

# 2020-21 PRE-BUDGET SUBMISSION



# 1 EXECUTIVE SUMMARY

CropLife Australia welcomes the opportunity to make this submission to the 2020-21 Federal Budget. This submission highlights opportunities for the Federal Government to sensibly invest in Australian agriculture, an industry key to economic growth and food security in Australia.

The plant science industry is critical to maintaining and improving Australia's agricultural productivity and sustainability, through crop protection and crop biotechnology advances and initiatives.

The investments recommended in this submission will drive plant science innovation, ensure the relevant regulatory systems can rapidly respond to emerging issues and allow Australian farmers to compete in global markets. The initiatives discussed in this document are intrinsically linked to the Federal Government's strategic priorities.

CropLife submits the following recommendations to the 2020-21 Federal Budget:

## **Recommendation One: Complete the overdue efficiency and effectiveness reviews of the Australian Pesticides and Veterinary Medicines Authority**

- a. Complete the First Principles Review commenced in 2012
- b. Replace the CRIS model initially designed for the Australian Pesticides and Veterinary Medicines Authority (APVMA) in 1984 and draft model proposed by Food Standards Australia New Zealand with a cost recovery regime that is fit for purpose in today's dynamic changing environment
- c. Fund public benefit activities that safeguard the independence of the Regulator

*Funded from* APVMA adopting common practice financial management principles (including actively managing their resources relative to budget and work priorities) and through reinvesting anticipated savings quantified in respect of business re-engineering improvements already commenced.

## **Recommendation Two: Strengthen the regulatory environment by removing identified barriers to innovation and growth of the agricultural sector**

- a. Improve access to crop protection for minor uses and specialty crops
- b. Impose acceptable timelines for review of applications by the Therapeutic Goods Administration for scheduling of chemicals
- c. Introduce national legislation for GM crops based on scientific evidential analysis, and remove state-based moratoria
- d. Introduce voluntary labelling requirements for approved GM crops
- e. Implement the recommendations from the Department of Health's Third Review of the National Gene Technology Scheme

**Recommendation Three: Recognise the significant adverse impacts of disruptive misinformation regarding agricultural biotechnology and launch targeted information education campaigns**

- a. Through designing communication strategies to increase knowledge of agricultural biotechnology, including genetic modification and gene-editing
- b. Funding public benefit activities of the Office of the Gene Technology Regulator to demonstrate both the independence of the Regulator and to keep the public better informed

**Recommendation Four: Provide seed funding to extend successful stewardship and recycling initiatives**

- a. Through pilot schemes for each state (approximately \$50,000 investment per state) in collaboration with industry partners (such as Agsafe)
- b. Through promotion of recycling of farm waste (in particular, silo wrap, twine, grain bags, greenhouse plastics, and irrigation plastics)
- c. Through providing information to inform and promote consumer behaviour in terms of the many benefits of buying recycled products

*Funded from* investment fund identified in December 2020 Mid-Year Economic and Fiscal Outlook for waste and recycling initiatives.

## 2 BACKGROUND

### 2.1 About CropLife Australia

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 and crop biotechnology products. CropLife is part of the plant science industry's 91 country international federation.

CropLife, with its subsidiary Agsafe, is a world leader in industry stewardship initiatives that contribute millions of dollars each year to activities to ensure the safe and effective use of crop protection and crop biotechnology products throughout their lifecycle.

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 its Pollinator Protection Initiative, including the world first BeeConnected app, and successful Agsafe programs, **drumMUSTER** and ChemClear®.

### 2.2 Plant science explained

Plant science is the study of any plant system. Two ongoing areas of innovation are: creating tools that protect crops from pests, weeds, and diseases; and developing stronger, healthier more useful varieties of crops. Both assist farmers to sustainably produce high-quality food, feed and fibre for Australia and abroad, driving economic growth in the process.

Since the earliest days of agriculture 10,000+ years ago, farmers have been working to improve the quality of crops by increasing yields and reducing unfavourable traits such as tough skins or hard seeds. These forward-thinking ancestors were the first plant breeders. Today's plant breeders have carried on this tradition by using plant breeding innovations such as biotechnology to identify genes, introduce beneficial genes, modify existing genes and remove detrimental ones with a range of very precise tools.

Since 1996 the plant science industry has been providing Australian agriculture with the benefits of crop biotechnology in the form of genetically modified (GM) crops, delivering significant benefits. Since their approval for commercial cultivation, GM canola and GM cotton crops grown in Australia have delivered Australian farmers more than AUD\$1.37 billion in additional farm income benefits. Future GM crops will bring further environmental benefits, such as more efficient use of water, have greater tolerance of salinity and acid soils, and produce healthier oils and starches.



## 2.3 Economic contribution

The agricultural sector at farm-gate contributes 3 per cent to Australia's total gross domestic product (GDP). The gross value of Australian farm production in 2016-17 was \$60 billion. Australian farmers export around 77 per cent of what they grow and produce. Australian farm exports earned the country \$44.8 billion in 2016-17, up from \$32.5 billion in 2010-11.

