to its international equivalents.

The fact that so many legislative changes and requirements remain outstanding, as referenced in the subsequent sections of this submission, really stands as testament to the fact that the Amendment Act was at best, a lost opportunity for genuine regulatory reform.

1.1 The true effectiveness of legislative reforms introduced in 2014 has been hidden by the disruption caused by the physical relocation of the APVMA

The disruption caused by the physical relocation of the APVMA is likely to be felt for some years after the relocation has been completed. Despite the APVMA's commendable efforts to overhaul its internal procedures, substantial reform is still urgently required to assist the APVMA during this very challenging period.

To assist in developing meaningful legislative amendments that enable the APVMA to meet their legislative requirements and conduct their core business during the transition of the Regulator to Armidale, CropLife provided the Department of Agriculture and Water Resources (the Department) with a range of urgent regulatory and legislative reform proposals for consideration in July 2017. These proposed measures would allow the APVMA to efficiently register products during the current capability crisis and ensure Australian agricultural productivity remains competitive. Disappointingly, few of these proposed legislative reforms have been included in the recent legislative amendment Bills, and those that have, have been amended such that they are unlikely to achieve the intended outcome of the original proposal.

1.2 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 efficiency[1].

Promising signs emerged in 2016, with the APVMA's timeframe performance for assessing pesticide applications within statutory timeframes reaching 83 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 2017 quarter. While timeframe performance for approvals of crop protection products has improved

[1] *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*

recently, it has taken two years to return to the level seen prior to the relocation announcement in the September 2016 quarter, at 86 per cent in the December 2018 quarter. These improvements in overall performance are welcomed, however, it is alarming that just 57 per cent of complex applications that would deliver Australian farmers 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, further limiting the ability of farmers to improve productivity and compete internationally. Again, it must be emphasised that any measurement of the operational gains made by the 2013 legislative reforms are confounded by the high attrition of experienced technical staff from the agency due to its relocation to Armidale.

The Department imposed the previous Government's 2013 reform package on the APVMA without realistic implementation timeframes or sufficient funding, which has also directly contributed to the poor assessment by the ANAO. The proposed legislative changes presented in the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*, currently before 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.

Nevertheless, following public consultation, the Operational Efficiency Bill 2017 received not only industry support, but also bipartisan government support, until the Government introduced an amendment to that Bill to deliver on its announcement during the 2018 Federal Budget to reinstate the APVMA's Governing Board. As a result, the Operational Efficiency Bill 2017 has not yet passed the Senate, further delaying the introduction of the proposed measures to rectify errors contained in the 2013 reform package.

1.3 Calls for urgent, targeted and well-considered reform unheeded

The proposed additional legislative changes presented in the *Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulations) Bill 2018* (the Streamlining Regulations 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, and indeed transition it to a next generation regulator. The one proposal that may have delivered tangible efficiency gains for industry and delivered critical crop protection tools to Australian farmers – a pathway for provisional registration – was removed from the Streamlining Regulations Bill following consultation with affected industries, as it contained limitations that would have negated any potential benefit. Instead, the proposed measure would simply have created additional administrative burden for the APVMA to implement. The Streamlining Regulations Bill came at a historic low-point in industry confidence in the Department's capability to deliver effective and implementable regulatory reform.

CropLife has, for more than 12 months, sought the urgent implementation of well-considered regulatory reform to address the expected significant resource and capability losses of experienced regulatory scientists by the APVMA during its transition to Armidale. Despite constructively engaging in several reform consultation processes with the Department, numerous legislative reforms, which would have significant benefit to industry, are yet to be passed into legislation.

CropLife and our members are disappointed by the Government's apparent lack of urgency in drafting and implementing the urgent and necessary legislative reform required to assist the APVMA in meeting their legislative requirements and conducting their core business during the transition of the Regulator to Armidale. To assist in achieving this outcome, CropLife and our members developed a range of urgent regulatory and legislative reform proposals, which were submitted to the Department for consideration in July 2017.

Urgent, well-considered reform is required to maintain a high level of integrity in Australia's agricultural and veterinary chemical regulatory system, and in-turn maintain community confidence.

