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

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12 February 2016

Mr Paul Lindwall
Presiding Commissioner
Regulation of Australian Agriculture
Productivity Commission
Locked Bag 2, Collins Street East
MELBOURNE VIC 8003

Dear Mr Lindwall

On behalf of CropLife Australia I provide the attached submission to the Productivity Commission Inquiry into the Regulation of Australian Agriculture.

CropLife's submission focuses on the use of regulation to create a stronger and more productive agriculture sector in Australia, specifically by improving access to new technologies and agricultural chemicals.

CropLife submits that a truly productive, competitive and sustainable agricultural industry in Australia that improves market returns at the farm gate is not achievable in the long-term without ensuring that regulatory oversight is efficient, effective and where necessary commensurate with the risks, costs and benefits to the broader community.

Crop protection products and crop biotechnologies are crucial to modern farming. It is essential that government works with industry to reduce unnecessary 'red tape' or regulation that is not commensurate with risk and creates nationally harmonised regulations and legislation to maintain the ability for Australian farmers to access the latest innovative tools in plant science.

Meeting the challenges presented by sustainably increasing food production to meet growing global demand will require science-based regulatory policies that support all farming production systems, including existing and future production tools.

Please do not hesitate to contact me should you require clarification or elaboration in respect to any aspect of this submission.

Yours sincerely

(SIGNED)

Matthew Cossey
Chief Executive Officer

Attach:

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

CropLife AUSTRALIA

CROPLIFE SUBMISSION TO PRODUCTIVITY COMMISSION INQUIRY INTO REGULATION OF AUSTRALIAN AGRICULTURE

12 FEBRUARY 2016

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1. INTRODUCTION AND SUMMARY OF KEY ISSUES

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 and small and large companies and accordingly, advocates for policy positions that deliver whole of industry benefit. 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 $17.6 billion a year to the Australian economy and directly employs thousands of people across the country. CropLife Australia is a member of CropLife Asia and part of the CropLife International Federation of 91 CropLife national associations globally.

CropLife and its members are committed to the stewardship of their products throughout their lifecycle and to ensuring that 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 and effective use of their products. CropLife ensures the responsible use of these products through its mandatory industry code of conduct and has set a benchmark for industry stewardship through programs such as ***drum****MUSTER*, ChemClear® and Agsafe Accreditation and Training. Our stewardship activities demonstrate our commitment to managing the impacts associated with container waste and unwanted chemicals.

The world's population is predicted to increase to 9.7 billion by 2050, requiring an increase in global food production of more than 70 per cent. Providing enough food in the context of production constraints, volatile consumption patterns and a changing climate will be an unprecedented scientific, agricultural, industrial, economic and public policy challenge. The situation provides an opportunity for Australian farmers to both assist in the global food security effort and to profit from increased demand for their agricultural products. By adopting innovative farming practices, such as the sustainable and efficient use of crop protection products and genetically modified (GM) crops, the Australian farming sector will be able to produce more sustainably and with greater productivity.

A truly productive, competitive and sustainable agricultural industry in Australia that improves market returns at the farm gate is not achievable in the long-term without ensuring that regulatory systems are efficient, effective and only commensurate with the genuine risks, costs and benefits to the broader community.

Crop protection products and crop biotechnologies are crucial to modern farming. It is essential that government works with industry to reduce unnecessary 'red tape' or regulation that is not commensurate with risk and create nationally harmonised regulations and legislation to maintain the ability for Australian farmers to access the latest innovative tools in plant science.

This submission expands on the following key messages:

Crop Biotechnology Regulation (Section 2)

- State-based GM crop moratoria and the lack of nationally consistent regulatory scheme has created uncertainty in the agricultural biotechnology industry in Australia and undermined the effective regulation of GM crops. *(Section 2.3)*
- Australia's regulatory environment governing the path to market for GM crops continues to impose a regulatory burden on many agricultural businesses through inconsistent regulation and lengthy decision-making. *(Section 2.3)*
- A comparison of the regulatory data requirements for assessment of GM products with incorporated pest and/or disease control by the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Office of the Gene Technology Regulatory (OGTR) and Food Standards Australia New Zealand (FSANZ) shows a high level of concordance. Acceptance by the APVMA of OGTR and FSANZ risk assessments, or the removal of APVMA regulatory responsibility for pesticides expressed *in planta* would be consistent with the Australian Government's commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals, business and community organisations. *(Section 2.4)*

- Unnecessary regulation and oversight of products developed using new breeding techniques (NBTs) will result in costly regulatory burdens, stifle innovation and prevent the uptake of scientifically advanced, innovative breeding applications by the public and private sectors. The Government needs to avoid regulating products developed through NBTs that are similar to, or indistinguishable from products resulting from traditional breeding methods, since such products do not differ in their safety. *(Section 2.5)*
- Voluntary third-party food certification schemes, such as those used by the organic industry, have resulted in claims being made that organic products are free from GM ingredients, even for products for which there is no GM input equivalent. This could be considered a misleading and deceptive representation under Australia's fair-trading laws. *(Section 2.6)*
- In normal farming practice, producers of a premium product bear the risks associated with producing that product in expectation of a higher farm gate return. Organic producers do not see it this way and expect their neighbours to bear their risk, particularly when it comes to the zero tolerance for the presence of safe and approved GMOs in Australia's convoluted and opaque organic certification schemes. *(Section 2.6)*
- CropLife supports FSANZ's rigorous and transparent process for assessing the safety of GM foods, based on internationally established scientific principles and guidelines. 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 can reinforce misconceptions in the community. *(Section 2.7)*
- A major disincentive to private investment in developing agricultural biotechnology tools is that regulatory data generated for assessment by the OGTR and FSANZ is not protected in the same way as regulatory data that is submitted to the APVMA. CropLife believes commercially sensitive data that is submitted for regulatory purposes should be protected for a minimum of ten years from unauthorised use by competitors. *(Section 2.8)*
- The dysfunctional regulatory framework for the commercialisation of GM crops in the EU has resulted in European biotechnology companies pulling their R&D and commercial operation out of Europe, and shifting them to the United States, where the regulatory process is more predictable. It is extremely important the Australian regulatory system for gene technology remain science based, focused on risk assessment and free from political influence by the governments of the day. *(Section 2.9)*

Agricultural Chemical Regulation (Section 3)

