



Representing *the best* of the plant science industry



1 INTRODUCTION

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. CropLife's membership is made up of both patent holding and generic Australian and international small and large companies. Accordingly, CropLife advocates for policy positions that deliver whole of industry benefit and hence strengthens the nation's farming sector and the Australian agricultural sector more broadly. CropLife Australia is part of the CropLife International Federation of 91 national associations globally.

The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than \$3 billion annually to the Australian economy, employs thousands of people across the country and directly underpins more than \$18 billion a year of Australian agricultural crop production.

Like pharmaceuticals, all crop protection products, which include chemical and biological based herbicides, insecticides and fungicides (pesticides), must go through an independent and scientifically rigorous regulatory assessment before registration and made available on the Australia market. This is the core function undertaken by the Australian Pesticides & Veterinary Medicines Authority (APVMA)

The challenges the plant science industry face in supporting Australian farmers with innovative crop protection products are significant. 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 and takes over 11 years to bring just one new successful crop protection product to the market. A third of those costs are directly related to regulatory compliance.

The FAO estimates that with access to current crop protection products, between 20 and 40 percent of global crop yields are reduced each year due to the damage wrought by plant pests and diseases¹. Without access to these tools, up to 50% of current crop production would be lost. By way of example, Australian farmers would not be able to commercially produce almonds, apples, asparagus, grapes, hops, lettuce, nectarines, peaches, pears, strawberries, many other fruits, vegetables, nuts and many other crops without crop protection products².

Farmers need these products because of the benefits they provide to their businesses. Consumers need these products to ensure they have access to safe, affordable and nutritional food. These products also enable land and environment managers, such as parks and wildlife services, to protect Australia's native flora and fauna from noxious weeds and invasive pests.

¹ Food and Agriculture Organization of the United Nations, 'Plants vital to human diets but face growing risks from pests and diseases', <http://www.fao.org/news/story/en/item/409158/icode/>, 4 April 2016

² Deloitte Access Economics 'Economic Activity Attributable to Crop Protection Products' 2013



A streamlined, effective regulator capable of delivering timely risk assessments, approvals and registrations is essential for Australian agricultural productivity. Relocating the APVMA from Canberra to a regional centre without adversely impacting its ability to regulate consistency, predictability and efficiency presents a significant challenge. The core concern is the loss of key senior and experienced technical assessment staff, which is a key driver of the regulator's capability and efficiency.

A significant negative disruption to the operations of the APVMA is not just a threat to the plant science industry or individual crop protection product companies, it is a threat to the nation's farming sector and its productivity, profitability and international competitiveness.

2 APPLICATION OF THE ORDER

The APVMA is an independent Australian government statutory authority, currently located in the Canberra suburb of Symonston, employing approximately 172 staff of which most are technical regulatory science specialists. When considering the application of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016* (the Order) on the APVMA, one must be cognisant of the history and origins that led to the APVMA's existence.

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA), which subsequently became the APVMA, was established in 1993 under Commonwealth and state and territory agreement and corresponding legislation to centralise the registration of all agricultural and veterinary chemical products into the Australian marketplace. Prior to this, each state and territory government had its own individual system for the registration for agricultural and veterinary chemical products.

The APVMA evaluates, registers and regulates agricultural and veterinary chemical products up to the point of sale. The APVMA has the functions and powers conferred upon it by the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals Code Act 1994*. The states and territories are responsible for control of use. The Department of Agriculture and Water Resources manages the legislation under which the APVMA operates, including amending current legislation or introducing new Bills. This can only occur, however, where Commonwealth, state and territory governments have agreed there is a need.

The APVMA is a globally respected, scientifically and technically sound regulator of agricultural chemicals. The Authority's expertise and scientific credibility are well recognised within Australia, throughout the Asia Pacific and globally. Although CropLife has publicly and privately criticised the APVMA, that criticism however has always been restricted to the regulator's efficiency and not its technical competence.

The application of the Order on the APVMA, poses a real and genuine threat to the APVMA's ability to perform its function.

This threat is simply through the significant loss of their existing, core, highly specialised regulatory scientific staff. There is in fact a serious national and global shortage of regulatory scientists which is why their loss poses an immediate, medium and longer term problem for the effective operations of the APVMA. It is important to recognise that CropLife supports, in principle, government initiatives that improve the economic activity in rural and regional Australia. Relocating the APVMA to Armidale in its current form, and in isolation will, however, not deliver a net benefit to the efficient operations of the regulator, the plant science industry or the Australian farming sector in the short, medium or long-term.