Each Australian farmer produces enough food to feed 600 people, 150 at home and 450 overseas. Australian farmers produce almost 93 per cent of Australia's domestic food supply.

Australian farmers remain internationally competitive through efficiencies and productivity growth. The growth in the farm sector has increased steadily overtime, consistently out-performing other sectors.

The 2018 Deloitte Access Economics report, *Economic Activity Attributable to Crop Protection Products*, estimates \$20.6 billion of Australian agricultural output (or 73 per cent of the total value) is attributable to the use of crop protection products. The same report found the plant science sector contributes 9,225 in full time equivalent employees. This consists of 1,725 directly in the manufacturing sector and 7,500 in the sectors that supply inputs to the industry.

Australian agriculture and its associated industries generate over \$155 billion each year and underpin 12.1 per cent of Australia's GDP. The plant science industry is an integral input driving this performance and must be well supported.

There are over 300,000 people directly employed in agriculture. The complete agricultural supply chain, including the affiliated food and fibre industries, provide over 1.6 million jobs to the Australian economy.

## 2.4 Environmental sustainability

Australian farmers are frontline environmentalists, owning, managing and caring for 48 per cent of Australia's land mass.

Access by Australia's agricultural sector to the latest chemical and biotechnology innovations of the plant science industry is crucial if the nation's farmers are going to be able to continue to improve their sustainability and further improve their productivity. Furthermore, CropLife's subsidiary, Agsafe, conducts programs that support and enhance product stewardship of agricultural chemicals throughout the supply chain. This work ensures the personal safety of employees and clients of rural resellers and distributors, and minimises the potential for environmental pollution. The **drumMUSTER** program is responsible for collecting and recycling more than 34.7 million containers from end-users that would have otherwise been burnt, dumped in landfill or abandoned on farms. Under the ChemClear® program, end-users can register for any unwanted chemicals to be collected. This program greatly reduces the risks of environmental pollution or human health concerns on farms.

## 2.5 Supporting government's strategic priorities

Per the Federal Budget 2019-20 and Mid-Year Economic and Fiscal Outlook 2019-20 (MYEFO) the following strategic priorities link to initiatives outlined in this submission.

### ○ **Overarching priority**

A disciplined approach to managing the budget, prioritising new spending that supports Australia's economy and guaranteeing the essential services on which Australians rely is fundamental to funding decisions. This imperative underpins the matters discussed in this document.

### ○ **Grow and support the agriculture sector**

A bold target to grow agriculture to \$100 billion in farm gate output by 2030 has been set by the National Farmers' Federation. Per the December 2019 MYEFO, significant funding has been set aside by government for supporting initiatives in respect of:

- drought-affected farmers and their communities (\$342 million for FY2019-20 and \$310 million for FY2020-21);
- product stewardship programs (\$20 million over four years);
- support of recycled commodities due to ban of export waste (\$15 million over two years and \$100 million recycling investment fund);
- pilot programs to enhance collaboration between universities and industry (\$9.6 million over two years);
- strengthening and showcasing the agriculture sector in relation to the role of bees (\$1.5 million over two years); and
- better education of Australian students about agriculture (\$10 million over three years).

Based on these funding initiatives, it is evident that the recommendations in this paper supporting the agriculture sector, product stewardship, education and better waste management are aligned with the direction set by government.

### ○ **Remove regulatory congestion**

The Federal Government has identified tackling regulatory congestion and helping businesses to invest and create jobs as a priority. The next wave of deregulation outlined in the December 2019 MYEFO focuses on making it easier to export more Australian food, streamlining major project approval processes, helping small business employ more Australians, and creating a one-stop shop for business to update, manage and maintain their business registry data in one location.

### ○ **Support research and development**

The Government announced in the December 2019 MYEFO refinements to the Budget Measure for better targeting the research and development in the tax incentive, including introduction of simplified R&D premiums for large companies (those with aggregated annual turnover of \$20 million or more).

### **3 UNPRECEDENTED CHALLENGES**

The agriculture sector is facing unprecedented challenges relating to climate, rapidly changing scientific-engineering-technology advances and socio-political-economic pressures. The recommended actions outlined in this document are framed within the backdrop of these specific challenges as discussed below.

#### **3.1 Bushfires**

The scale of Australia's 2019-20 bushfires is unparalleled by historic and global standards. In comparison, the 2018 California fires burnt some 2 million acres; the 2019 Amazon fires 2.2 million; and the 2019 Siberian fires 6.7 million. By the end of the first week of January 2020, Australia's 2019-20 fires had burnt 12 million acres, with two more months of summer still to come.

The impacts on the agricultural sector are dire – vast areas of scorched property, destruction of seasonal crops, elimination of orchards and crop stock varieties built up over years, devastation of bee colonies and hives (with impact on pollination of future crops) and loss of farming infrastructure (such as sheds, irrigation equipment and harvesting equipment).