- The responsible use of agricultural chemicals must be supported by a regulatory scheme that maximises the benefits associated with their responsible use, while minimising the costs from excessive, unnecessary, inappropriate and/or ineffective regulation. *(Section 3.1)*
- The Risk Profiling Tool currently being developed by the APVMA and the University of Melbourne's Centre of Excellence for Biosecurity Risk Analysis is expected to achieve regulation of agricultural chemicals that is proportionate to risk. *(Section 3.2)*
- The APVMA already accepts and uses international data if relevant to the proposed use of the product in Australia. However, better utilisation of hazard assessments conducted by international regulators that operate to a similar standard of assessment to the APVMA will deliver regulatory efficiencies and thereby reduce unnecessary costs and delays by avoiding the re-assessment of data to revalidate the same endpoints. *(Section 3.3.1)*
- Complete or final registration decisions on the registration of agricultural chemicals by overseas regulators should not be accepted as the sole justification for registering or cancelling a product or active constituent in Australia. *(Section 3.3.4)*
- The previous recognition that APVMA labels comply with WHS regulations must be urgently reinstated to avoid the unnecessary cost to manufacturers and therefore Australian farmers, as well as the inherent increased risk to worker health and safety. *(Section 3.4)*

- The delays and unpredictability associated with poisons scheduling are resulting in substantial additional and unnecessary delays to the introduction to the Australian market of new and innovative crop protection products. Improvements in timeliness and predictability are crucial to ensure this unnecessary regulatory burden and internationally embarrassing situation is urgently corrected. *(Section 3.5)*
- The inability to recover the significant costs of the mandatory regulatory system in a relatively small market means crop protection products are only registered in circumstances where there is a direct financial incentive for registrants to do so. Minor and specialty crops are, therefore, unlikely to be registered for use in Australia without ongoing funding from government and legislated incentives for registrants to add minor uses to agricultural chemical product labels. *(Section 3.6)*
- As previously recommended by the Productivity Commission, harmonisation of state control of use regulations in Australia would remove duplication and inconsistencies, and reduce unnecessary costs to industry and therefore Australian farmers. *(Section 3.7)*

Cost Recovery (Section 4)

- CropLife supports regulatory cost recovery where it is justifiable, appropriate and proportionate to undertaking core business, and not used to subsidise budget shortfalls. Unfortunately, all too often we have seen attempts by regulatory agencies to use regulatory cost recovery as a means to balance budgets or make applicants pay for work not related to the regulatory risk assessment of a particular product.

2. CROP BIOTECHNOLOGIES

2.1 Introduction

Genetically Modified (GM) crops, an application of modern agricultural biotechnology, are just another step along the same path of technological innovation that led to Australian agricultural inventions such as the combine harvester and 'Federation' wheat varieties. The utilisation of these innovations has delivered safe and affordable food to the nation and the world. Despite a proven record of safety, every GM crop is subjected to intense global scrutiny. Globally, government regulators have independently reached the same conclusion – that cultivation of GM crops poses no greater risk to human health or the environment than cultivation of conventional (non-GM) varieties. More importantly, they are a necessary and vital tool in meeting the global food and nutrition security challenge.

GM crops currently under research and development in Australia will help Australian farmers to combat environmental stresses such as drought, acid soils and salinity, which are being caused by climatic changes and previous non-sustainable farming practices. There is also considerable Australian research into GM traits that will bring health benefits to consumers, such as healthier starches and oils modified to be lower in saturated fats and with improved cooking qualities.

The most recent annual report on the global socio-economic and environmental impact of GM crops from the British consultancy firm PG Economics indicated continued considerable economic and environmental benefits to farmers and the general public in countries where GM crops are grown[1]. The report indicated that the net benefit at the farm level in 2013 from growing GM crops was US$20.5 billion. For the 17 year period (1996-2013) covered by the report, the global farm income gain has been US$133.5 billion. Australian GM cotton and canola farmers have realised a benefit of more than US$885 million in the period 1996-2013[2].

The PG Economics report also notes that GM crops have contributed significantly to reducing the release of greenhouse gas emissions from agricultural practices. This resulted from less fuel use and additional soil carbon storage from reduced and no-tillage farming systems associated with GM crops. In 2013, the permanent CO_2 savings from reduced fuel use were the equivalent of removing 940,000 cars from the road and the additional probable soil carbon sequestration gains in 2013 were equivalent to removing 11,520,000 cars from the road[3]. This is equal to 71 per cent of all motor vehicles registered in Australia.

Bringing a new GM trait to market is a significant investment made by the plant science industry. To determine the relative cost and duration of the process, CropLife International commissioned consultancy firm Phillips McDougall to survey the plant science industry's largest developers. The survey found that it takes 13 years research and development (R&D) plus US$136 million to develop each new GM crop trait[4].

The cost and duration of new GM trait development, particularly navigating the regulatory process, highlights the need for a transparent and workable regulatory system based on sound science and harmonised risk assessment. Improvements to state and territory participation in the national gene technology regulatory framework will help remove unnecessary barriers to innovation and trade for Australia, assisting the nation in achieving a clean, green and sustainable agricultural sector.

Every legitimate scientific and regulatory body that has examined the evidence has arrived at the conclusion that GM crops and the foods they produce are as safe as their conventional counterparts. This includes the World Health Organization, the Australian Academy of Science, the European Commission, the American National Academy of Sciences, the Royal Society of Medicine and many more. GM crops currently grown around the world and the food they produce have been studied extensively and repeatedly declared safe by scientific bodies and regulators globally, and with three trillion meals containing GM food having been consumed with not one single substantiated health claim anywhere, the evidence and science on the safety of GM Crops on the environment and human health is clear.

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1 Brookes G and Barfoot P 2015. 'GM crops: global socio-economic and environmental impacts 1996-2013'. *PG Economics*, Dorchester, May.

2 Australian GM cotton farm income benefit US$844.3 million 1996-2013; GM canola farm income benefit US$41 million 2008-2013.

3 Brookes G and Barfoot P, *Op. cit*

4 Phillips McDougall, 2011, 'The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait'. A consultancy study for CropLife International, September 2011.

One threat to the potential success of this important agricultural innovation is the lack of a nationally consistent scheme for gene technology regulation in Australia. Unnecessary and overly stringent regulation brings with it an equally unnecessary cost burden. All regulation should be commensurate with the associated risk, cost and benefit to the community. The current gene technology regulatory system in Australia already imposes a much greater level of regulatory burden on the industry than occurs in some other countries and this burden is exacerbated by unclear and inconsistent market interventions by state governments.