This submission focuses on the application of the Order on the APVMA. The process leading to the making of the Order, and the Government's policy of relocating corporate Commonwealth entities with agricultural policy or regulatory responsibilities are not matters which CropLife seeks

to make comment on beyond our previous stated position of supporting government initiatives relating to rural and regional Australia as state above.

3 IMPACT ON PERFORMANCE

The Government's own \$272,000 independent cost-benefit analysis shows the relocation is all cost and no benefit to Australia's agriculture industry.

In good faith, CropLife invested significant time and resources to, and participated in, the August 2016 cost-benefit risk analysis undertaken by the Ernst & Young (EY)³. The analysis determined that the potential impact of relocating the APVMA could cost the agricultural sector for crops alone up to \$193 million per annum, and identified key risks that included:

- the APVMA may be unable to relocate, or recruit and replace, key APVMA executive, management and technical assessment staff;
- during transition and in the short term, the APVMA may not be able to sustain its rate of effort for registration of new agricultural and veterinary chemical products; and
- the APVMA may be unable to maintain and grow its capability in the medium term.

Many of the risks identified by the report are now being realised, without a comprehensive plan with specific mitigating initiatives outlined or implemented.

Steady improvements in performance by the APVMA have been obliterated by the impact of the Order.

The APVMA recently released its October 2016 - December 2016 performance statistics, which showed a sharp drop in the regulator's performance. This performance equals the abysmal performance 12 months ago when the regulator was struggling with the poorly conceived and drafted 2014 legislative reform. The poor result is more stark, as it follows steady improvements in previous quarters, which were raising hopes and confidence that the regulator would soon regulate in a new, significantly more efficient manner.

The performance statistics show that the APVMA only processed 50 per cent of crop protection product applications within statutory timeframes. This is a sharp fall from processing 82 per cent of crop protection product applications within statutory timeframes in the previous quarter and below the 57 per cent recorded in the 2015-16 December quarter. Thus, the number of crop protection product applications currently 'in progress' has also increased with only 69 per cent of those are still within timeframe, indicating that performance is unlikely to improve in the short to medium-term.

These poor results reflect the significant loss of experienced regulatory scientists in critical assessment areas for crop protection products since the Order was made. The loss of assessment staff confirms that the key risks that CropLife feared from relocating the APVMA are now occurring. A broad range of significant measures must be urgently implemented to minimise assessment staff losses, attract new assessment staff and streamline the assessment and registration processes.

³ Department of Agriculture and Water Resources website, sourced 14 March 2017, <http://www.agriculture.gov.au/SiteCollectionDocuments/apvma-cost-benefit-analysis.pdf>

Access to the innovative tools the plant science industry provides is crucial for Australian farmers' global competitiveness and any product registration delays gravely affect the ability of the industry to continue to spearhead national economic growth.

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. The impact of relocating the APVMA and the associated loss experienced regulatory scientists will slow down regulatory processes and, therefore, the registration of new and innovative crop protection products for Australian farmers. This will result in 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 more than \$4 billion each year, with an impact on the environment that is similar in magnitude⁴. 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 to be internationally competitive and productive.

It is important to note that the relocation of the APVMA will not have an adverse impact on the protection of human health or the environment, as regulatory processes will be slowed, not diminished. That stated, the relocation will potentially slow the regulators response to biosecurity threats, impacting Australian farmer's ability to address serious disease and pest incursions in a timely manner.

Adopting and implementing measures to ensure that the APVMA can continue to fulfil its obligations to administer the *Agricultural and Veterinary Chemicals Code Act 1994* will not be without cost. The APVMA is, however, an industry fee and levy-based regulator and any costs associated with a relocation should be borne by the Department of Agriculture and Water Resources and not the APVMA. While it is appropriate for the APVMA to operate on a fee-for-service model, this should not extend to applicants and approval holders bearing additional costs from the relocation, which is neither supported by industry nor likely to deliver an efficiency dividend.

CropLife has consistently opposed relocating the APVMA to Armidale for precisely the reasons that are now becoming apparent. We are, however, eager and remain committed to work with the Government to ensure that impacts on product approvals, and consequently on use of those crucial products by the nation's farmers, are minimised. Without this significant and urgent action, the successful future of both the APVMA and the realisation of a centre of excellence will be severely compromised.

⁴ 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.