1.4 Missing reforms

Disappointingly, few of CropLife's proposed measures have been included in the recent legislative amendment Bills, which instead include proposals that are predominantly administrative corrections, aimed at delivering minor internal efficiency improvements. 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 closely similar products registered and available to the market.

Similarly, CropLife has long advocated for increased utilisation of international regulatory information. 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.

Both proposed legislative reform measures would achieve the Department's intention of improving the access of farmers to key crop protection tools that only their international counterparts currently enjoy, while improving the internal operational efficiency of the Regulator and allowing them to focus on achieving their core business goals. It is therefore disappointing to CropLife and our members, as well as to Australian agriculture more broadly, that neither proposal was included in the Streamlining Regulations Bill.

It is beyond time that the Department and the APVMA deliver tangible ongoing improvements to the regulation of agricultural chemicals in Australia, otherwise the hundreds of millions of dollars every year in lost productivity currently experienced due to regulatory inefficiency will continue and worsen into the future.

CropLife and our members have constructively engaged for years in all previous reform agendas and proposed specific initiatives to improve the system. Despite our frustration with the slow process and lack of proper implementation of these reforms, we remain committed to continuing to work constructively with the Government to ensure Australia has the world's best agricultural chemical regulator.

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 simply beyond time for the development and implementation of real reform that delivers genuine improvements to the Regulator's efficiency. That stated, the industry does not have faith that the Department has the capacity, competencies or inclination to properly develop such a legislative reform package, and also has concerns that the APVMA needs a period of some years to stabilise in light of the disruption it has been subjected to over the last five or more years.

2 APPLICATION ASSESSMENT EFFICIENCY AND EFFECTIVENESS

The true measure of the effective operation of the amendments contained in the Amendment Act is being hidden by the disruption caused by the physical relocation of the APVMA to Armidale. While timeframe performance for approval of crop protection products has improved recently, it has only just recovered to the level seen prior to the relocation announcement in the September 2016 quarter, at just 86 per cent in the December 2018 quarter. These improvements in overall performance are welcomed, however, it is alarming that just 57 per cent of complex applications that would deliver Australian farmers with new, innovative crop protection products are being approved within timeframe.

While CropLife and our members have observed some recent improvements in predictability of assessment timeframes, it is unclear whether this is a direct consequence of the introduction of an 'elapsed time' model to replace the previous 'stop the clock' model. Instead, it appears this improvement is a consequence of operational efforts by the APVMA to meet timeframes more consistently and is unrelated to the method used to measure assessment timeframes.

Nevertheless, the introduction of timeshift applications has significantly improved the predictability of applications eligible for that pathway. CropLife has long advocated for and supported the expansion of the current timeshift application options contained in the *Agricultural and Veterinary Chemicals Legislation Amendment Regulations 2018*. CropLife welcomes the passing of these reforms into legislation.

These changes will incentivise registrants to begin the longer assessments of chemistry, worker health and safety and environmental safety, while residue, efficacy and crop safety trials are being conducted. This will contribute a meaningful improvement to market access, ultimately improving farmers' access to innovative, new crop protection products.

The intent of the 2014 regulatory reforms, which was to restrict the information that the APVMA can take into account when considering an application, must be maintained, However, to ensure the efficiency gains delivered in that reform process are not compromised, it is essential that project plans are structured in such a manner that data packages developed and submitted following project plan initiation are submitted in full.

CropLife and our members consider that the 'shut the gate provisions' have been effective in improving application quality. Expansion of the APVMA's current timeshift application provisions will enable applicants to negotiate project plans with the APVMA, to set out the timeframe for conducting necessary assessments and facilitate more timely application assessments. In this manner, applicants may provide data required for chemistry and toxicology assessments while Australian-specific efficacy and environmental safety data is generated in a structured and predictable manner. Similarly, the pre-application assistance program provides applicants with additional confidence that an application meets the APVMA's requirements prior to submission.