2.2 Regulation of gene technology in Australia

Australia has a national legislative scheme for gene technology, comprised of the Commonwealth *Gene Technology Act 2000* (Cth) ('the Act') and corresponding state and territory legislation.

The federal laws were enacted to protect the health and safety of people and the environment, by identifying risks posed by gene technology and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

The Commonwealth Act, however, does not take into account trade or marketing considerations, which is at the discretion of the states.

In Australia, the Gene Technology Regulator is responsible for approving any dealings with live and viable GMOs. Food Standards Australia New Zealand (FSANZ) is required to approve any genetically modified (GM) food ingredient and the Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates those GM crops with inbuilt pest protection. The GM canola and GM cotton crops that are grown in Australia have passed all of these regulatory assessments.

The Office of the Gene Technology Regulator (OGTR) carries out risk analysis to identify and manage any risks posed by new GM crops before allowed field trials ('limited and controlled releases') and before seeds can be commercially produced and sold to farmers. Before a field trial or commercial licence is granted, the Regulator prepares a risk assessment and risk management plan. This includes:

- *Identifying if a new characteristic of a GM crop may cause harm compared to its conventional counterpart – what are the risks and can they be adequately managed?*
- *Developing a management plan, on a case-by-case basis to protect people and the environment – what actions might be needed, what are the consequences of those actions, and how can they be monitored?*
- *Asking for input and feedback on the risk assessment and management plan – from experts and the public, on ethical as well as technical issues.*

FSANZ has a rigorous and transparent process for assessing the safety of GM foods, based on internationally established scientific principles and guidelines. New products are assessed on a case-by-case basis, because the questions to be asked may depend on the type of food and the genetic modification.

Each GM food is compared to an appropriate conventional (non-GM) food to determine if there are any differences from a molecular, toxicological and compositional point of view, and any differences then considered for safety and nutrition.

The goal is to make sure the GM food has all the benefits and no more risks than those normally associated with conventional food. If the risks associated with any food assessed by FSANZ are too great to be managed, FSANZ will not grant approval for that food to be sold or consumed in Australia.

2.3 Lack of a nationally consistent regulatory scheme for gene technology

Transgenic cotton, soy, maize and canola with productivity enhancing input traits have all been rapidly adopted globally[5]. This rapid adoption of these GM crops can be expected to force downward pressure on their prices in international markets. Given that Australian farmers also compete in these markets, barriers to future Australian commercialisation of GM crops will mean that Australian farmers will receive a reduced benefit from their crop and a concomitant reduction in profit[6]. By facilitating a clear path to market for future crop biotechnology traits, the Australian Government would be in the best position to ensure that Australian farmers can remain internationally competitive.

The *Gene Technology Act 2000* (Cth) was intended to establish a national system of regulating GMOs. Despite this intention, most states have implemented legislation to address 'marketing concerns' that are neither consistent nor transparent. This unclear path to market was well demonstrated in 2003 when the Gene Technology Regulator approved GM canola for commercial release and all the canola growing states immediately implemented politically motivated moratoria on commercial cultivation of this crop. This led to years of delays, which reduced the management options for Australian farmers and created real uncertainty about the future of GM crops in Australia. State bans also cost food producers and consumers, with one analysis concluding that nationally, the bans on GM canola cultivation cost growers $157 million per annum[7].

In 2005, the then Australian Bureau of Agricultural Resource Economics (ABARE) reported that Australia's canola growers were suffering an economic loss as a consequence of the state moratoria on the commercial cultivation of GM canola. The report concluded that if the moratoria were to continue, it could result in a loss of $3 billion, in net present value terms, in the period to 2015[8].

A more recent ABARE report in 2008 indicated that the estimated economic benefit to Western Australia from adopting GM canola from 2008-09 for the following ten years would be $180 million in 2006-07 dollars. Over the same period, the benefit to New South Wales farmers (excluding those in the Murray Catchment Area) was estimated to be $273 million and South Australian farmers would receive a benefit of $115 million. While farmers in New South Wales, Victoria, Western Australia and Queensland had the opportunity to be one of the more than 18 million farmers globally growing GM crops in 2015, South Australian and Tasmanian farmers are **still** denied access to this technology.

New South Wales, Victoria and Western Australia now allow the commercial production of GM canola, however, this was only allowed after at least a five year delay following federal regulatory approval. It is not clear if such a delay will be repeated if future GM crops are introduced in Australia. Several states still have legislative bans on GM technology, maintaining vague 'market considerations' legislation, even in states where GM canola is now commercially produced. CropLife notes that the New South Wales Government announced on 1 June 2011 that it would be extending its *Gene Technology (GM Crops Moratorium) Act* until 2021, 25 years after GM cotton was first commercially grown in that state.

South Australia introduced the *Genetically Modified Crops Management Act 2004* (SA) to ensure that the cultivation of GM crops was regulated in that state. On 8 February 2008, against the advice of its own scientific advisory committee, the South Australian Government decided to extend its moratorium on growing GM canola in South Australia beyond the end of April 2008 when the regulations were due to expire. The South Australian Government has even gone beyond marketing concerns and banned the transport through their state of sealed bags containing GM seed. This intervention means there is no clear path to market for the developers of GM crops in South Australia, even when licence applicants have satisfied the requirements of the Commonwealth *Gene Technology Act 2000*. It has been clearly demonstrated in other states that effects on trade are negligible. In 2015, the *Adelaide Advertiser* reported that South Australian Agriculture Minister, the Hon Leon Bignell MP, admitted that the South Australian State Government did not have solid economic data to support its decision to maintain the South Australian GM moratorium[9].

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5 James, Clive 2015. 'Global Status of Commercialized Biotech/GM Crops:'2014'. *ISAAA Brief No. 47*. ISAAA: Ithaca, NY.
6 Apted et al 2005, *Op. Cit.*
7 Norton R.M., Roush, R.T., 2007, 'Canola and Australian Farming Systems 2003-2007'.
8 Apted S., McDonald D., Rodgers H., 2005, 'Transgenic Crops: Welfare implications for Australia' Australian Commodities, vol. 12, no. 3
9 *Adelaide Advertiser*, 24 July 2015.

