CropLife AUSTRALIA

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

Submission on the Agricultural and Veterinary Chemical Legislation Amendment Bill 2018

22 August 2018

1 INTRODUCTION

CropLife Australia is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents 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 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 (APVMA) to ensure they present no unacceptable risk to users, consumers and the environment.

In 1995, it took the assessment of 52,500 compounds to develop one new effective crop protection chemical active constituent. It now requires the assessment of more than 140,000 compounds and expenditure of more than US$286 million over a 11-year period to bring just one new 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 may potentially lose as much as 50 per cent of their annual production to pests, weeds and diseases. According to a Deloitte Access Economics report released in 2018, '*Economic activity attributable to crop protection products',* it is estimated 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.[1]

CropLife and its members are committed to the stewardship of their products throughout their lifecycle and to ensuring that there are no human health risks associated with agricultural chemical use in Australia, and that any environment and trade issues are responsibly and sustainably managed. Our member companies contribute millions a year on stewardship activities to ensure the safe, effective and sustainable 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 run by CropLife's wholly-owned stewardship and safety organisation, Agsafe. Our stewardship activities demonstrate our commitment to managing the impacts associated with container waste and unwanted chemicals.

CropLife recognises that the current regulatory system for agricultural chemicals in Australia is scientifically competent and technically proficient. CropLife's primary concerns with the current system relate to the ability of the APVMA to regulate agricultural chemicals efficiently, predictably and consistently.

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 target pests, 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 magnitude[2]. 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.

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

2 *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.*

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 efficiencies[3].

Promising signs emerged in 2016, with the Australian Pesticides and Veterinary Medicines Authority'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 recently, it is still below the level seen in the September 2016 quarter, at just 77 per cent in the June 2018 quarter. These improvements in overall performance are welcomed, however, it is alarming that just 47 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, further limiting farmers ability to improve productivity and compete internationally.

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, which has also directly contributed to the recent poor assessment by the ANAO. The proposed legislative changes presented in the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*, currently with the Senate, are not the urgent reforms needed to streamline APVMA operations in respect to the organisation's transition to Armidale. They are rather, 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 without any consultation. 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 2014 reform package.

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 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. 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 – contains limitations that will negate any potential benefit, and instead simply create an administrative burden for the APVMA to implement. The Bill comes at a historic low-point in industry confidence in the Department's capability to deliver effective and implementable regulatory reform.

[3] *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*

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 numerous reform consultation processes with the Department, not a single piece of legislative reform has been passed through by Government.

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.

Missing reforms

Disappointingly, the Bill has either excluded or amended all of CropLife's proposed measures and instead, includes proposals that are unlikely to achieve their intended outcome and could result in unintended adverse consequences. 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 of 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 Regulator and allowing them to focus on achieving their core business goals. It is disappointing, therefore, to CropLife and our members, as well as to Australian agriculture more broadly, that neither proposal has been included in the 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.

2 LEGISLATIVE PROPOSALS

2.1 Provisional registration or variation with conditions for efficacy

No significant efficiency gains will be realised by this proposed measure and the administrative burden imposed on the APVMA may, in fact, have a net-negative impact on the APVMA's operational efficiency. CropLife members are unlikely to bring an innovative new product or significant new use to market prior to conducting research trials under Australian-specific conditions. Hence, it is unlikely that the proposed measure will achieve the desired outcome of more efficiently bringing new, innovative products into the Australian market. Accordingly, CropLife reserves its right to seek further changes or oppose this measure if it becomes clear that the overall administrative effort and resources required for the APVMA to implement the measure will substantially outweigh any associated potential minor efficiency gains.

By disallowing applicants to apply for provisional registration and rather, leaving the application of the proposed measure to the APVMA's discretion, CropLife is concerned that the APVMA would simply request additional information prior to approving an application. Furthermore, the proposed measure encourages less reputable applicants to submit incomplete applications, without necessarily intending to generate the required efficacy data to acquire full registration. While the Government's intention for this proposed measure is not to provide a second-tier pathway for products where there is no evidence to support efficacy claims, or deal with poor quality submissions, it is not clear how these scenarios would be avoided. It is also unclear how the additional compliance measures that would be required to monitor products with provisional registration will be resourced and enacted.

