



Representing *the best* of the plant science industry

# **CropLife Submission to the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017**



**19 July 2017**

# 1 INTRODUCTION

CropLife Australia (CropLife) 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 2013, '*Economic activity attributable to crop protection products*', it is estimated that up to \$17.6 billion of Australian agricultural output (or 68 per cent of the total value of crop production) is attributable to the use of crop protection products.

CropLife and its members are committed to the stewardship of their products throughout their lifecycle and to ensuring that any human health, environment and trade issues associated with agricultural chemical use in Australia are responsibly and sustainably managed. Our member companies contribute more than \$13 million 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 **drumMUSTER**, 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<sup>1</sup>. It is imperative that the regulation of crop protection products in Australia is efficient and effective to ensure Australian farmers have access to the innovative tools the plant science industry provides. This will improve the ability of Australian farmers to be internationally competitive and productive.

Defined efficiency gains from legislative reforms introduced in 2014, however, have not yet been realised and the APVMA is on the verge of being overwhelmed. The Australian National Audit Office's (ANAO) recent 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<sup>2</sup>.

<sup>1</sup> 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.

<sup>2</sup> 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>

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, have been devastated since that time, with the regulator achieving only 30 per cent of work within statutory timeframes for crop protection in the March 2017 quarter.

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* (the Bill) have eventually been delivered, two years later than originally promised. They come at a historic low-point in industry confidence in the Department's capability to deliver effective and implementable regulatory reform.

The proposed amendments contained within the Bill 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.

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 the 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 time for the development and implementation of real reform that delivers genuine improvements to the regulator's efficiency.

## 2 LEGISLATIVE PROPOSALS

### 2.1 Clarifying confidential commercial information provisions

The APVMA clarified and updated the process for dealing with Confidential Commercial Information (CCI) in 2014 to be in line with the Government's Protective Security Policy Framework. From this point, the APVMA ceased indirectly disclosing CCI and began treating CCI as it always should have, according to the law.

The outcome of recent court proceedings, however, resulted in the APVMA reviewing each relevant application's CCI considerations case by case. This is labour intensive and impacts the predictability, consistency and efficiency of affected regulatory decisions. Therefore, legislative amendments to provide clarity to the APVMA on the treatment of CCI are imperative to deliver efficiency in APVMA regulatory processes, particularly in the current environment of limited resources and capability.

The proposed amendments are intended to remove uncertainty for APVMA staff and reduce the handling time for applications, while retaining the original intent of the legislation of preventing unnecessary disclosure of CCI. CropLife contends that the proposed amendments will not deliver the original intent of the legislation of preventing unnecessary disclosure of CCI, and will instead result in the APVMA reverting to the pre-2014 practice of indirectly disclosing CCI in notifications.

CropLife is also concerned that the proposed amendments could technically allow the APVMA to directly disclose CCI, such as by disclosing a formulation in a refusal notice as part of the statement of reasons. For example, the APVMA could state in a refusal notice that they propose to refuse because applicant 'A' stated the formulation was 'x', but the formulation of the reference product is actually 'y'. Whilst this is unlikely to occur in practice through enforcement of APVMA operational policy, it is important to note that even in the unlikely event that indirect disclosure in certain notifications is necessary, direct disclosure is not and must never occur as an unintended consequence.

CropLife is cognisant of the need to streamline CCI considerations. Further investigation and consideration is, however, warranted to ensure amendments to remove uncertainty for APVMA staff and reduce the handling time for applications, do not have unintended consequences and misplace the original intent of the legislation of preventing unnecessary direct or indirect disclosure of CCI. Accordingly, CropLife reserves its right to seek further changes or oppose this measure if it becomes clear that it would compromise or undermine the original government policy principles and basis for the protection of CCI in the regulatory system.

### 2.2 Simplifying reporting requirements for annual returns

The APVMA, on behalf of and at the direction of the Department, resumed the collection of data on amounts of active constituents imported, manufactured and exported each financial year, commencing with the financial year 2015–16. This is as a result of section 69E of the Agricultural and Veterinary Chemicals (Administration) Act 1992, which has been in place since 1995, but not enforced by the APVMA since 2006.

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 immediately. Until last year, the information had not been collected by the APVMA since 2006, signifying that it is not relevant, useful or genuinely required.