In January 2014, the Tasmanian Government also extended its moratorium on GM crops in direct contradiction to two consultants' reports commissioned by the Government on the issue of market benefit from GM-free status[10,11]. With both reports concluding there was little to no indication of a price premium generated by a GM free status, the decision was clearly political and not based on actual scientific and economic evidence[12]. Without access to the latest technologies, Tasmanian farmers will miss out on the environmental and economic benefits GM crops are already bringing to mainland states and farmers across the globe. The Government's own commissioned report states that over the past decade, Tasmania's agricultural sector has suffered a $40 million net farm-gate loss due to this moratorium[13]. The situation in Tasmania is a prime example of how important decisions that affect the competitive future of an entire sector, with far-reaching implications for the environment and the state economy, should not be made on political and ideological grounds, but rather that on data and facts.

GM crops are intensively studied and rigorously regulated in Australia - all regulation should be commensurate with the associated risk, cost and benefit to the community. CropLife supports the continued use of science-based risk assessment as the basis for sensible decision making. It is a key principle of good governance that governments should only intervene in a market where there is demonstrated market failure. State government moratoria on commercial production of GM crops have, however, never identified any such failings.

The anti-competitive nature of regulation of GM crops by state governments creates uncertainty that acts as a major disincentive for private investment and as a brake on technological innovation in the sector. This uncertainty is exacerbated by the fact that the legislation is often written so that it prevents the relevant Minister from granting a licence unless certain conditions are met. It does not, however, compel the Minister to grant a licence if an application meets these same conditions. As a result, there remains a very real possibility that a company would invest significantly in bringing a technology to market in Australia with data to address all the federal and state regulations and still be unable to sell its product commercially.

This sort of significant disincentive to private investment in Australian agricultural biotechnology is counter-productive if Australia wishes to have a modern, sustainable and profitable agriculture sector in the future. Perhaps ironically, this situation is also a large threat to the otherwise highly successful public investments by state governments in developing GM crops.

The failure to implement a consistent national regulatory scheme has created crippling uncertainty in the agricultural biotechnology industry in Australia and completely undermined the effective regulation of GM crops. Both of these issues need to be addressed if Australia is to continue to have a competitive and productive food industry with safe and affordable food choices available to everyone.

The Australian Government should recognise that evidence to date has demonstrated that GM crops do not pose any risks to human health and the environment that cannot be identified and managed, and consequently the state and territory moratoria on these crops is anti-competitive and in no way commensurate with the risk.

A 2013 ABARES report found that:

> "Australia's regulatory environment governing the path to market of genetically modified food crops continues to impose an unnecessary burden on many agricultural businesses through inconsistent regulation and lengthy decision-making. Although the inconsistencies relate specifically to the moratoria, which are state matters, the Australian Government could play a coordination role in negotiating for a shorter, well-defined regulatory path to market and by providing information on various market considerations, as well as information that could feed into the development of coexistence strategies."[14]

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10 FreshLogic 2013, *An attitudinal assessment of key domestic market gatekeepers to gauge perception of and attitudes towards Tasmania, GM crops and food grown in areas that allow the cultivation of GM food and non-food crops*, Hawthorn VIC.

11 Macquarie Franklin 2012, *Market Advantage of Tasmania's GMO-free Status*, Devonport TAS.

12 http://dpipwe.tas.gov.au/Documents/Final%20Report_v.final_16-12-13.pdf

13 Macquarie Franklin, *Op. Cit.*

14 Gibbs, C, Harris-Adams, K & Davidson, A 2013, Review of Selected Regulatory Burdens on Agriculture and Forestry Businesses, ABARES Report to client prepared for the Agricultural Productivity Division of the Department of Agriculture, Canberra, November

It is worth also noting that the state moratoria on GM crops were identified in the March 2015 Harper *Competition Policy Review* as a significant example of a regulatory restriction on competition[15].

2.3.1 Impact of GM moratoria on canola pricing at port

States that permit the cultivation of GM canola do not appear to suffer a price penalty for certified non-GM canola at port, as shown in Table 1 below. In fact, South Australia, which has a total ban on GM canola production, commands the lowest price in Australia for certified non-GM canola. The states which do allow GM canola production, receive higher prices for their certified non-GM product. This pricing indication is strong evidence that allowing GM canola cultivation does not affect the pricing of certified non-GM canola; demonstrating that coexistence of the two crops is working effectively in Australia.

Table 1: Average price at port 5 Feb 2016 for certified non-GM canola

STATE	AVERAGE PRICE AT PORT
Western Australia	$550 (Kwinana Port Zone)
New South Wales	$541 (Newcastle Delivery Zone)
Victoria	$540 (Melbourne Delivery Zone)
South Australia	$515 (Port Lincoln Port Zone)
Tasmania	Data not available

2.4 Regulatory duplication of crop biotechnologies

Unnecessary duplication of regulation is undesirable because it increases the regulatory burden for applicants with no associated benefit.

In 1996, in the absence of other regulation, a policy decision was made to treat biologically active GM genes/proteins as agricultural chemicals, even though they remained *in planta*. This policy decision allowed the APVMA to regulate GM insect-resistant cotton prior to the establishment of the Gene Technology Regulator as the arbiter of dealings involving GMOs in Australia.

Section 14 of the *Agricultural and Veterinary Chemicals Code Act 1994* (*the Code*) establishes that the APVMA is required to register an agricultural chemical product when it is *'satisfied'* that a range of issues have been addressed. Prior to granting registration of an agricultural product, the APVMA must be satisfied that a product will:

- Be effective for all the uses claimed
- Be safe to humans, target and non-target species
- Not pose unacceptable risks to the environment or trade with other nations.

A comparison of the data requirements for assessment of GM products with incorporated pest and/or disease control by the APVMA, the OGTR and FSANZ shows a high level of concordance. Product efficacy and resistance management considerations stand out as differentiators of the APVMA.

CropLife notes that the APVMA have traditionally outsourced risk assessments for some modules to other government entities such as the Office of Chemical Safety (OCS; i.e. toxicology), and the Department of Environment (DoE; i.e. environmental risk).

Outsourcing of risk assessments to other government agencies has led to significant time delays in the evaluation of some applications, with issues having included, for example:

- Disagreement between agency assessments (i.e. OGTR and DoE)
- Knock-back in the assessment of modules due to a lack of relevant expertise.

[15] Harper I, Anderson P, McCluskey S and O'Bryan M 2015, *The Australian Government Competition Policy Review*, pp116.

Section 6 of *the Code* provides opportunities for the APVMA to accept the risk assessments of the OGTR and FSANZ as part of their assessment. Further, *the Code* allows for certain products to be classified partially or completely exempt from APVMA regulation.

Acceptance by the APVMA of OGTR and FSANZ risk assessments, or the removal of APVMA regulatory responsibility for GM products with incorporated pest and/or disease control would be consistent with the Australian Government's commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals, business and community organisations.