The rebuild of farms and crops will be dependent on maximising crop growth on available land, eliminating the spread of weeds and pests and introducing crop strains that are fast growing and strong.

#### **3.2 Drought**

Since 2017, large parts of New South Wales, Queensland and South Australia have suffered under extreme drought conditions. During this period, the northern half of New South Wales and adjacent southern Queensland have experienced their lowest rainfall on record.

This is having a devastating effect on the communities in these regions – not only farmers, but the many businesses and people that rely on the agricultural sector for their living.

The social and economic losses have been compounded by the bush fires in many of the same areas. Drought conditions are expected to reduce farm GDP in 2019-20 by 3 per cent and rural exports by 8.5 per cent. This correlates to over a \$1 billion in lost revenue.

The extremely dry conditions are resulting in low soil moisture and dam storage levels, with falls in both the area of crops planted and average yields.

Overall, the drought has had a negative effect on the income of Australian farmers with farm unincorporated business income around 15 per cent less than it was a year ago.

There is also the human cost. For example, a recent medical survey of the farming communities across New South Wales indicated increased levels of personal drought-related stress, community drought-related stress and general psychological distress. This survey identified that farmers who are under 35, who live and work on a farm, who were in outer regional, remote or very remote areas experienced greater financial hardship and were the most adversely affected within the survey group.

### **3.2 Extensive lead time for crop protection and biotechnology products**

It takes over 11 years of research and development, requiring the testing of more than 140,000 compounds, to bring just one new successful crop protection product to market. This carries a cost of over US\$286 million. Without access to these products, Australian farmers could lose up to two-thirds of their annual production to pests, weeds and diseases.

In terms of a new GM crop, it takes around 13 years and costs US\$136 million to bring a new crop to market. The majority of the of time delay and cost is due to gathering the data required for global regulatory approvals. This is longer than it takes to get a new medicine from the laboratory to the pharmacy shelf, and longer than it takes from concept to market release of some new aircrafts.

### **3.3 Technology developments and accelerated pace of change**

Technology growth continues at exponential speed. This is driving radical transformation and disruption across all sectors, including agriculture.

Anticipated trends include:

- Expansion of the Internet of Things worldwide by 2025 to 75 billion devices – a five-fold increase in ten years, enabling greater connectivity and supporting smart buildings and infrastructure for all sectors;
- AI-driven technologies and robotics to increase the range and amount of work that can be done by smart machines with 38 per cent of jobs likely to be automated within the next decade impacting on all professional service organisations, including regulators;
- Robotic Process Automation (to automate repetitive tasks) and Business Process Automation (to automate end-to-end processes), which will provide the strategic foundation for digital transformation supporting among other things, research, manufacture and regulatory assessments;
- Unified communications (UC) cloud-based platforms that will provide an effective hub for a digital workforce, supporting remote workforce, streamlining workflow, facilitating collaboration, and increasing efficiencies. This should result in significant efficiencies to professional service organisations (such as the APVMA), whilst providing a dynamic, well-skilled and agile workforce;



- Quantum Computing to process data thousands of times faster than traditional silicon-chip-based computers while using less power. This exponential increase in computing capacity makes it possible to run complex AI-powered applications, supporting analytics and modelling, allowing organisations to leverage a large amount of data available. This will impact all organisations performing specialist review services based on data collected such as the APVMA.

### **3.5 Disruptive misinformation**

Misinformation is harmful to all communities. It makes the world less informed and it erodes trust. It's not a new phenomenon and many parties — technology companies, media companies, newsrooms, teachers, governments, industries — have a responsibility to do their part in addressing the issue.

Technology companies are working to fight the spread of false news in three key areas:

- disrupting economic incentives because most false news is financially motivated;
- building new products to curb the spread of false news; and
- helping people make more informed decisions when they encounter false news.

For example, Facebook recently joined a group of over 25 funders and participants, including tech industry leaders, academic institutions, non-profits and third party organisations, to launch the News Integrity Initiative, a global consortium focused on helping people make informed judgments about the news they read and share online. The initiative's mission is to advance news literacy, to increase trust in journalism around the world and to better inform the public conversation. The initiative, which is administered by the CUNY Graduate School of Journalism, will fund applied research and projects, and convene meetings with industry experts.

Much of the recent published commentary regarding glyphosate and GM crops is not supported by scientists, the farmers who have used these products over many decades, nor the government's own regulators. Facts are being ignored in the public debate, drowned out by disruptive and false sensationalised media. The adverse impacts of this extends to disruption of viable farming and agricultural businesses, threatening food security, and may even result in the general public's fear of beneficial agricultural technologies.

The Federal Government needs to ensure its information and legislative initiatives support the work being undertaken by agtech companies and peaks to promote educated views and analysis, and to limit the spread of ill-informed disruptors spreading non-factual information.