CropLife strongly supports the proposed requirement for applicants to agree to a project plan with the APVMA to provide the additional efficacy information required to progress from provisional to full registration. CropLife contends that the APVMA should have the power to cancel the registration after a pre-determined interval if the applicant fails to adhere to the project plan, without sufficient explanation, rather than waiting until the full three-year period has ended.

CropLife and our members remain concerned with the practicalities of implementing the proposed measure, particularly as it relates to labelling requirements for provisional use patterns. The intention of the proposal is to require a label statement highlighting where a particular use pattern or product has been provisionally registered. Due to the inflexibility of the current system for changing labels, such a provision could prove problematic for registrants. Once the outstanding data has been provided to the APVMA and assessed and full registration is granted, amending the physical label on existing products would be costly and burdensome. The minor benefits of increasing the number of use patterns on a registered label may well be outweighed by this additional burden, manifesting as a disincentive for applicants to utilise this pathway.

Furthermore, any potential method for indicating that a product or use pattern is provisionally registered that does not require altering the physical label (e.g. including a sticker etc., as suggested in the consultation document), would require agreement from the states and territories. As such, CropLife is concerned that the proposed measure may lead to a substantial, time and resource consuming process of altering the product labelling requirements across jurisdictions, which would be entirely disproportionate to any potential efficiency benefits.

While not convinced that the proposed measure will deliver the intended outcome of increasing the number of new, innovative products registered for use in Australia, CropLife has long advocated for a system whereby new generic chemical products and variations to existing registered products could be registered without undertaking crop safety, efficacy and chemistry assessments, providing that the associated data packages have been developed and are available.

As product efficacy data is typically generated simultaneously with crop safety data, it would be unusual for an applicant to be in a position to submit crop safety data without efficacy data. Including crop safety data in the proposed measure would align it more closely with the US approach, where both efficacy and product safety assessments are considered for provisional registration.

Under this system, all relevant data would have been generated, thus providing greater assurance to the APVMA and exposing applicants to less risk when applying for registration. While this alternative proposal would only be appropriate in limited scenarios, it would considerably lessen the timeframe required for the APVMA to assess suitable products.

Similarly, CropLife has long advocated for the ability for the APVMA to grant provisional registration while a range of outstanding lower regulatory risk requirements are completed, such as stability data generation, delegate sign-off and peer review. Some additional flexibility to provide minor confirmatory data or information in other assessment areas would also be beneficial and provide an approach that was more proportionate to the risks involved. Again, this provisional registration scheme would require that all relevant safety data had been generated, thus exposing applicants to considerably less risk than the proposed measure.

As described above, the proposed measure is unlikely to achieve its intention of more efficiently allowing for the introduction of new, innovative products. CropLife and our members consider that a more effective method for improving farmers' access to innovative, new crop protection products would be achieved by expanding the APVMA's existing time-shift option to apply to any application requiring two or more technical assessment modules. In this scenario, applicants would be incentivised to begin the longer assessments of chemistry, worker health and safety and environment, whilst residue, efficacy and crop safety trials are being designed. This would contribute a much more meaningful improvement to market access.

Similarly, the crop groupings project currently underway at the APVMA will provide a potential avenue for 'permit to label', i.e., adding new uses to existing labels, thereby delivering the intended outcomes of the proposed measure and further minimising any potential benefit. The proposed measure may be suitable for granting provisional registration to crop protection products while aerial application trials are conducted. It is unlikely that an applicant will utilise this pathway, however, without first generating positive efficacy data, due to the considerable and prohibitive cost of trial crop destruction following generation of residue data to determine maximum residue limits.