2.5 Regulatory oversight of products developed through New Breeding Techniques

CropLife recognises the importance of new techniques in plant breeding. In most cases, new breeding techniques (NBTs) are innovative improvements and refinements of traditional breeding methods used to optimise plant health, nutritional quality and yield. An increasing number of plant varieties are being developed using NBTs in countries all around the world by both the private and public sectors. As a result, NBT products may be subject to different regulatory requirements leading to differences in the regulation among trading partners, and may result in potential trade issues and enforcement problems globally.

Although the relevant Australian regulators (OGTR and FSANZ) have yet to reach a decision whether products developed using NBTs will be regulated as gene technology, CropLife is concerned about the unnecessary regulation of products developed using NBTs simply based on the breeding technique employed and not the characteristics of the final products. In many cases, NBTs result in products that are similar or indistinguishable from products developed through traditional breeding methods. Adding regulatory burdens based on the method used to develop a product bears the risk of stalling innovative solutions without enhancing product safety.

Regulations, if required, should be based on sound scientific principles and proportionate to the degree to which the product is creating new potential safety concerns to the environment or human health, and not on the process by which it was produced. Small, single nucleotide changes need to be viewed in light of the inherent natural variability of plant genomes.

The Australian Government needs to avoid regulating products developed through NBTs that are similar or indistinguishable from products resulting from traditional breeding methods, since such products do not differ in their safety.

It is well understood that regulatory approaches have the potential to influence perceptions of the hazard of technologies and products, unduly raise public concern and negatively impact the global trade of goods produced through such technologies. Like the private sector, public sector breeders and scientists have significant opportunities to employ NBTs in their breeding programs, especially for minor crops, such as trees and vegetables. However, the adoption of these technologies by both sectors is highly dependent on the regulatory requirements for products developed using NBTs.

Unnecessary regulation of such products, based on the method of development, would result in undue, costly regulatory burdens, stifle innovation and prevent the uptake of scientifically advanced, innovative breeding applications by the public and private sectors. In addition, the regulatory status of NBTs will impact trade not only in seeds but also in agricultural commodities derived from these seeds. Different government approaches risk disrupting international commodity trade flows, particularly in a scenario where various levels of regulation are applied to the same type of product, with asynchronous pre-market approvals.

The impact that unnecessary regulation can have on the commercialisation of agricultural biotechnology products is most clearly illustrated in the example of European overregulation of GM crops (see Section 2.9), which has resulted in industry pulling out of that market altogether.

2.6 Third-party certification schemes seeking quasi-regulation of conventional farmers

Voluntary third-party food certification (a marketing attribute) is often confused with legislated (regulatory) pre-market food approvals (a safety attribute) and indeed there is little evidence of the owners of private food certification schemes taking any action to clarify that misconception. For example, you often see certified organic food marketed as 'healthier' (it's not[16]), pesticide free (it's not[17,18]) and more sustainable (it's not[19]) than conventionally produced foods.

CropLife has two major concerns with organic certification schemes. The first is the blanket claim that organic products are free of GMOs, even for products for which there is no GM equivalent. For example, a manufacturer would unlikely be allowed to make a fat-free claim for a product that had no fat to start with (i.e. orange juice), so why is the organic industry permitted under their private certification scheme to claim products are non-GM when for the vast majority of products there is no GM alternative? Fair trading laws and food laws in Australia require that labels do not misinform through false, misleading or deceptive representations. In Australia, this legislation includes the Australian Consumer Law contained in the *Competition and Consumer Act 2010* and state and territory fair trading and food acts.

CropLife recommends the Productivity Commission consider referring Australia's organic certification schemes to the Australian Competition and Consumer Commission to determine whether misleading and deceptive representations are in fact occurring on certified organic food labels in an attempt to gain a perceived marketing advantage over conventionally produced foods.

The second major concern that CropLife has with organic food certification schemes is the attempt by organic growers to impose the strict conditions of their private third-party contracts with organic certifiers onto their conventional farming neighbours. In normal farming practice, producers of a premium product bear the risk of producing that product in expectation of a higher farm gate return. Organic producers don't see it this way and they expect their neighbours to bear their risk, particularly when it comes to the zero tolerance to the presence of GMOs in Australia's organic certification schemes.

This situation whereby the neighbour of an organic grower was expected to bear the organic grower's risk in respect of the presence of GMOs came to a head in the recent Western Australian Supreme Court case of *Marsh v Baxter*[20], whereby an organic oats grower (Marsh) sued his GM canola growing neighbour (Baxter) for pure economic loss following the suspension of his organic certification resulting from the alleged presence of GM canola from Mr Baxter's property on Mr Marsh's farm.

In dismissing the Marsh case against Baxter on all grounds in the initial hearing, Justice Kenneth Martin of the WA Supreme Court outlined how the Marshes had a very strong case against their organic certifier, NASAA Certified Organic (NCO), where he held, "There is therefore a very strong body of evidence in this trial to suggest that there was no legitimate contractual basis for NCO to decertify, for nearly three years, paddocks 7 to 13 of Eagle Rest, as regards a use for pasture or for crops."[21]

The findings of the original trial judge were upheld by the Court of Appeal in Western Australia in 2015[22]. The appellants have subsequently sought special leave to appeal to the High Court of Australia.

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16 See Harvard Medical School *Organic food no more nutritious than conventional food* http://www.health.harvard.edu/blog/organic-food-no-more-nutritious-than-conventionally-grown-food-201209055264

17 In the United States, 43% of tested organic produce was found to contain conventional pesticide residues, see http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101234. As far as CropLife is aware, there is no pesticide residue testing of products marketed as 'organic' in Australia.

18 In Australia, there are numerous so-called 'natural' pesticides permitted in certified organic production systems, see http://austorganic.com/wp-content/uploads/2013/11/ACOS-2013-final.pdf. These 'natural' pesticides may in some cases be more toxic to human health and the environment than the synthetic chemicals they are designed to replace.

19 A meta-analysis in *Nature* found that organic farming yields 25% less on average than conventional agriculture. More land is therefore needed to produce fewer crops—and that means organic farming may not be as good for the planet as advocates claim. See http://www.nature.com/news/organic-farming-is-rarely-enough-1.10519

20 [2014] WASC 187

21 *Ibid* at para 737

22 [2015] WASCA 169

The refusal of private organic certifiers to recognise the central tenet of coexistence in agricultural supply chains will continue to lead to further conflict between farmers unless Australia's organic certification system is changed to acknowledge that the unintentional presence of a GMO on an organic property should not result in that producer being stripped of their certification through no fault of their own. The zero tolerance to GMOs that gave rise to this conflict in Western Australia is not a government imposed limit, rather it is an interpretation made of the standard by private third-party certifiers, who are then using this 'magic zero number' they have created as the basis for conflict in Australia's rural communities.