4 CENTRE OF EXCELLENCE

A true centre of excellence that features a next generation regulator requires visionary planning and structural changes to ensure agriculture continues to drive national growth.

Relocating the APVMA to Armidale in its current form, and in isolation, will not deliver a net benefit to the efficient operations of the regulator, the plant science industry or the Australian farming sector in the short, medium or long-term. The establishment of an Australian centre of excellence in agriculture, incorporating the APVMA, that drives agricultural productivity through innovation and efficiency could still, however, deliver a positive outcome for Australian agriculture.

Structural changes and initiatives are required that leverage technology to streamline APVMA and associated regulatory operations through more efficient data-sharing, digital communications and next-generation infrastructure.

An Australian centre of excellence in agriculture should be built on the following three pillars:

1. Next generation regulator

- Online platform
- Leverage National Broadband Network (NBN) accessibility
- Harness external domestic and international regulatory capacity
- Assist transition
- Structural regulatory agency reform to achieve whole-of-government outcomes

2. Policy functions

- Centre of excellence for agriculture must have agricultural policy development capacity
- Improved policy development that delivers for agriculture
- Synergy with University of New England (UNE)

3. Minor use and speciality crops program

- Enhance existing program by adopting a model more consistent with the IR-4 (US program)
- Truly leverage an association with UNE
- Alleviate existing economic and regulatory market failure
- Deliver more sustainable pest management practices and increase the Australian gross domestic product (GDP)

Next generation regulator

Increasing contestability of assessment services supports the Australian Government Efficiency through Contestability Programme, which seeks to shift the emphasis of Commonwealth entities from the functions to be carried out, to the desired outcome governments seek to achieve.

CropLife has, for many years, raised concerns about the APVMA's inability to meet its statutory timeframes. Assessments undertaken by third-party assessors in recent times have been completed within significantly shorter timeframes, at a lower cost and to an equivalent or higher scientific standard than those undertaken by the Australian Government Department of the Environment and Energy or the Department of Health.

The findings from the APVMA's 'Contestability of the efficacy assessment' pilot should be used to shift the function of more assessment types, such as residues, toxicology and chemistry, to external

accredited service providers. The APVMA should, however, retain peer review functions and the final decision.

The APVMA needs to also better utilise overseas assessment capacity. Issues managing access to confidential information are currently limiting access to domestic assessors only. In the current resource constrained environment, this situation is untenable and needs to be rectified immediately to significantly broaden the number of external assessors available to the APVMA.

Developing an online platform is necessary for the development of a next generation regulator. This would allow evaluations and assessments to be undertaken remotely by either permanent employed regulatory scientific specialists or accredited third-party assessors, harnessing domestic and international regulatory scientific assessment capacity. An online platform would appropriately leverage the existing NBN that is already operational in Armidale and align with the Government's plan for smart cities.

CropLife International is currently working closely with CropLife Australia and other sister organisations to develop similar approaches internationally. The APVMA initiative would build upon the specific work currently being undertaken by the Organization for Economic Cooperation and Development on both the *Globally Harmonised Submission and Transport Standard* and draft guidance regarding Joint Reviews of Pesticides, specifically the *Communication and Information Resource Centre Administrator*.

With such a system implemented, the APVMA would no longer be restrained by internal capacity. By easily accessing internal and external regulatory expertise domestically and internationally, as required, the APVMA would deliver regulatory efficiency, which will benefit Australian agriculture broadly.

Technical assessment capacity building options both within the APVMA and externally need to be fully explored. Existing arrangements where external assessments are undertaken under a deed of standing offer severely limits the incentive for the private sector to invest and is therefore in urgent need of revision. Offering longer-term contracts, with associated quality and performance caveats, would vastly improve the commercial environment and result in substantial improvements in assessment capacity upon which the APVMA could draw.

Implementation of such initiatives provides a viable transition option and is urgently needed to help stymie the current exodus of key senior and experienced technical assessment staff, who are the key drivers of the regulator's capability and efficiency. Canberra based experienced and well-regarded regulatory scientists unwilling to move, won't need to.

It should be noted that CropLife does not believe that the existing commitment of \$25.6 million will properly cover the direct and indirect specific relocation and transition costs for the APVMA. Budgeting should allow for up to \$30 million so that industry and farmers do not unnecessarily bear the cost of relocation.