### **3.6 Socio-economic influences**

The Reserve Bank of Australia has cut interest rates to a record low of 0.75 per cent and is widely expected to throw in two more cuts in 2020 to bring the cash rate to a new record low of 0.25 per cent. Accordingly, there is little more that can be done in terms of monetary policy to stimulate economic activity without moving into the unconventional territory of quantitative easing or negative interest rates.

We support the recently announced initiatives by government to flow more money into the farming-agriculture sector that has been ravished by fire and drought.

## 4 ANALYSIS AND RECOMMENDATIONS

### 4.1 Improve the efficiency and effectiveness of the APVMA

- **Complete the First Principles Review of APVMA**

The then Department of Agriculture initiated a first principles review of the cost recovery arrangements for the APVMA in 2012. The final report titled *First Principles Review of Cost Recovery at the Australian Pesticides and Veterinary Medicines Authority* (the Report) was published in 2014. Not one of the Report's recommendations have been implemented.

A second First Principles Review was commenced in 2018 but remains uncompleted. In the absence of this work, the APVMA are endeavouring to revise an outdated costing model.

The major issues repeatedly raised by industry that have been ignored include: inefficiencies at the APVMA; subsidisation by industry for public good activities; lack of a costing/resourcing model being adopted by the APVMA that would support changing volumes and resourcing needs of industry; and improved timeliness.

Implementing the Report's recommendations would ensure the APVMA's cost recovery arrangements are transparent, equitable and consistent with government policy.

The Report proposes an effective way to fund the operations of the Regulator. It does not, however, include analysis of how the proposed framework will affect the agricultural chemical industry and Australian farmers.

- **Address the root cause of the APVMA's budget deficits**

The Cost Recovery Implementation Statement (CRIS) model was initially designed for the APVMA in 1984. It needs a cost recovery regime that is fit for purpose in today's dynamic changing environment.

ABC models can be adopted successfully when the majority of costs for service are variable and not fixed or semi-fixed in nature. This is not the case with the APVMA. For example, almost all employees (contributing over 70 per cent to the cost base) are permanent and on-going. Accordingly, the APVMA's ability to downsize if volumes fall or skills needs change dramatically and then upsize quickly if volumes rise, is not possible.

In all likelihood, given the resourcing model and current lack of strategic planning for workforce needs, the APVMA will continue to generate deficits despite the increased fees and levies presented to industry.

- **Fund overarching advisory functions that reinforce the independence of the Regulator**

For Business as Usual activities for the year ended 30 June 2019, the APVMA is receiving funding via fees, charges and levies imposed on agricultural chemical and veterinary medicines registrants. Comparable regulators internationally receive a significant level of public funding. For example, the European regulator for agvet products, the European Food Safety Authority, was publicly funded by the EU at a cost of approximately €79 million for 2017<sup>1</sup>, while the United States Environmental Protection Agency (US EPA) and Health Canada's Pest Management Regulatory Agency (PMRA) operate on a partial cost recovery basis. Under this arrangement, the PMRA received approximately CAD\$36.5 million in government funding in 2016-17, with an additional CAD\$7.9 million received via cost recovery.<sup>2</sup> Similarly, the US EPA received US\$128.3 million in government funding in 2017, along with approximately US\$46 million via industry fees.<sup>3</sup>

Currently, the cost of the APVMA is almost entirely met through application fees and levies recovered from applicants and registrants of agvet products. This has led to some public criticism that agricultural chemical manufacturers have captured the APVMA, leading to perceptions that the decisions of the APVMA are not independent.

In contrast, the Office of the Gene Technology Regulator is entirely funded via government appropriation, receiving more than \$8 million each year to conduct its regulatory responsibilities.

A cost recovered regulatory environment poses no scope for undue influence from the industry it regulates. CropLife recognises, however, that the perception of independence by the Australian public – and therefore confidence in the APVMA – would be considerably increased under a public funding arrangement. Adequate funding for public benefit activities should be provided in accordance with the Federal Government's own cost recovery guidelines.

Comprehensive public funding for the APVMA would address and neutralise the ongoing criticisms from activist organisations who claim the APVMA is not independent of industry as a result of its funding structure. Comprehensive public funding would significantly reduce barriers to market entry for smaller registrants and facilitate the deployment of new products by small and medium businesses tailored for lesser grown crops and smaller industries.

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<sup>1</sup> [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/ar2017.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/ar2017.pdf)

<sup>2</sup> <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/annual-report-2016-2017.html#a8>

<sup>3</sup> <https://www.epa.gov/pria-fees/annual-reports-pria-implementation>

○ **Remove reliance on industry to subsidise the regulator's public benefit activities**

- ***The APVMA Chief Scientist***

At a bare minimum, the role of Chief Scientist should be publicly funded.

- ***Website and publications***

The APVMA website and other corporate publications are for both government and non-government audiences. The website is largely a platform for the communication of information to both industry and the general public.