In *Marsh* (2014), Justice Martin recognised this distinction in his comment "A failure by NASAA/NCO to recognise and then apply the distinction between a case of the deliberate or negligent presence of GMOs in an organic operator's system, as opposed to an adventitious presence of GMOs, would be, in my view, a serious misapplication of the language of the standards – which clearly mandate this necessary differentiation be respected."[23]

2.6.1 Coexistence of agricultural products

Coexistence is the practice of growing crops with different quality characteristics or intended for different markets in the same vicinity without becoming commingled and thereby possibly compromising the economic value of both. Coexistence is based on the premise that famers should be free to cultivate the crops of their choice using the production system they prefer, be it conventional, organic or biotech.

Coexistence of various production methods is not a new concept to the agricultural community. Farmers have practiced coexistence for generations to meet demands for different types of products. Historical experience shows that coexistence of a wide range of production methods is not a problem, provided technical and procedural guidelines are carefully followed and cooperation between neighbouring farmers is encouraged.

Coexistence is not about environmental or health risks because it refers only to the growing of crops that have been authorised as safe for the environment and for human health by the regulatory authorities in the country in which the crop is being grown, and which are therefore available commercially to farmers in the area.

Coexistence is the foundation of all Australia's farming. There are systems in place to ensure farmers can keep commodities sufficiently separate so that all customers can get what they paid for. The same systems apply to GM crops, because approved GM plants are no harder to control, and pose no greater risk than conventionally bred plants. All farming systems need to work together to ensure that no farmer is exposed to unnecessary economic risk because of unreasonable commodity standards

In Australia, GM and non-GM canola has been grown side-by-side successfully and productively without creating marketing issues. With 7 years under our belt of growing GM canola, there has not been one incident across more than 5.6 million tonnes of canola seed delivered domestically, or more than 15 million tonnes delivered internationally, where an end user (seed crusher / oil or meal buyer, or food/feed manufacturer) has not received what they had ordered in terms of the GM status.

Accessing ready export markets such as China has been a boon for Australian farming since the Asian nation re-opened its borders to importation of canola in 2013. Since then, 1.75 million tonnes of Australian canola (GM and conventionally farmed) has been sold to China for a value of nearly A$1.1 billion. China is a large importer of GM grain, as evidenced by the 2-3 million tonnes of canola imported from Canada (95 per cent GM) and 60 million tonnes of mostly GM soybeans imported from North and South America per annum. Similarly, Japan is a large user of GM grain, importing around 2 million tonnes each of Canadian canola and US/South American soybeans per year.

[23] [2014] WASC 187 at para 528

2.7 Mandatory labelling of GM foods and food ingredients

Food Standard 1.5.2 mandates the pre-market safety assessment and labelling of GM foods and food ingredients in Australia. Labelling of GM food has nothing to do with the health or safety of the food. All approved GM foods sold in Australia have been rigorously assessed and found to be safe by the responsible regulator - Food Standards Australia New Zealand (FSANZ).

In contrast to the legislated mandatory pre-market safety assessment of GM foods, private third-party food certification schemes (such as those for organic) are first and foremost marketing schemes, designed to net both the manufacturer of the food product and the certifier a profit in exchange for being allowed to market the food as being produced a certain way in order to appeal to a pre-defined group or groups of consumers.

CropLife supports food manufacturer's choices to voluntarily label food products for any issues that are not a specific health or safety matter, noting certain attributes (i.e. organic, low fat, low sugar) based on their customers' preferences and providing the label is truthful and not misleading. Voluntary labelling permits food manufacturers to provide adequate information relating to food in line with consumer purchasing behaviour. In return for a price premium, private certification schemes provide consumers with an assurance that their food has been produced using desired production practices.

CropLife supports FSANZ's rigorous and transparent process for assessing the safety of GM foods, based on internationally established scientific principles and guidelines. 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 can reinforce misconceptions in the community.

Food from plant varieties developed using breeding techniques such as radiation or chemical mutagenesis (and referred to as 'traditional' breed) is not subject to mandatory labelling because, like approved GM foods, from a regulatory and scientific perspective it poses no risk to human health. It makes no sense and is indeed absurd, that approved GM foods are subject to mandatory labelling when food derived from plants developed using other breeding techniques, which are equally as safe, is not.

A labelling system for FSANZ-approved GM foods and food ingredients should, and is be done on a voluntary basis and would react more quickly to consumers losing interest in particular marketing information on a food label. For example: if a manufacturer was not providing 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 demanded certain information and preferentially purchased products that contained that information, then manufacturers would also react promptly.

CropLife strongly supports the Productivity Commission recommending that Food Standard 1.5.2 of the Australia New Zealand Food Standard Code be amended to remove the requirement for mandatory labelling of approved GM foods and food ingredients.

2.8 Protection of regulatory data

A major disincentive to private investment in developing agricultural biotechnology tools is that regulatory data that is generated for assessment by the OGTR and FSANZ is not protected in the same way as regulatory data that is submitted to the APVMA. Until recently, this has not been of huge consequence because the GM traits were protected by a patent on the technology. However, the first patents on GM crops are expiring in coming years.

Patent expiry will result in the possibility to combine GM traits that are off-patent. The regulatory costs of doing this are large and there is a real possibility that competitors will be able to utilise the approval of off-patent traits without having to bear the development and regulatory costs. CropLife believes that the Government should consider introducing data protection provisions for regulatory data that is submitted to all regulators. This would prevent free-riding as competitors would not have the advantage of having a free-ride on the investment made by the originating company. Free-riders are considered poor economic policy because they discourage private investment by reducing the competitive advantage that is given to the company that originally invests in the technology. This reduces research that is required to bring about new innovative products that are necessary to meet new challenges and support competitiveness.

CropLife believes that data that is submitted for regulatory purposes should be protected for a minimum of ten years from unauthorised use from competitors, as recently agreed in the Trans Pacific Partnership negotiations.

2.9 The cost of overregulation of crop biotechnology in the EU

Despite some of the concerns raised in this submission, CropLife strongly believes the Australian regulatory system for GM crops is robust, science-based, transparent and provides certainty to applicants.