2.2 An accreditation scheme for assessors in the future

CropLife has long advocated for and as such, supports the introduction of a system that enables the APVMA to formally recognise third-party scientific assessors. If implemented effectively, efficiency gains could be achieved by broadening the APVMA's capability for assessing applications in a timely manner. By offering long-term contracts with associated quality and performance caveats, the timeliness, consistency and reliability of scientific assessments could be greatly improved. The proposed measure also allows for the secondment of suitable Australian and overseas staff to overcome current and future shortages in regulatory scientists.

For this proposed measure to be implemented effectively, it is imperative that the resultant legislative instrument clearly indicates where the responsibilities and boundaries lie for sign-off by the third-party assessor and APVMA delegate.

CropLife considers that a one-off, upfront fee (payable by the third-party assessor) is warranted to cover the cost of the APVMA determining whether a person applying to be an accredited assessor is satisfactorily qualified. CropLife also supports the proposal to implement an audit and compliance program to ensure the quality and consistency of third-party assessors. Any additional costs associated with the audit and compliance of third-party assessors should be covered by an annual accreditation fee.

CropLife and our members are concerned that the proposed sanctions regarding penalties for contravening the conditions of accreditation may deter potential third-party assessors from participating in the scheme. It is essential that a clear distinction is made between offences and civil penalties that apply to deliberate misconduct, and those arising from accidental negligence.

2.3 Prescribed approvals and registrations

It is unlikely that any significant efficiency gain will be associated with this proposal, however, CropLife does not oppose it, and supports the provision for the APVMA to cancel an approval or registration if given false, misleading or incorrect information.

While simplifying the process for bringing additional generic products to market, the proposed measure will not assist farmers accessing new, innovative crop protection products to which their international counterparts have access. In the absence of additional investment in the APVMA's compliance activity, simplifying the pathway for registration of generic products may result in inferior products being introduced to the market, along with subsequent product failure or crop damage.

CropLife understands that the intention of this proposal is to apply a lighter touch to approval and registration for certain lower regulatory risk chemicals, such as swimming pool chemicals and cleaners, dairy sanitisers and anti-fouling paints. CropLife contends that entirely removing these products from the APVMA's regulatory scheme would better allow it to focus more of its resources on its core business of assessing, approving and registering agricultural and veterinary active constituents and products.

Further clarity is required, as it not clear whether low-risk products, such as those considered to be 'generally recognised as safe' (GRAS), would be considered under the proposed measure, via either a legislative instrument or an amendment to the Regulations.

The additional resources required, and administrative burden imposed on the APVMA to alter the process by which these chemicals are regulated, rather than removing them from the APVMA's regulatory scheme, may negate any minor efficiency gains associated with this proposed measure. CropLife proposes that to avoid having duplicative pathways, the proposed measure replaces the current listed chemical provision, which is a cumbersome, time-consuming process. As there is likely to be, at best, minor efficiency gains as a result of the proposed measure, CropLife supports the longer lead-time of 12 months (instead of six months), to ensure that the measure is implemented with minimal disruption to the APVMA's ability to carry out core business activities.

2.4 Data protection incentives for certain uses of chemical products

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. 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.

In some circumstances, the benefits of longer limitation and protection periods will likely outweigh the costs of registering new products for new uses. In other circumstances, however, these incentives may not be adequate to cover the cost of data generation. For example, six residue trials would be required to register a product for use on almond trees, with only an additional two required in macadamias to register the product for use in the entire 'tree nuts' group. In contrast, while just eight residue trials would be required to register a product for use in bananas, 38 trials would be required for the product to be registered for use in the entire 'tropical fruit, inedible peel' group. In the latter scenario, the cost of conducting an additional 30 residue trials would not come close to being offset by the additional data protection period as outlined in the proposed measure.

Such an imbalance in data protection periods may have the unintended consequence of reducing applications to register products in minor groups, or for whole crop groupings. In the above example, registrants may continue to submit applications for registration of a product in the 'tree nuts' group, while declining to apply for the 'tropical fruit, inedible peel group', simply because of the high number of residue trials required. As such, not only would the intention of the proposed measure not be realised, the exact opposite outcome would eventuate, with less minor uses included on product labels.