The proposed amendment to simplify reporting requirements for annual returns to align with existing levy reporting requirements is at least a compromise. Unfortunately, despite working constructively with the Department since 2014 to achieve a worthwhile compromise, the delivery has been unnecessarily delayed. This means registrants are 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. This reflects extraordinarily poorly on the Department and its own inefficiencies. This reform must be expedited to take immediate effect, or exemptions granted so annual return information is not required to be submitted until the new legislation comes into effect.

In addition, the proposed approach implies that the APVMA collects levy data for unregistered products sold/distributed under permit. Considering levy data for unregistered products sold/distributed under permit do not appear in the APVMA portal for levy returns, it is not possible for relevant holders to provide returns or levy figures in such situations.

CropLife understands that the data reported to the Department by the APVMA is not intended to identify holders or intentionally disclose commercial information. It is not clear, however, what form of confidentiality will be provided by the Department, nor is it clear how single product data will be disguised so as not to pass on highly confidential or commercially sensitive information into the public domain. In situations where levy information is reported on a new product based on a unique active ingredient, any public release of this information would be a breach of confidentiality. It is imperative that the Department ensures that this data is not allowed to get into the public domain or into any accessible reports.

### **2.3 Increase the APVMA's flexibility to manage minor errors in applications at preliminary assessment**

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.

Care must, however, be taken in its implementation as this proposal could easily result in unintended consequences. An increase in administrative burden could potentially result if mistakes that are considered by the APVMA to be reasonably rectifiable can be repeatedly made by an applicant. Consequences in the form of penalties or additional fees could assist in ensuring applicants do not repeat mistakes. It is also paramount that sufficient guidance is developed operationally by the APVMA to ensure consistency in what is considered to be reasonably rectifiable.

### **2.4 APVMA amendment of relevant particulars or conditions in a variation application**

Provisions providing the same flexibility the APVMA has for determining applications to register a chemical product or approve a label to relevant particulars or conditions in a variation application will remove an unnecessary administrative burden and is therefore supported.

### **2.5 Timeframe for notifying FSANZ about variations to the MRL Standard**

Allowing the APVMA to provide notice to Food Standards Australia and New Zealand (FSANZ) before a chemical product approval is given is considered a sensible approach. It would allow the APVMA to assess whether a variation to the Maximum Residue Limit (MRL) Standard is likely, while still allowing FSANZ sufficient time to consider the notification.

## 2.6 Enable a person to apply to vary the particulars of a label approval that is suspended

Removing the administrative block to addressing suspended chemical products where a variation to the label would be sufficient to revoke the suspension is supported.

## 2.7 Amend the definition of 'expiry date'

The proposed approach to amend the definition of expiry date from when a chemical product should not be used, to must not be used, could potentially lead to a significant increase to the waste stream disposal of expired products that are still perfectly safe and efficacious to use. To avoid this situation, provisions such as a permit or similar are necessary to allow the expiry date to be amended, on the basis of proving that the product remains safe, efficacious and does not cause unmanageable risks.

## 2.8 Add antimicrobial resistance as a specific safety consideration

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

CropLife is, however, concerned that the proposed amendments may result in the assessment of all chemical agents for the potential for human exposure to antimicrobial resistant microorganisms, which in most cases would be unnecessary and burdensome for both industry and APVMA staff. The proposed amendment should specify that the assessment of antimicrobial resistance be specific to animal medicines that possess antimicrobial properties.

## 2.9 Including civil penalty provisions for false or misleading information

Amendments providing appropriate civil penalties relating to the provision of false and misleading information, similar to those in the *Biosecurity Act 2015*, are supported.

## 2.10 Minor technical amendments to the Administration Act and Agvet Code

The removal of redundant provisions and technical amendments to improve clarity of some provisions within the *Agricultural and Veterinary Chemicals (Administration) Act 1992* is supported.

### 3 CONCLUSION

Agricultural chemicals are a cost effective, efficient, essential and sustainable option 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 more timely risk assessments, approvals and registrations is essential. Any meaningful regulatory reform proposals should focus on improving the ability of the APVMA to regulate agricultural chemicals efficiently, predictably and consistently.

CropLife remains concerned that the previous government's 2014 reform package, imposed on the APVMA without realistic implementation timeframes or sufficient funding, has not yet delivered any quantifiable ongoing efficiency dividend. While more than two years later than first promised, the proposed legislative changes presented in this Bill are necessary minor amendments that will, overall, reduce regulatory burden and improve operational efficiency. Substantial reform is still urgently required to assist the APVMA in its transition to Armidale.

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.