Retention of the preliminary assessment process is supported. The preliminary assessment process is essential for ensuring that an application has been submitted correctly and that all relevant assessment modules have been addressed by the application.

CropLife supports the view that providing the APVMA more flexibility to manage minor errors at preliminary assessment would remove some of the unnecessary administrative burden currently placed on the APVMA and applicants. As such, the proposal presented in the *Agricultural and Veterinary Chemicals Legislation Amendment Regulations 2018* consultation document to enable the APVMA to provide one opportunity for an applicant to address identified deficiencies during preliminary assessment is supported. It is paramount, however, that sufficient guidance is developed operationally by the APVMA to ensure consistency in what is considered to be reasonably rectifiable. Until such guidance has been developed and the APVMA's requirements are clear, imposing additional fees on applicants for not providing all required information is not acceptable.

Limiting the proposed measure to just one opportunity for the applicant to address identified deficiencies is essential to avoid increasing administrative burden by allowing applicants to repeatedly correct mistakes that are considered by the APVMA to be reasonably rectifiable.

CropLife has long advocated for increased utilisation of international regulatory information and is pleased that the APVMA has improved their use of international data and assessments via practical and efficient operational improvements. The improved use of international data and assessments is now being realised as efficiency gains in the application assessment process.

It is disappointing, however, that CropLife's proposal to introduce an interim international recognition registration system has not been included in recent legislative amendment Bills. In specific situations where the proposed use pattern is the same, interim international recognition registration would enable access by Australian farmers 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.

Both 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 Regulator and allowing them to focus on achieving their core business goals.

CropLife does not support the introduction of greater flexibility in the time period within which applicants may rectify defects in applications. The information required to rectify an application is non-technical and generally administrative. As such, the additional information can be provided quickly by the applicant. Allowing greater flexibility for applicants to provide non-technical and administrative information may inadvertently erode the efficiencies gained by implementing the 'stop the clock provisions'.

While CropLife supports efforts by the Department and the APVMA to improve application quality, it is essential that tailored, detailed guidance material is developed in collaboration with industry to ensure that the APVMA's requirements are fully realised by applicants.

3 RECONSIDERATIONS

The introduction of work plans and statutory timeframes for the completion of reconsiderations has improved transparency regarding the intent and progress of chemical reconsiderations. In addition, focussing reconsiderations on specific areas of concern, and specifying the information the APVMA must take into account for a reconsideration, have significantly improved the efficiency of the reconsideration process.

Prior to July 2014, chemical reconsiderations were not time-limited. That is, the APVMA was not required to complete reconsiderations within a statutory timeframe. Instead, the timeframe of each reconsideration varied, determined by its scope. Under the previous legislative requirements, companies were permitted to provide information relevant to the reconsideration at any time. While it is extremely important that the APVMA has access to all available scientific information in order to conduct their detailed assessments, allowing for the provision of additional data during the reconsideration process often resulted in the revision of component risk assessment reports. This, in turn, required additional consultation and publication, significantly delaying the finalisation of the review.

Legislative amendments that came into effect on 1 July 2014 limited the maximum prescribed timeframe to complete a formal reconsideration to 57 months and a prescribed formula was developed to determine the appropriate timeframe required to assess each chemical. Companies are still required by law to immediately provide any relevant, new scientific information to the APVMA that either contradicts the current information entered in the record or shows that a product or constituent may not meet the safety, trade or efficacy criteria. In order to be considered as a part of the reconsideration process, the new data must, however, be provided within defined timeframes (with exceptions where absolutely necessary).

These legislative amendments ensure that future reconsiderations will be conducted in a more transparent, predictable and efficient process. Unfortunately, while a number of significant chemical reconsiderations were tracking to be completed by their newly determined statutory deadlines during 2017 and 2018, CropLife believes the relocation of the APVMA to Armidale from Canberra and subsequent loss of experienced staff delayed their finalisation.

This disruption is likely to be felt for some years after the relocation has been completed. As the APVMA's reconsideration program is a public benefit function, CropLife recommends it be funded through general revenue, in line with the APVMA's international regulatory counterparts. This would improve the Regulator's capability in this important area and neutralise criticisms and concerns regarding the APVMA's independence.