- ***Consultative committees, presentations and seminars***

The agvet industry is not the only recipient of services relating to consultative committees, presentations and seminars provided by the APVMA. Each has an element of providing information to the public and/or other government sectors involved in Federal Government policy.

- ***Risk mitigation oversight activities for the public good***

The APVMA's monitoring, compliance and enforcement activities are critical to supporting and maintaining the integrity of the regulatory system. This does require the APVMA to take a broad approach to monitoring and compliance. The APVMA must not only focus on product registrants and approval holders, but manufacturers and importers that deliberately seek to avoid Australia's regulatory system.

Publicly funding monitoring, compliance and enforcement activities of pesticides will offer significant benefits to governments, industry and the community. It will:

- Ensure the magnitude and scope of compliance and enforcement activities can be effectively matched to the size of the problem. It will not be restrained by the APVMA's limited budget;
- Demonstrate that registrants and approval holders have not captured the Regulator and increase public perception of an independent compliance function; and
- Facilitate greater voluntary stewardship initiatives by industry to support government compliance functions.

An appropriately funded regulatory scheme should reflect the commitment of all interested parties to enforcing the scheme. CropLife recommends the Federal Government increase public resourcing for monitoring, reconsideration, compliance and enforcement.

CropLife recommends it be funded through general revenue, in line with the APVMA's international counterparts. This would improve the Regulator's capability in this important area and neutralise criticisms regarding the APVMA's independence.



CropLife also recommends public funding of the reconsideration program as the APVMA's reconsideration program is a public benefit function.

Following initial registration, the ongoing human, animal health and/or environmental safety of an agricultural or veterinary chemical product is constantly monitored. As part of the regulatory process, all new scientific information regarding an agricultural or veterinary chemical product is considered in a timely manner.

This system provides a highly responsive regulatory review system, whereby a formal review or 'reconsideration' that focusses on new scientific information, rather than a purely administrative process, can be initiated at any time.

If any new, relevant scientific information that contradicts the current information entered or shows a product or constituent may not meet the safety, trade or efficacy criteria, the registrant is required by law to provide it to the APVMA. Legislative amendments implemented in 2014 were intended to ensure that reconsiderations are conducted in a transparent, predictable and efficient process. A number of significant chemical reconsiderations were tracking to be completed by their newly determined statutory deadlines during 2017 and 2018. CropLife believes, however, that the relocation of the APVMA to Armidale from Canberra, and subsequent loss of experienced staff, has delayed their finalisation.

- ***Corporate governance***

The annual report is not only an information tool for external stakeholders, but a key government reporting tool required under legislation. The annual report is used by the Department of Agriculture and the Department of Finance in the preparation of consolidated reports.

Other corporate publications are also used for a variety of purposes, by government and non-government stakeholders.

CropLife recommends the APVMA should be subject to the same productivity dividends as other government agencies, with dividends either reinvested into core operations of the agency or providing fee relief to registrants. A more equitable split between cost recovered and government funding should encourage the APVMA and the Department of Agriculture to seek out and implement genuine efficiency and productivity reforms.

It is imperative that the Federal Government's Cost Recovery Guidelines (CRGs)<sup>4</sup> provide clarity on what can and cannot be cost recovered, and what agency expenses can be included for calculating cost recovery fees and levies. The current CRGs are not sufficiently clear on this matter.

Similarly, there remains a lack of clarity around when levies can be used in addition to fees under a cost recovery model. Equally important is a justification of the efficiency of a levy system, particularly with regard to ensuring agency operations are not being inappropriately subsidised by larger levy payers.

## 4.2 Strengthen the supporting regulatory environment

### ○ Facilitate access to crop protection for minor uses and specialty crops

Manufacturers of agricultural chemicals rarely make applications for minor and specialty use (including emergency use). Applications for minor and specialty use are predominately made by farming sector groups or individual farmers seeking permission to use an existing crop protection product for an off-label use.

In the 2014 Federal Budget, where very few project proposals received funding, the Federal Government committed an initial \$8 million over four years towards helping farmers gain improved access to safe and effective agricultural chemicals. Further funding of \$4 million over two years was announced in the 2018 Federal Budget towards correcting the market failure caused by a mandatory regulatory system, by better enabling the inclusion of minor uses and specialty crops on agvet labels.

These investments, leveraged by additional funding from CropLife, its members and research and development corporations, have begun to deliver significant value to the Australian agricultural sector through the approval of label uses for minor crops and specialty uses. In 2017:

- 360 unique crop/pest issues were identified by grower industry bodies
- 160 of these had no identified solution, for which 51 new potential solutions were identified by registrants
- An additional 64 new solutions were identified by registrants adding to existing options proposed by industry

The economic gains achieved so far could be exponentially more. Structural change and further funding is required to alleviate the existing economic and regulatory market failure, deliver more sustainable pest management practices and increase the Australian GDP.

