

SUBMISSION ON THE AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT REGULATIONS



20 February 2019

1 INTRODUCTION

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

The current regulatory system for agricultural chemicals in Australia is scientifically competent and technically proficient. CropLife's only concerns with this system relate to the ability of the Australian Pesticides and Veterinary Medicines Authority (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. An inefficient regulatory system means access to fewer crop protection tools for Australian farmers, facilitating 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 \$4.8 billion each year, with an impact on the environment that is similar in magnitude¹. It is imperative that the regulation of crop protection products in Australia is efficient and effective to ensure Australian farmers have access to the innovative tools the plant science industry provides. This will improve the ability of Australian farmers to be internationally competitive and productive.

¹ <https://invasives.com.au/wp-content/uploads/2019/01/Cost-of-weeds-report.pdf>

2 PROPOSED AMENDMENTS

2.1 Timeshift applications

CropLife has long advocated for and as such, supports the expansion of the Australian Pesticides and Veterinary Medicine Authority's (APVMA) current timeshift application option. The current timeshift option enables the flexible assessment of what would otherwise be Item 1 to 4 and 15 applications by facilitating the use of a project plan developed and approved by both the APVMA and registrant.

Expanding the APVMA's existing timeshift option to apply to all applications requiring two or more technical assessments, namely Items 5, 10, 11 and 14, would provide greater flexibility for other complex application types and improve regulatory efficiency.

The proposed measure 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 designed. This would contribute a meaningful improvement to market access, ultimately improving farmers' access to innovative, new crop protection products.

The intent of the 2014 regulatory reforms to restrict the information that the APVMA can take into account when considering an application must be maintained to ensure the efficiency gains sought in the 2014 reform process are not compromised. It is, therefore, 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 are not in favour of a formal, prescriptive mechanism for amending project plans. Amendment of the project plan should instead, only require signatory approval from both the applicant and APVMA as is currently the case. CropLife recommends that the APVMA develop, in consultation with the regulated industries, operational guidelines regarding expectations for amending project plans, including timeframes required for notification of amendments.

2.2 Ministerial orders

CropLife supports the proposed approach for amending the Regulations via Ministerial Orders to enable a more contemporary and efficient avenue for implementing Regulatory amendments, whilst maintaining appropriate oversight in the process.

2.3 Chemical product declarations

CropLife has long advocated for the scope of the APVMA's regulatory responsibility to be refined to improve efficiency in the core registration operations of the APVMA and as such, supports the concept outlined by the proposal. While the proposed measure is limited to carbon dioxide and nitrogen, citronella oil and sheep branding substances, it is not opposed by CropLife.

It is recommended that consideration be given to further refining the APVMA's regulatory responsibility, by excluding anti-fouling paints, dairy sanitisers, pool and spa chemicals and plant material (including whole viable seeds) in future regulatory reforms.

2.4 Notifiable variations and prescribed variations

CropLife supports the proposed approach to enable the APVMA to make notifiable variations and prescribed variations to active constituent approvals and product registrations via legislative instruments.

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. For example, the ability to manage variations such as increasing a pack size beyond the originally registered range (with appropriate requirements based on formulation type and the currently registered pack size); addition of “similar” tank mix partners and correcting minor errors in relevant label particulars (such as spelling errors) etc. via legislative instruments would greatly reduce the administrative burden currently associated with such minor applications.

It is essential, however, that sufficient time is provided prior to the implementation of this measure to ensure that appropriate legislative instruments are developed by the APVMA and are in place.

2.5 Hormonal growth promotants

CropLife recognises that Animal Medicines Australia and the Veterinary Manufacturers and Distributors Association have expertise and in-depth understanding in this area and defers to their assessments on this specific measure.

2.6 Section 88 exemption (allowing advertising)

While no efficiency gains will be realised by this proposed measure, the proposal to allow advertising of chemical substances for which advertising is currently not permitted is, in principle, supported.

There are circumstances, however, where advertising a permitted use may be inappropriate and is therefore not supported. Where a party other than the registrant of a product wishes to advertise the use of a specific, named product under an approved permit, **it is recommended** that authorisation from the product registrant is required. Allowing third-parties, such as grower groups, to advertise the use of a specified, named product without the registrant’s approval is not supported.

Advertising the use of a product that is permitted only under a research permit would be wholly inappropriate and is not supported. Until the required research has been completed to confirm that the product will have no unintended negative effects on human or animal health, the environment or trade, the use pattern should not be advertised.

2.7 Restricted information

While no efficiency gains will be realised by this proposed measure, CropLife supports the proposal to clarify when the APVMA can use information provided by another party to support the registration of a proposed party.

There is concern, however, that using multiple terms to define similar concepts (i.e. ‘protected information’, ‘restricted information’, ‘confidential commercial information’, ‘protected data’, etc) will result in considerable confusion among applicants, as well as the APVMA. This confusion could result in the unintentional release of confidential information by the APVMA or provision of insufficient information by an applicant during a registration application. This proposed measure highlights the requirement for a comprehensive review of the terminology and definitions currently utilised in the primary legislation and regulations to ensure clarity among both registrants APVMA staff.

Furthermore, these confusing definitions are currently presented interchangeably in APVMA material, including on the website. **It is recommended** that a comprehensive review of currently available information and guidance material is conducted to ensure standardisation and adherence to the definitions provided in the Regulations.