We would under no circumstances want to see the Australian regulatory system for GM crops end up like that in Europe, where politics can override scientific decision-making, there is no certainty for applications and no transparency in decision-making.

The UK House of Lords Science and Technology Committee recently concluded that the EU regulation of GMOs is 'failing lamentably' and risks squandering the benefits that could be gained from the technology.[24]

The European Ombudsman, Emily O'Reilly, recently decided that between 2012 and 2014 the European Commission repeatedly failed to meet the legally binding deadline for processing applications for the import of genetically modified organisms (GMOs) for food and feed and did not make its decisions within a reasonable time, constituting maladministration.[25]

The dysfunctional regulatory framework for the commercialisation of GM crops in the EU has resulted in European biotechnology companies pulling their R&D operations out of Europe and shifting them to the United States, where the regulatory process is more predictable[26]. US biotech companies have simply ceased seeking approvals for commercial cultivation of GM crops in Europe altogether[27].

The situation in Europe is a real world example of the cost of overregulation resulting in industry pulling out of a market all together. It is extremely important that the Australian regulatory system for gene technology remains science-based, focused on risk assessment and free from political influence by the governments of the day.

[24] http://www.parliament.uk/business/committees/committees-a-z/lords-select/science-and-technology-committee/news-parliament-2015/gm-insects-report-published/ accessed 3 February 2016.

[25] http://www.ombudsman.europa.eu/cases/decision.faces/en/63025/html.bookmark accessed 3 February 2016.

[26] BASF moves GM crop research to US http://www.nature.com/nbt/journal/v30/n3/full/nbt0312-204b.html accessed 5 February 2016.

[27] Major GM food company Monsanto 'pulls out of Europe' http://www.telegraph.co.uk/news/earth/environment/10186932/Major-GM-food-company-Monsanto-pulls-out-of-Europe.html accessed 5 February 2016.

3. CROP PROTECTION

3.1 Introduction

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$250 million over a 10 year period to bring just one new successful crop protection product to the market. 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.

Crop protection products must be used sparingly, carefully and responsibly. The responsible use of crop protection products must be supported by a regulatory scheme that maximises the benefits associated with their responsible use, while minimising the costs from excessive, inappropriate and ineffective regulation. Farmers need these products because of the benefits they provide to their businesses and consumers need these products to ensure they have access to safe, affordable and nutritional food. While it is important for governments to provide for appropriate and rigorous regulation of crop protection products, any regulation must be mindful of the effects that poorly considered and excessive regulation will have through increasing production costs, discouraging investment and innovation, while not delivering any improvement in safety, health or environmental outcomes.

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[28]. 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.

3.2 Regulatory scope

CropLife strongly supports the regulation of agricultural chemicals in line with the important principle of regulation being proportionate to risk. The Risk Profiling Tool currently being developed by the APVMA and the University of Melbourne's Centre of Excellence for Biosecurity Risk Analysis intends to develop a risk framework to better align regulatory risk with an appropriate level of regulatory oversight. Ensuring that the legislative tools are available for the APVMA to enact the outcomes from this work, such as self-registration for products of low regulatory risk, is of the utmost importance.

This work will also enable the APVMA to better focus its regulatory activities on the assessment and registration of products that pose greatest risk. The introduction of provisional registration would enable Australian farmers' access to products while outstanding data requirements addressing lower regulatory risk requirements are completed.

CropLife has previously nominally supported a concept of significantly reducing the APVMA's regulatory scope as a quick and dramatic way of forcing efficiency in the core registration operations of the Regulator. This was a course pursued when the APVMA did not appear to be able to effectively allocate effort and resources according to risk. We recognise reducing the scope of products regulated by the APVMA does not enable risk proportionate regulation for products that no longer reside within the APVMA's scope. The APVMA is funded by the fees and levies paid by registrants of regulated products and are therefore only funded to undertake compliance activities on those regulated products.

[28] 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.

Products requiring any form of regulatory oversight, even if it is only for compliance purposes, must remain within the regulator's scope so any such work is funded appropriately. With the proper and effective implementation of the Risk Profiling Tool as proposed, CropLife is of the view that all products currently within the APVMA's scope will now be able to be regulated proportionate to risk and as such, a reduction in the APVMA's scope is unnecessary.

CropLife has long highlighted the regulatory duplication that exists for whole viable seeds that are genetically modified with incorporated pest and/or disease control, being regulated by the Office of the Gene Technology Regulator and Food Standards Australia New Zealand, as well as the APVMA. CropLife considers exclusion of whole viable seeds from regulation as an AgVet chemical as a viable solution with significant efficiency gains.

3.3 Use of international regulatory information

CropLife supports in principle the Australian Government's Industry Innovation and Competiveness Agenda and its guiding principle *that if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is a good reason to do so*. In response, the APVMA has developed a policy document on the use of international data, assessments, standards and decisions and is in the process of developing criteria on how the APVMA can better utilise this information as part of the approval of an active constituent, registration of a product or approval of a label.

It is imperative that the APVMA uses the appropriate level of caution to ensure the safety of users, the broader community and the environment. The responsible use of agricultural chemicals must be supported by a regulatory scheme that maximises the benefits associated with their responsible use, while minimising the costs from excessive, unnecessary, inappropriate and/or ineffective regulation. CropLife sees the approach being undertaken by the APVMA as providing appropriate regulation of agricultural chemicals and essential to providing the community with confidence that the food they eat is safe, and that appropriate environmental protections are in place. Community confidence in the APVMA is crucial if Australian farmers are to maintain and gain access to the necessary agricultural chemical tools they need to be productive.

3.3.1 Use of international data

The APVMA already accepts and uses international data if relevant to the proposed use of the product in Australia. The APVMA is also actively engaged in programs of the Organisation for Economic Co-operation and Development (OECD) and most types of data generated by an OECD country to OECD test methods will be accepted by the APVMA in support of an application for registration of an agricultural chemical product. The APVMA does, however, need to further consider the acceptance of data from certain non-OECD countries when undertaken according to acceptable test methods.

3.3.2 Use of Assessments prepared by overseas regulators and international organisations

- Hazard assessments

  CropLife supports the acceptance of hazard assessments conducted by international regulators that operate to a similar standard of assessment to the APVMA. Hazard assessments assess the intrinsic hazard of a product, defining various endpoints and unlike exposure assessments, hazard assessments do not consider the likelihood of exposure and therefore potential harm to the user, consumer or the environment. As such, hazard assessments are relatively consistent wherever they are undertaken globally when based on the same data set and using contemporary assessment methods.