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<sup>4</sup> Department of Finance, 'Australian Government Cost Recovery Guidelines', Resource Management Guide No. 304, July 2014 - Third edition

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 and receives government funding of approximately US\$14 million a year. The success of the IR-4 Project, with additional U.S. 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. Part of its success is due to the program leveraging a network of university researchers. With appropriate funding from government, the University of New England could accomplish similar feats in Australia.

In 2002, the Ministers of Health Canada and Agriculture and Agri-Food Canada announced funding of CAD\$61.8 million to address problems in the minor use system. These included slow access to pesticides, loss of uses due to reliance on older chemistry, international competitiveness, and the high cost of data generation to support minor uses.

The Department of Agriculture has received grant applications totalling over the \$8 million allocated. This shows significant demand and need for an additional and ongoing funding commitment.

CroPLife recommends the Federal Government continue this funding commitment.

- **Impose acceptable timelines for review of applications by TGA for scheduling of chemicals**

The Department of Health, via the Therapeutic Goods Administration (TGA), is responsible for scheduling medicines and chemicals, which controls how they are made available to the public. Medicines and chemicals are classified into schedules according to the level of regulatory control over the availability of that medicine or chemical required to protect public health and safety.

In 2017, the Department of Health initiated a review of the Scheduling Policy Framework (SPF). The review was completed in early 2018, with the updated SPF and accompanying Scheduling Handbook published on 18 January 2018. Resulting from the review, the SPF now allows for applications for scheduling of chemicals to be submitted directly to the TGA, in a manner similar to the one previously only available for pharmaceuticals.

Although it is now legislated, the TGA is not supportive of receiving scheduling applications for agricultural chemicals directly from manufacturers, citing a lack of available resources to complete application assessments and implement the new legislation. As such, agricultural chemical scheduling applications must still be made directly to the APVMA for assessment and evaluation prior to being referred to the Department of Health for scheduling.

The unpredictability associated with poison scheduling has long been a significant concern of the plant science and Australian farming sectors. It leads to unnecessary delays to the introduction of new and innovative crop protection products to the Australian market.

Considering scheduling of chemicals is a public benefit, CropLife recommends the costs associated with resourcing the Department of Health to implement the 2018 legislative amendments and carry out their legislative requirement be funded by the Federal Government.

Enabling applicants to submit scheduling applications directly to the TGA will provide the registrant with more control of when submissions are made for scheduling and therefore reduce the risk of missing key deadlines during the product registration process. Implementation of this legislation would, in principle, remove unnecessary discrimination of agricultural chemicals compared to their pharmaceutical chemical counterparts.

- **Introduce national legislation for GM crops based on scientific evidential analysis, and remove state-based moratoria**

Regulating GM crops at a state level undermines the National Regulatory Scheme for Gene Technology. As recommended in the Final Report of the Productivity Commission's Inquiry into the Regulation of Australian Agriculture, "the New South Wales, South Australian, Tasmanian and ACT Governments should remove their moratoria on GM crops. All states and territories should also repeal the legislation that imposes or gives them powers to impose moratoria on GMOs by 2018".

The circumvention of the national scheme is facilitated by section 21(1)(aa) of the Gene Technology Act 2000, which states:

The Ministerial Council may issue policy principles in relation to the following:

recognising areas, if any, designated under State law, for the purpose of preserving the identity of one or both of the following:

- (i) GM crops;
- (ii) Non-GM crops;

for marketing purposes.

Section 21(1)(aa) allowed the then Gene Technology Ministerial Council to introduce the Gene Technology (Recognition of Designated Areas) Principle 2003. In doing so, states and territories have the power to disallow the cultivation of GM crops for marketing purposes.

The principle was used by Western Australia, South Australia, Tasmania, Victoria, New South Wales and the ACT to legislate for moratoria on the commercial cultivation of GMOs, leading to what was identified in the March 2015 Harper Competition Policy Review as a significant example of a regulatory restriction on competition.

Section 21(1)(aa) is a costly disincentive for private investment in Australian agriculture. It has been demonstrated to be unnecessary for preserving the identity of GM and non-GM crops and it removes farmer choice, with Australian farmers missing out on billions in additional farm income.

Since their introduction, the moratorium on GM crops in Western Australia has been repealed and the Moratorium regulations in South Australia removed by Ministerial instrument. However, it is expected the South Australian decision via regulation will be subject to a disallowance vote in that Parliament in the coming months.

CroPLife recommends the repeal of s21(1)(aa) in the Commonwealth Gene Technology Act 2000, the repeal of the corresponding section in state and territory acts, and the immediate disallowance by the responsible Minister of the Gene Technology (Recognition of Designated Areas) Principle 2003.

- **Introduce voluntary labelling of genetically modified foods**

CroPLife supports Food Standards Australia New Zealand's () rigorous and transparent process for assessing the safety of GM foods, based on internationally established scientific principles and guidelines.