2.8 Assessment periods and fees (active approval as part of registration)

CropLife recognises that Animal Medicines Australia and the Veterinary Manufacturers and Distributors Association have expertise and in-depth understanding in this area and defers to their assessments on this specific measure.

2.9 Consequential and other amendments

The proposal to amend the Regulations to remove unnecessary provisions, correct errors and deal with inconsistencies is supported.

2.10 Transitional provisions

The proposal to amend the Regulations to include the described transitional and application provisions to facilitate implementation of proposals 1 to 9 is supported.

2.11 Voluntary recalls

The proposal to amend the Regulations to facilitate proposed measures described in the *Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2017* (Streamlining Regulation Bill 2018) regarding voluntary recalls is supported. CropLife is pleased that the Department has extended the timeframe within which a registrant must notify the APVMA of a voluntary recall to two days.

In some circumstances, it may be necessary for the APVMA 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.

The term “voluntary recall” is generating considerable confusion among end-users, with some apparently under the impression that ceasing use of and returning the product is in fact voluntary. **It is therefore recommended** that the current terminology be reviewed. CropLife and our members are committed to adhering to voluntary recall processes that align with world’s best practice and will continue to work to ensure any voluntary recalls are managed efficiently and effectively. The confusion among end-users regarding the terminology used to describe voluntary or “manufacturer-initiated” recalls requires further consideration and stakeholder consultation to ensure the product recall system serves the best interests of the Australian farming sector. It is, however, imperative that urgent recalls based on human health concerns continue to be distinguished from other recalls that pose no health risks to users or consumers.

2.12 Determining applications

Significant efficiency gains are unlikely to be realised for crop protection product registrants by this proposed measure. The proposed measure may, however, 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.

CropLife supports the proposal to restrict the measure to scenarios that do not require a technical assessment and is pleased the Government is not proposing to prescribe additional fees or extensions to the assessment period where additional non-technical information is requested.

The scenarios in which this proposed provision would apply should be limited to non-technical information, such as clarifying details of submitted data, replacing a file attachment where the original was corrupted or scanned incorrectly, and being clearly prescribed in the Regulations. As this non-technical information can be provided quickly by the applicant, a short timeframe should be required by the APVMA.

2.13 Improving application quality

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. 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 enable the APVMA to provide just one opportunity for the applicant to address the deficiencies identified during preliminary assessment is supported. An increase in administrative burden could result if mistakes that are considered by the APVMA to be reasonably rectifiable can be repeatedly made by an applicant.

In addition to the proposed retrospective review process, **it is recommended** that the applicant is notified prior to a fee being applied, to allow the registrant to choose not to proceed with a particular use pattern, thereby avoiding a fee being applied. Similarly, a provision should be implemented whereby a request for a fee to be paid can be reversed where the APVMA has requested information in error.

The proposal to set a fee based on an hourly rate commensurate with the APVMA's effort in assessing the required information is supported, however, **it is recommended** that a maximum threshold is set.

2.14 Annual returns reporting and false or misleading information

CropLife holds to the long-established view that section 69E of the Agricultural and Veterinary Chemicals (Administration) Act 1992 is an unnecessary regulatory burden, serves no genuine policy purpose and should be removed completely and immediately.

The proposed amendment to simplify reporting requirements for annual returns to align with existing levy reporting requirements is at least a nominal efficiency. Unfortunately, the delivery was unnecessarily delayed after 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. This means registrants were required to yet again undertake detailed data assessment to provide ultimately worthless information to the APVMA for the 2016-17 and 2017-18 financial years.

CropLife appreciates that the proposed measure is intended to apply to the 2018-19 financial year, provided that Part 1 of Schedule 1 to the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017* (Operational Efficiency Bill 2017) has commenced. It is deeply disappointing that the Operational Efficiency Bill 2017 has not yet passed the Senate, further delaying the introduction of the proposed measure. **It is therefore strongly recommended** that the proposed measure be expedited to apply immediately if the Operational Efficiency Bill 2017 has not passed the Senate prior to the 2018-19 financial year reporting period.

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.

The proposal to expand the APVMA's existing timeshift option is welcomed. CropLife has long contended that expanding the existing timeshift option to include any application requiring two or more technical assessments would provide an effective method for improving farmers' access to innovative, new crop protection products. The proposed measure 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 designed.

The disruption of 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. Consequently, substantial reform is still urgently required to assist the APVMA during this very challenging period.

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 recent legislative amendment Bills, with those that have, being amended such that they are unlikely to achieve the intended outcome of the original proposal.

With the exception of the proposal to expand the APVMA's existing timeshift option and enable amendments to the Regulations to be enacted via Ministerial Orders, significant efficiency gains are unlikely to be realised for crop protection product registrants by the proposed amendments to the Regulations. The remaining proposed measures contained in the Regulations amendment will, at best, provide minor improvements to administrative procedures within the APVMA.

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.

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.²

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

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. Access to fewer crop protection tools would facilitate faster development of resistance among targeted pests, diminishing the efficacy of remaining chemical options. The economic impact of weeds alone is estimated to be over \$4 billion each year, with an impact on the environment that is similar in magnitude³.

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.

² https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf

³ *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.*