Requirements for residue assessments are generally fixed and are based on international best practice. Consequently, the data protection period could be determined, in part, relative to the amount of residue data required for the application. This would also create a level playing field for the crop protection and veterinary medicine industries.

Similarly, 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*[4], which was funded by the Department.

CropLife considers that this measure and associated amendments to the Regulations, once amended as per the above comments, require urgent implementation, to avoid applicants delaying the submission of applications in order to ensure eligibility for the proposed additional data protection time periods. Similarly, this measure should be implemented for all eligible applications currently being assessed by the APVMA, which have not yet been finalised, to ensure equity. CropLife is keen to work with the APVMA and the Department to refine this proposed measure and develop appropriate Regulations to ensure the proposed measure delivers the maximum benefit to increase the number of product uses on labels and ensure that Australian farmers receive access to critical crop protection tools and more uses in a timely fashion.

2.5 Prescribe certain information that can be taken into account if provided during an assessment

Significant efficiency gains are unlikely to be realised for crop protection product registrants by this proposed measure. At best, this proposed measure may provide minor efficiency gains by allowing for additional, non-technical information to be provided and included in an assessment in a less time-consuming manner.

While supporting the proposal to restrict the measure to scenarios that do not require a technical assessment, CropLife questions the necessity of including a provision to increase fees and timeframes. Where no technical assessment has been conducted, there can be no need to impose additional fees and timeframes on applicants.

The scenarios in which this proposed provision would apply should be limited to non-technical information, such as clarifying details of submitted data, and being clearly prescribed in the Regulations.

CropLife and our members are of the view that other, less administratively burdensome pathways may provide similar or improved efficiency gains. Expanding the APVMA's time-shift option to apply to any application requiring two or more technical assessment modules would better deal with scenarios where additional technical information was required.

Under the time-shift option, applicants are required to enter into a project plan agreement with the APVMA to manage the submission of additional information at pre-determined dates. Standard project plans for information commonly requiring later submission, such as shelf-life stability data, will further streamline the associated administrative burden for both the APVMA and the registrant. Utilising this pathway would also allow for applicants to submit non-technical information as agreed with the APVMA during the assessment process.

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

2.6 Provide for computerised decision-making

The provision that the APVMA may choose to utilise computerised decision-making as part of its approval and registration processes is supported. This proposed measure should provide minor efficiency gains by reducing the administrative burden on APVMA staff and finally allow the outcomes of the risk profiling tool to be implemented, which was completed and published on 24 December 2015.

CropLife supports the proposal to implement this measure gradually to assist in the development of the necessary systems and processes. A gradual implementation would also ensure that the computerised decision-making is used in an appropriate manner and the computer-generated decisions are correct and consistent.

The proposal to enable the APVMA to substitute a decision for an incorrect decision made by a computer program within 60 days of the original decision, and to consider the original decision as being 'reconsidered', is supported. To ensure that the system is equitable, however, the applicant should be asked to comment on the APVMA proposal to substitute a decision, in a manner similar to that followed for other internal reconsiderations.

2.7 Improve the transparency of voluntary recalls

CropLife member companies are obligated to adhere to the *CropLife Australia Code of Conduct* (the Code). The Code is based on the Food and Agricultural Organization of the United Nations (FAO) *International Code of Conduct on Pesticide Management*, and as such, enforces the highest standard.

The Code mandates that member companies must be able to verify the quality and purity of crop protection products offered for sale and that, on the rare occasion that problems occur, members voluntarily take corrective action and assist the APVMA in resolving the issue. This proposed measure will impose the same standards to the wider agricultural and veterinary chemical industry that CropLife members already adhere to via the Code. As such, CropLife supports this proposal.

CropLife contends that the proposed approach requiring holders to notify the APVMA prior to conducting a recall should be modified to provide more flexibility. Thus, the alternative proposal for holders notifying the APVMA within two days of conducting the recall, similar to section 128 of Schedule 2 to the Competition and Consumer Act, is supported.

CropLife supports the proposed requirement for holders to complete an approved form to advise the APVMA of the recall.