Every legitimate scientific and regulatory body that has examined the evidence has arrived at the conclusion that approved GM crops and the foods derived from them are as safe as their conventional counterparts. This includes the World Health Organization; the Australian Academy of Science; the European Commission; and the American National Academy of Sciences.

CroPLife does not support the mandatory labelling of GM foods and food ingredients in Australia where it bears no relevance to the health or safety of the food or ingredients. Mandatory labelling for non-health and safety reasons can imply a regulatory concern where none exists and only serves to reinforce misconceptions in the community.

A food label has finite space and can only contain a certain amount of information. Unnecessary mandatory requirements reduce the ability of food manufacturers to provide product information that might be more important to consumer purchasing decisions. All information on labels comes at a cost. Consumers should not be required to pay for mandatory information where there is no risk to human health or safety.

CroPLife supports voluntary labelling of foods and food ingredients where that information is not misleading or deceptive. Voluntary labelling recognises a balance between the provision of consumer information with the cost and other practicalities of providing it. Food manufacturers will voluntarily provide production information according to consumer demand. For example, 'organic', 'low-fat', 'low-salt' and 'free-range' are all marketing terms widely and voluntarily used by food manufacturers in response to customer preference.



A voluntary labelling system for approved GM foods and food ingredients would allow flexibility for manufacturers regarding what information is of interest to consumers. For example: if a manufacturer chose not to provide certain voluntary marketing information to consumers and producing food at a lower cost without losing market share, then competitors would quickly emulate this approach. Alternatively, if a large proportion of consumers preferentially purchased products containing certain voluntary information, manufacturers would react to this promptly.

CropLife recommends amending Food Standard 1.5.2 of the Australia New Zealand Food Standard Code to remove the requirement for mandatory labelling of approved GM foods and food ingredients.

- **Implement the recommendations from the Department of Health's Third Review of the National Gene Technology Scheme**

In October 2018, the Legislative and Governance Forum on Gene Technology met to endorse the Third Review of the National Gene Technology Scheme and its 27 recommendations. Forum Ministers said these recommendations will enhance and strengthen the Scheme, crucial to ensuring it addresses future developments and challenges across health, medicine, agriculture, plants and animals. A Forum Action Plan has been produced to progress these recommendations.

- **Support world-leading stewardship initiatives**

In addition to funding the regulatory scheme for agricultural chemicals, CropLife and its member companies contribute to, and sponsor a range of other stewardship programs. These programs support the safe, sustainable and responsible transport, handling and use of agricultural chemicals. CropLife's subsidiary Agsafe's **drumMUSTER** and ChemClear® programs are world-leading initiatives to responsibly deal with waste containers and chemical products. Our resistance management strategies support the effective and responsible use of chemical products to delay and prevent the development of pest and weed resistance. Our Agsafe Accreditation and Training Program ensures that facilities handling and storing agricultural chemical products are compliant with all Commonwealth, state and territory legislative requirements. These activities minimise the burden on jurisdictions to enforce their legislation.

The plant science sector contributes significant resources each year to stewardship activities for agricultural chemicals throughout their lifecycle.

Crop protection products must be used sparingly, carefully and responsibly. The effective and responsible use of agricultural chemicals must be supported by an efficient and appropriately balanced regulatory scheme that maximises the benefits associated with their responsible use, and support of product stewardship activities.

### 4.3 Shortcomings in current CRIS models

Prohibitive cost recovery arrangements from government regulators leads to inequity and reduces Australia's agricultural competitiveness. Currently, the cost of the APVMA is almost entirely met through application fees and levies recovered from applicants and registrants of agricultural chemicals and veterinary products. This has led to some public criticism that agricultural chemical manufacturers have captured the APVMA, leading to perceptions that the decisions of the APVMA are not independent.

A cost recovered regulatory environment poses no scope for undue influence from the industry it regulates. CropLife recognises, however, that the perception of independence by the Australian public and therefore confidence in the APVMA would be considerably increased under a public funding arrangement. This would align the APVMA with the Office of the Gene Technology Regulator, which is entirely funded via government appropriation, receiving more than \$8 million each year to conduct its regulatory responsibilities

Every GM crop in Australia is subjected to intense scrutiny and rigorous regulatory assessment. The Gene Technology Regulator protects the health and safety of people and the environment by identifying risks posed by gene technology and then managing those risks through regulation. Food Standards Australia New Zealand (FSANZ) is required to approve any GM food or food ingredient and the APVMA regulates GM crops with inbuilt pest protection.

Implementation of the 2014 legislation highlighted the APVMA's failure to maintain the currency and capability of its Information and Communication Technology systems. Under current cost recovery arrangements, funding for these systems and their maintenance has already been provided by the agricultural and veterinary chemicals industry. Any future capital improvements necessary to rectify this failure must be funded by the Federal Government. It is entirely inappropriate for industry to have increased costs imposed on it due to previous management failures of the APVMA.