Policy functions

A centre of excellence for agriculture can only truly be achieved if it incorporates both the regulator and relevant policy development functions, allowing for significant synergies with UNE to be created and leveraged. While there is no direct synergy to be achieved between the APVMA regulatory assessment function by being co-located with the UNE, there is a significant direct and

indirect benefit to agriculture broadly by having agricultural chemical policy development undertaken in a regional and rural agriculture centre.

Building agricultural chemical policy development capacity within the centre of excellence for agriculture would deliver a specific and substantial synergy with the existing expertise and skill set at UNE.

Minor use and specialty crop program

In the 2014 Federal Budget where very few project proposals received funding, the Australian Government finally committed an initial \$8 million over 4 years towards helping farmers gain improved access to safe and effective agricultural chemicals. This investment, leveraged by additional funding from CropLife, its members and Research and Development Corporations, will deliver significant value to the Australian agricultural sector through the approval of label uses for minor crops and specialty uses.

The momentum achieved so far, however, is only the tip of the iceberg. Structural change and additional government funding is required to alleviate the existing economic and regulatory market failure, deliver more sustainable pest management practices and increase the Australian GDP.

Similar programs in the United States have demonstrated that every dollar invested in the minor use program, generates a net return to the economy of US\$500. The minor use and specialty crops program in the US, known as IR-4 or Interregional Research Project number 4, began over 50 years ago.

The success of the IR-4 Project, with additional United States Department of Agriculture funding, is proven and can be measured in its development of data to support nearly 20,000 food use and ornamental horticulture label approvals. IR-4 is managed by Rutgers, The State University of New Jersey and its success is due in no small part to how the program leverages its network of university researchers. With appropriate funding from government, UNE could accomplish similar feats in Australia. Such an investment by government is necessary for a true centre of excellence for agriculture to be established.

5 TRANSITIONAL ARRANGEMENTS

The relocation of the APVMA should not come at a cost to Australia's plant science industry or the national farming sector and any cost caused by delays to product registrations should not be borne by registrants.

The creation of a centre of excellence for agriculture requires detailed planning and significant input from the relevant industry sector (APVMA's customers) to ensure best outcomes and minimal disruption. Even with the best planning and implementation, however, relocating the regulator within a centre of excellence and the implementation of a new online operating model will still cause disruption to APVMA operations and have significant negative impact to regulatory efficiency in the interim.

Transitional offsets for registrants are necessary to account for delays to product registration resulting from anticipated operational difficulties during implementation of the centre of excellence. A delay to product registration encountered by a registrant should result in the application fee being refunded and a 12-month waiver granted for the sales levy.

It is foreseeable that delays due to implementation issues would be experienced for at least three years and therefore, such transitional arrangements would need to be in place for at least that period. The Department of Agriculture and Water Resources would need to provide the APVMA with that lost revenue so that operations were not unduly impacted.

6 CONCLUSION

The APVMA is currently considered a globally respected, scientifically and technically sound regulator of agricultural chemicals. The Authority's expertise and scientific credibility are well recognised within Australia, throughout the Asia Pacific and globally. However, the Order forcing the relocating the APVMA from Canberra puts this reputation at risk.

The application of the Order on the APVMA, poses the real and genuine threat to the APVMA's ability to perform its function. The Order has already lead to significant disruptions for the plant science industry, delaying access by the nation's farmers to crucial products that underpin more than \$18 billion of agricultural production every year. This will continue to compound the comparative disadvantage that the Australian farming sector already has in accessing essential crop protection products compared to their North American and European trading competitors.

The APVMA's recently released performance statistics highlight the impact the relocation is already having on performance, due to the associated loss of key senior and experienced technical assessment staff. Experienced regulatory scientists are in short supply globally, and are the key drivers in the APVMA's capability and efficiency. Substantial initiatives and efficiency drivers are immediately necessary to allow the regulator to continue to function.

While CropLife supports, in principle, government initiatives that improve the economic activity in rural and regional Australia, relocating the APVMA in isolation will not deliver a net benefit for agriculture in the short, medium or long-term. The establishment of an Australian centre of excellence in agriculture, incorporating the APVMA, that leverages technology to streamline APVMA and associated regulatory operations could, however, still deliver a positive outcome for Australian agriculture. Development towards delivering the necessary initiatives and reforms to truly create a centre of excellence for agriculture is of the utmost urgency.

A range of urgent measures are required to be implemented to minimise and mitigate what are significant disruptions and serious consequences from the relocation. These measures would also be the basis that would create a genuine centre of excellence for agriculture and ensure that Australia had a worlds-best next generation regulator for the important plant science and farming sector.