CropLife strongly supports repeal of the re-approval and re-registration scheme in Australia which was enacted by the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014.*

The APVMA takes new data and scientific information into account when considering the ongoing safety of a registered product. Under Section 161 of the *Agricultural and Veterinary Chemicals Code Act 1994*, agricultural chemical registrants have a statutory obligation to provide the APVMA with any relevant new data regarding their products, as and when it becomes available. Information is relevant if it either contradicts the current information entered in the record or shows a product or constituent may not meet the safety, trade or efficacy criteria.

This provides a highly responsive regulatory review system, where a formal review or 'reconsideration' focusses on new scientific information, rather than a purely administrative process and it can be initiated at any time. Under this regulatory scheme, the ongoing human, animal health and/or environmental safety of an agricultural or veterinary chemical product is constantly monitored and action triggered by the provision of credible, new scientific information that questions the existing regulatory conditions. Far from highlighting a failure of the regulatory sector in Australia, the APVMA's proactive and comprehensive response to the 2015 International Agency for Research on Cancer (IARC) monograph on glyphosate highlights the responsive and transparent nature of the APVMA's regulatory process.

APVMA regulatory decisions following nominations for reconsideration are based on science and evidence, not the commercial interests of the various industry stakeholders affected by the APVMA's decisions, or the political pressure resulting from activist, anti-modern farming campaigns that rapidly permeate the media commentary and community sentiment. Anyone can nominate a chemical or chemical product for reconsideration by the APVMA, however, a nomination is only accepted where there is a scientific basis for the nomination.

The APVMA often initiates interim regulatory action during a formal reconsideration to mitigate any risks identified in relation to the use of the chemical under investigation. In this manner, unacceptable risks associated with the use of an agricultural or veterinary chemical product can be managed prior to the finalisation of a complex and lengthy formal reconsideration.

All proposed regulatory decisions relating to the reconsideration of an existing product are subject to a comprehensive and transparent period of public consultation prior to being finalised.

While the European Union (EU), Canadian and American regulators all employ cyclical re-approval and re-registration schemes, this model demonstrates in all jurisdictions that it is unnecessarily burdensome and duplicative, resulting in lengthy delays to assessment timeframes.

Health Canada's Pesticide Management Regulatory Agency (the PMRA) has publicly stated that the current re-evaluation workload is not sustainable, and the agency lacks the resources to cope with the upcoming wave of re-evaluations. In fact, the PMRA is currently reviewing its re-approval and re-registration program to explore adopting alternative post-market review processes. There are more than 70 active constituents scheduled for cyclical re-evaluation by the PMRA. This number is, however, expected to increase significantly over the next 10 years, as around 370 older active constituents re-evaluated in the early 2000s are scheduled to enter the cyclical re-evaluation system. Similarly, as of June 2018 there are 23 active constituents subject to a Special Review. Although these reviews typically take around two to four years to complete, the PMRA has indicated that they expect almost half (43 per cent) to exceed four years.

Similar to Canada's PMRA, the US Environmental Protection Agency (EPA) conducts registration reviews of registered pesticides every 15 years to determine whether they continue to meet existing standards for registration and has the ability to conduct a Special Review at any time. As of the end of the 2017 financial year, the US EPA has completed and implemented the final decisions of less than one-third of registration reviews commenced since 2007. [2]

When compared with single jurisdiction countries, such as Australia, the United States and Canada, the EU regulatory system, with the ability to split the considerable regulatory burden of re-assessing all chemicals every 10 or 15 years[3] among member states, should be more capable of managing a cyclical re-assessment program. The EU re-assessment program is, however, not delivering the desired outcomes in a timely fashion, with less than 14 per cent of scheduled re-assessments finalised since its introduction in 2007.[4] Noting that approval is extended where the re-assessment is delayed for reasons beyond the control of the applicant[5], it is difficult to see just what this process is achieving, other than draining the regulator's resources, clogging up the regulatory system and distracting European regulators from reacting to, and assessing genuine areas of concern.