The proposal recognises that products may be withdrawn from the market for a variety of reasons, which are often unrelated to defects with the product. CropLife supports the proposed restriction of the measure to situations where the recall relates to the product's compliance with the statutory criteria or distribution of an unregistered chemical product. It is essential that where a product is either returned or voluntarily recalled for reasons that do not relate to compliance with the statutory criteria, there is no requirement to notify the APVMA.

In some circumstances, it may be necessary for the APMVA to be informed of a voluntary recall without necessitating publication of the notice, e.g., where the product label contains all required safety directions, etc. but is missing the booklet with the directions for use. Where the APVMA has been notified of this error but supports the measures proposed by the distributor, there is no tangible benefit from publishing the recall notice. Publishing recall notices arising from this and other minor issues risks diluting the impact of publication of recall notices and shifting the focus off genuine recalls that may impact the end-user of the product. Retaining a degree of flexibility for the APVMA to determine when to publish voluntary recall notices would reduce the administrative burden on the regulator and maintain value in the publication system.

CropLife supports the proposal for the APVMA to be exempt from publishing voluntary recall notices where the chemical product has not yet been supplied to the end user.

2.8 Require relevant information to be provided in relation to label approvals and variations

While it is unlikely that any significant efficiency gain will be associated with this proposal, CropLife does not oppose it, as this proposed measure will align requirements for label approvals and variations with those for active constituent approvals, product registrations, permits and licenses.

2.9 Standards for registered chemical product constituents

The proposed measure to reduce the regulatory burden on industry and the APVMA by allowing defined variations to the constituents in chemical products is supported. The current legislation presents neither a practical nor realistic endpoint for dealing with routine (safe) variations in constituent concentrations arising from manufacturing processes.

Globally, manufacturers take self-regulating measures through the implementation of CropLife International's *Contamination Prevention in the Manufacture of Crop Protection Products Guidelines and Best Practices* and associated addenda. CropLife has long been advocating that the introduction of a legislative amendment to section 83 of the Agvet Code to recognise and align with international industry best practice would provide a practical and realistic endpoint for residual impurities. The proposed measure providing for the regulations to prescribe standards for ranges of constituents in chemical products would achieve this objective, by allowing for reasonable (safe) variations in constituents resulting from manufacturing processes.

Alternatively, the legislative amendment could provide for the APVMA to implement a legislative instrument that makes reference to international best practice to similarly allow for reasonable variations in constituents arising from manufacturing processes. This pathway would allow for a simpler, more reactive option for addressing this deficiency in the current legislation relating to residual impurities.

Similarly, the current Agvet Code Regulations 1995 do not reflect the intention to allow for normal variations in the concentration of non-active constituents required for good manufacturing practices, rather than providing a specific range of variation. The proposed measure would allow for standards allowing for normal variations in non-active constituents to be developed to align with the current legislation regarding active constituents. Consideration of approaches used by other crop protection product regulators worldwide will enable the APVMA to determine the most appropriate manner in which to address this anomaly between the current reality of the Regulations and its intent.

It is imperative that the flexibility outlined in the proposed Bill is retained to allow registrants to tailor the registered range of non-active constituent concentration where desirable, with APVMA approval.

To rectify the current legislative failing regarding routine (safe) variations in constituent concentrations arising from manufacturing, the proposed standard or alternative legislative instrument must be retrospective, encompassing all currently registered products.

2.10 Suspension or cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval

While no efficiency gains will be realised by this proposed measure, the suspension or cancellation of active constituent approvals and product registrations for providing false or misleading information is supported.

2.11 Addressing an inconsistency in label particulars

While no efficiency gains will be realised by this proposed measure, the proposal to require product labels to contain only relevant particulars that are required to be included on a label is supported.

2.12 Improving dealings with suspended approvals and registrations

The proposed measure to allow for variations to the relevant particulars and conditions for a product registration that is suspended is supported. Permitting an applicant to apply to vary the relevant particulars and conditions for a product registration that is suspended should provide minor efficiency gains by reducing the administrative burden on the APVMA. This measure will also allow applicants to deal with the problem that resulted in the suspension and return the product to market more efficiently.