The APVMA's operations are inconsistent with the Australian Cost Recovery Guidelines July 2014 (CRGs) in that it is not currently operating in an efficient manner, with no driver of efficiency identified in the proposed cost recovery framework. A cost recovery model attempts to recover the full cost of an activity. Under such a framework, however, an inefficient process cannot be highlighted through financial analysis. There is a need to conduct a Business Process Review, linked to cost recovery, within the APVMA to ensure processes subject to cost recovery can be made as efficient as possible.

The 2012 previously referred to and entitled *First Principles Review of Cost Recovery at the Australian Pesticides and Veterinary Medicines Authority* (published in 2014) and subsequent independent reviews of APVMA's CRIS correctly identify the suitability of Commonwealth Appropriation for the APVMA to ensure their cost recovery arrangements are consistent with the CRGs. Activities such as informing policy and other activities requested by government should be at the cost of government. Commonwealth Appropriation is the right mechanism for funding these activities. However, the current level of Commonwealth Appropriation is substantially insufficient to fund the level of services the government receives from the APVMA. There are APVMA activities not included in the proposed model that, under the CRGs, should also not be subject to cost recovery from industry.

### **Food Standards Australia New Zealand Cost Recovery Plans**

In July 2018, FSANZ released a Cost Recovery Implementation Statement for public comment. It was implemented in July 2019 following the acceptance of many of industry's suggested amendments.

There remains one outstanding concern raised by CroPLife that was not addressed by FSANZ. Maintaining a 'fixed charge' that is not refundable is unacceptable and results in the process ceasing being cost recovery and becoming a 'fee-for-service' model. This becomes even more important a concern considering the significant increase in the proposed 'fixed charge' when compared to the previous upfront refundable administration fee.

CroPLife does not object to an upfront initial charge, with a refund if less time is spent, for the component of tasks that FSANZ has identified as being common to all applications.

CroPLife raised our concerns with the non-refundable nature of the proposed 'fixed charge' with the Federal Minister for Agriculture, Senator the Hon Bridget McKenzie. The intention is to review the fixed charge after 12 months of operation and revise it based on timesheet data collected by FSANZ. This review should be appropriately funded.

## 5 CONCLUSION

Without new, innovative agricultural products, Australian agriculture's productivity cannot grow. Crop protection and GM products are core components of agricultural innovation that enable Australian farmers to be internationally competitive, which benefits the Australian economy.

Regulatory oversight must be efficient, effective and where necessary, commensurate with the risks, costs and benefits to the broader community. Only then will we realise a truly productive, competitive and sustainable agricultural industry in Australia.

A greater investment of public funding in the agricultural chemicals regulatory system and a thorough review of APVMA activities, in line with cost recovery and ensuring public benefit activities are appropriately funded by Commonwealth Appropriation, is consistent with the Cost Recovery Guidelines and will lead to better international regulatory equity. Further investment to improve access to crop protection for minor uses and specialty crops has the potential to significantly improve Australia's agricultural productivity through continued innovation and development of plant protection products for minor and emerging industries.

Specific investments in monitoring, compliance and enforcement will also improve consumer perceptions regarding the independence of the APVMA. While CropLife does not accept the claims that the APVMA has been 'captured' by industry, specific investments to enhance the monitoring, compliance and enforcement functions of the APVMA would substantially address concerns regarding regulatory capture.

Costs unnecessarily imposed on industry throughout the food and chemical regulation processes all add up to costs to farmers and consumers. The APVMA functions that are currently being cost recovered that are a public benefit, should instead be government funded.

Government should also adequately resource the Department of Health, so the Therapeutic Goods Administration have the available resources to complete scheduling for agricultural chemicals, as is now legislated. Implementation of this legislation would, in principle, remove unnecessary discrimination of agricultural chemicals compared to their pharmaceutical chemical counterparts.

GM technologies (cotton and canola) have delivered Australian farmers more than AUD\$1.37 billion in additional farm income benefits over the past 20 years. Access to these agricultural innovations has helped the agriculture industry significantly contribute to Australia's economy. The implementation of the Productivity Commission's report recommendations would lead to a significant reduction in unnecessary and costly regulations while also ensuring Australians are aware of the benefits of GM technologies. The repeal of state and territory-based moratoria on GM crops would alleviate regulatory restriction on competition and ensure Australian farmers have real choice to grow federally regulated and approved GM crops.

Misinformation about GM technology could result in the community forgoing the benefits of GM foods. There is an opportunity for governments and regulatory agencies to provide more information and to clarify misinformation about GM technologies.

The Productivity Commission's recommendation to amend food regulation guidelines to make labelling of GM foods voluntary would prevent unnecessary labelling costs – particularly given there is no risk to human health or safety.

The Third Review of the National Gene Technology Scheme was recently released, along with 27 recommendations which have formed a Forum Action Plan. To progress these recommendations, (endorsed by all Forum Ministers) successfully, they must be adequately funded.

If the Australian economy is to take full advantage of the innovation from the plant science and broader chemical industries, these recommendations must be seriously considered.