Rather than directing regulatory attention to specific areas where there is credible scientific evidence demonstrating potential risks to human and animal health or environmental safety, EU regulators are instead conducting lengthy, unnecessary reviews of entire data packages, where there is no cause for concern. This distraction does not serve the best interests of government, chemical product manufacturers, farmers or consumers within the EU.

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2 https://www.epa.gov/sites/production/files/2018-03/documents/mf-accomp-reevaluation-fy17-final_1.pdf

3 Active substances are renewed for 15 years under the current Regulation (EC) 1107/2008 Article 14.2, and for 10 years in the preceding legislation Directive 91/414/EEC Article 4.4

4 ECPA (European Crop Protection Association) estimations

5 Regulation (EC) 1107/2009, Article 17

The demonstrated inability of these much larger and highly experienced regulators to implement a successful, efficient re-registration program, despite receiving substantial government funding, serves to highlight that such programs are not feasible and do not serve the best interests of our community. Introducing a similar, unnecessary and duplicative system in Australia should continue to be avoided.

4 COMPLIANCE AND ENFORCEMENT

CropLife has long advocated for increased compliance and enforcement powers to be granted to the APVMA and, as such, supported the provisions contained within the Amendment Act. While it could be argued that insufficient time has passed to allow a thorough consideration of the operation of these provisions, the APVMA appears to have utilised the increased ability to enforce compliance to good effect. Noting the significant and growing problem of counterfeit and illegal crop protection products around the world, it is crucial that the APVMA has all necessary powers and ensures that its compliance and enforcement efforts remain focused on the highest threat and risk areas to the community and farming sector.

As the APVMA's compliance and enforcement capabilities perform a public benefit function, CropLife recommends it be funded through general revenue, to further improve the Regulator's capability in this important area.

While CropLife supports any effort to simplify the legislation, replacing legislative offences with conditions of registration serves only to shorten the legislation and does not resolve its inherent complexity or simplify compliance activities.

CropLife support the use of a single consolidated legislative instrument governing Commonwealth compliance activities. Triggering the regulatory powers act will significantly reduce the length of the APVMAs legislation, improve consistency in decision-making and make it easier for the industry to know their rights and responsibilities.

CropLife strongly supports the use of legislative instruments to enable the APVMA to quickly and efficiently enact change. This activity must, however, be sufficiently resourced and empowered through the APVMA with a transparent mechanism to allow industry engagement. CropLife's experience with legislative instruments has demonstrated that once the Department becomes involved, productivity and efficiency gains diminish significantly. It is noted that the current licencing scheme for veterinary chemical products is captured by an existing legislative instrument. CropLife does not support any extension of the licensing scheme to include the manufacture of agricultural chemical products in Australia.

5 IMPROVE CONSISTENCY IN DATA PROTECTION PROVISIONS

CropLife has long advocated for greater incentives in the form of extended data protection periods for product registrants to generate data to support the ongoing registration of crop protection products in Australia, and to extend the use of registered products into minor uses and specialty crops. While CropLife and our members support the extension of data protection periods, the provisions remain complex and difficult for product registrants to understand.

Insufficient time has elapsed to facilitate a thorough assessment of the introduced measure to extend the data protection period provided to applicants when submitting relevant, required data to a chemical reconsideration. Nevertheless, CropLife and our members consider that increasing the data protection period to eight years from the reconsideration decision point is a significant incentive for applicants to invest in conducting relevant trials to generate the required data to support the ongoing registration of a registered product.

CropLife has long advocated for and as such, supports the introduction of additional data protection for the addition of minor uses to existing product labels, as proposed in the Streamlining Regulations Bill 2018. This proposal will complement the crop groupings project and minor use programs. We do not, however, support the proposal to provide longer data protection periods to animal species, simply because of the small number of animal commodity groups. The duration of additional data protection periods should instead reflect the cost of data generation and identified industry priorities. Consideration should be given to linking the proposed increases in limitation and protection periods with identified industry priorities, as outlined in the 2016 project report *Delivery of Access to AgVet Chemicals Collaborative System*[6], which was funded by the Department.