2.13 Address anomalies in matters that can be prescribed for the statutory criteria

While it is unlikely that any significant efficiency gains will be realised by this proposed measure, CropLife does not oppose the proposal to allow for the regulations to prescribe matters the APVMA must have regard to for the purposes of being satisfied that a label meets the labelling criteria. The proposed measure would allow for similar regulation making powers as those regarding product safety, efficacy and trade that are currently provided for.

CropLife has long advocated for the APVMA to make greater use of overseas trials and experiments and commends recent efforts of the APVMA to implement operational improvements regarding their use of international information. These operational improvements, however, will minimise the impact of the proposed measure to provide for an amendment to the regulations such that the APVMA must have regard to the matters in section 160 of the Agvet Code (overseas trials and experiments, which could include international standards, assessments and data).

The APVMA's chemical reconsideration program ensures that any new, credible scientific information relating to the approval of active constituents or registration of products is assessed as required. Any additional requirements imposed by the proposed measure would provide no additional benefit to this existing program, instead imposing a substantial administrative and technical burden on the APVMA and potentially diverting resources away from core business activities, including the chemical reconsideration program.

CropLife therefore contends that the proposed measure should only apply to overseas trials and experiments that have been provided to the APVMA by an applicant, as part of an application for approval of an active constituent or registration of a product.

2.14 Simplifying APVMA corporate reporting requirements

While no efficiency gains will be realised by this proposed measure, CropLife does not oppose the proposal to simplify the APMVA's reporting requirements and reduce duplicative reporting.

2.15 Align the 2014 legislation review with the overarching review of agvet chemical legislation

While no efficiency gains will be realised by this proposed measure, CropLife supports the proposal to align the timing of the review required under section 4 of the Amendment Act and that of the review that is required under section 72 of the Administration Act. CropLife supports the proposal to consolidate the timing of the two reviews, thereby avoiding the need for separate and potentially confusing (and overlapping) reviews of agvet legislation.

2.16 Make minor and machinery changes to the Administration Act and Agvet Code

While no efficiency gains will be realised by this proposed measure, CropLife does not oppose the proposal to modernise the Agvet Code and Agvet Code Regulations by removing redundant provisions.

2.17 Other amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016

While no efficiency gains will be realised by this proposed measure, the proposed measure to implement amendments included in the Agriculture and Water Resources Legislation Amendment Bill 2016 (the Omnibus Bill) is long overdue and supported by CropLife.

3 CONCLUSION

Agricultural chemicals are cost effective, efficient, essential and sustainable tools for farmers to use to control pests, weeds and diseases and as such 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, still has not delivered any quantifiable ongoing efficiency dividend, three years after implementation of the original reform package.

Disappointingly, the proposed legislative changes presented in this 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 that has been and will continue to be seen during the transition of the regulator to Armidale. The disruption of the physical relocation of the APVMA is likely to be felt for some years after the relocation has been implemented, 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 predominantly of proposed administrative corrections, which will deliver minor internal efficiency improvements, at best. The proposal to introduce a pathway for provisional registration, which may have delivered tangible efficiency gains for industry and delivered critical crop protection tools to Australian farmers, contains limitations that will negate any potential benefit, and instead simply creates considerable administrative burden for the APVMA to implement.

To assist in developing meaningful legislative reform amendments that would 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 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 reform measures have been included in the Bill, with those that have, being amended such that they are unlikely to achieve the intended outcome of the original proposal.

CropLife recommends amending the proposed measures as described above, to maximise any associated efficiency gains. The Bill includes proposed measures that the Government intends would allow for the introduction of new, innovative products to the Australian market more efficiently. CropLife contends, however, that the proposed measures are unlikely to achieve that intended outcome and propose instead that expanding the APVMA's existing time-shift option to apply to any application requiring two or more technical assessment modules would be a more effective method for improving farmers' access to innovative, new crop protection products.

CropLife looks forward to continuing to work with the Department and the APVMA to create a more efficient regulator that 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.