CropLife and our members support, in principle, the proposal to consider 'protected information' and 'information with limits on its use' equitably and consistently throughout the Agvet Code, thereby increasing the protection period associated with 'protected information' to eight years instead of the current three to five years. However, it is noted that CropLife has consistently advocated for a period of 10 years or longer to encourage innovation in new crop protection technologies.

CropLife does not consider that the responsibility for determining compensation for the use of protected information or information with limits on its use to lie with the APVMA. The responsibility for determining both the use of, and compensation for the use of protected information or information with limits on its use should lie solely with the holder of that information. As such, CropLife does not oppose removing Part 3 from the Agvet Code.

6 https://www.agrifutures.com.au/wp-content/uploads/publications/17-019.pdf

6 LEGISLATION IMPROVEMENTS

CropLife and our members consider that the reorganisation and simplification of the Agvet Code has improved its readability, however, it remains a complex legislative document. Rather than the current piecemeal amendments, any future revision of the Agvet Code should be comprehensive and would benefit from better resourcing to ensure a more thorough and well-considered outcome for both the APVMA and industry. That stated and as previously referenced, the industry, as a result of the previous experiences with regulatory reform in this area, does not have confidence in the ability of the Department to undertake such a major legislative reform process and it is clear that a period of legislative stability may be required to allow the APVMA to continue to focus on internal operational efficiencies.

7 VARIATIONS TO RELEVANT PARTICULARS AND CONDITIONS

The ability to vary relevant particulars and conditions of an approval or registration in certain circumstances via 'notification' or as a 'prescribed variation' is valuable. It has proven to be very effective for the Australian plant science industry. The expansion of this instrument via the March 2019 revision is welcomed.

CropLife supports the proposal to further expand this concept to other application types and particulars as the proposed measure presents opportunities to reduce regulatory burden on the agricultural and veterinary chemical industries, as well as the APVMA, by enabling certain low risk regulatory variations to be made via legislative instruments.

It is essential, however, that sufficient time is provided prior to the implementation of this measure to ensure that appropriate legislative instruments are developed in consultation with industry.

8 CONCLUSION

Approved and registered crop protection chemical products are safe, cost-effective, efficient, essential and sustainable tools for farmers to use for control of 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.

The expansion of timeshift to all complex applications in March 2019 is welcomed as it will significantly improve the predictability of applications, provide greater flexibility for registrants and improve regulatory efficiency.

CropLife does not support an entirely unnecessary, non-value added, bureaucratic and administrative re-approval and re-registration program. The demonstrated inability of much larger modern regulators to implement a similar program, despite receiving substantial government funding, serves to highlight that such programs are not feasible, or required, and do not serve the best interests of the community. In fact, it is clear from all overseas experience that these programs only serve to diminish and distract regulators from effectively focusing on critical areas essential for the protection of the farming sector and our broader community. Introducing a similar, unnecessary and duplicative system in Australia should continue to be avoided. The APVMA currently has a world-renowned regulatory scheme with a responsive chemical reconsideration program. Regulatory action is triggered by the provision of credible, new scientific information that questions the existing regulatory conditions of a product, such that a reconsideration can be initiated at any time. This is a proven highly effective and targeted method of addressing risks as and when they arise. Those who criticise it or argue for an arbitrary time-based reconsideration mechanism seem to be driven by a shallow and intellectually weak political agenda, rather than a genuine and well considered recommendation to improve the existing system to create a next generation regulator.

CropLife and our members have constructively engaged for years in all the previous reform agendas and proposed specific initiatives to improve the system, both in its effectiveness and its efficiency. Despite our frustration with the slow process and lack of proper implementation of these reforms, we remain committed to continuing to work constructively with the Government to ensure Australia has the world’s best agricultural chemical regulator.

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.

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.[7]

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. 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 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 $4.8 billion each year, or $13 million per day.[8]

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.

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

8 https://invasives.com.au/wp-content/uploads/2019/01/Cost-of-weeds-report.pdf