The better utilisation of hazard assessments conducted by trusted international regulators will deliver regulatory efficiencies and thereby reduce unnecessary costs and delays by avoiding the re-assessment of data to revalidate the same endpoints. The provision of hazard assessments by recognised overseas regulators, together with the full data package in support of an application should not, however, lead to the APVMA undertaking a duplicative re-assessment, unless there is a compelling scientific reason for so doing. While a review may be required to confirm the validity of studies contained therein, a re-assessment of the data to determine similar endpoints is in most cases, likely to be duplicative and unnecessary.

- Exposure assessments

  Exposure assessments, unlike hazard assessments, are based on how the formulated product is going to be used according to the local environment. CropLife supports the continued development of the APVMA's Risk Profiling Tool being conducted in conjunction with the University of Melbourne's Centre of Excellence for Biosecurity Risk Analysis. This Tool will help to identify where the APVMA may accept exposure assessments for products where the risk is the same as the use proposed in Australia. However, agricultural chemical products are unlikely to feature in this category except for very specific situations where the environment is the same, such as protected cropping.

  CropLife is hopeful that once completed, the Risk Profiling Tool will be able to quickly identify products registered overseas where the risks are the same as the use proposed in Australia, as this will avoid situations where the regulatory effort required to determine whether the risk is similar outweighs any potential benefit. Improvements gained in this area will enable the APVMA to focus resources where they are needed, resulting in faster and more predictable registration outcomes for new and innovative agricultural chemical products for use by Australian farmers.

  As with hazard assessments, the provision of exposure assessments by recognised overseas regulators, together with the full data package in support of an application, should not lead to the APVMA undertaking a duplicative re-assessment, unless there is a compelling scientific reason for so doing. While a review may be required to confirm the validity of studies contained therein, a re-assessment of the data to determine similar endpoints is in most cases, likely to be duplicative.

- Global Joint Reviews

  CropLife fully supports the APVMA's ongoing involvement in the Global Joint Review (GJR) program. Such involvement should correspond to benefits for the regulator, farmers in the respective countries and the applicant through process efficiencies, common regulatory endpoints, reduced barriers to international trade and wider product registrations. It should also lead to continued improvement in the understanding of, and confidence in overseas regulatory processes resulting in greater acceptance by the APVMA of assessments conducted by overseas regulators, minimising regulatory duplication.

  That stated, it should be noted that the optimism and original expectations of efficiency gains through the GJR program have not yet been realised in any way, and the resulting re-assessment of international information by the APVMA does not lead to improved regulatory efficiency or a reduction in regulatory burden or cost. Systems and processes that genuinely reduce the APVMAs required assessment effort must be the core focus of any policy and procedure development. An accompanying cultural shift by APVMA technical assessors must also accompany this policy development if it is to lead to actual improved outcomes.

3.3.3 Use of International Standards and Guidelines

CropLife supports the APVMA's ongoing involvement in international standard setting and the adoption of international standards where appropriate.

3.3.4 Use of International Decisions

Complete or final registration decisions by overseas regulators cannot be accepted without considerable understanding of, and alignment with the regulatory basis that led to the decision. Noting the significant variance in pre- and post-market regulatory activity internationally, this understanding and alignment is very unlikely to be achieved for agricultural chemical products regulated by the APVMA.

CropLife is of the view that decisions by overseas regulators should not be accepted as the sole justification for registering or cancelling a product or active constituent in Australia. Acceptance of decisions by overseas regulators could be warranted if limited to products registered by the APVMA where the exposure and environmental risks in Australia are equivalent to those in the overseas jurisdictions. In terms of agricultural chemicals, these situations are likely to be limited to protected cropping, household, home garden and in certain situations, label extensions to enable new uses of existing approved products. For the vast majority of agricultural chemical products, there are likely to be considerable components of registration decisions by overseas regulators that cannot be extrapolated for Australian specific conditions.

Utilisation of overseas decisions in the limited situations described, would avoid the re-assessment of data and assessments to revalidate the same conclusions. This would therefore be expected to deliver regulatory efficiencies and thereby reduce unnecessary costs and delays. It would also achieve greater alignment between risk and regulatory burden. Enabling registration on the basis of decisions of international regulators would, however, be impacted by regulatory changes made by those overseas regulators that will limit its utility unless Australian specific data is generated to support the registration in its own right.

Information supporting equivalency to products registered by the international regulators would need to be provided to the APVMA, without compromising the Intellectual Property of the international data owners.

3.4 Unnecessary labelling requirements

Agricultural chemical labels are currently regulated by the APVMA under the *Agricultural and Veterinary Chemicals Code Act 1994 (Cth)*. Each product undergoes an expert technical risk assessment and hazard warnings are applied that reflect the outcomes of that assessment. Previously, Work Health and Safety (WHS) regulations considered APVMA approved agricultural chemical labels to be compliant with WHS regulations. Safe Work Australia's (SWA) *Model WHS Regulations 2011*, however, remove this recognition and from 1 January 2017 agricultural chemical product labels must also include additional and unnecessary intrinsic hazard statements as stipulated by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This is irrespective of whether or not product formulation or prescribed use mitigates the risk of the hazard to negligible levels.

GHS is a hazard-based system and does not reflect the outcomes of an expert assessment undertaken by an independent, technically proficient regulator. Compliance with two separate sets of fundamentally conflicting regulations is not only costly for manufacturers, just one of our member companies expects the cost of compliance with the extra regulation to be in excess of $800,000, but it is likely to confuse users and subsequently threaten worker health and safety.

Therapeutic Goods Administration approved labels for pharmaceutical chemicals received and continues to receive the same recognition previously received by APVMA approved labels. Agricultural and pharmaceutical chemicals are both tightly regulated by dedicated agencies, with hazards identified, risks assessed and approved uses prescribed on the label. The only difference being that the Department of Health proactively secured the ongoing recognition when consultation about changes to WHS regulations began before 2009, whereas the Department of Agriculture and Water Resources under the previous government did not. The Department of Agriculture and Water Resources has since made its strong objections known to SWA.

CropLife and our members will always support whichever scheme offers the best outcomes for the protection of worker-based risk assessment system used by the APVMA as already providing this. This aligns with the Food and Agriculture Organization of the United Nations' recommendation of a risk-based approach, considering local environmental and exposure conditions for agricultural chemicals in countries where the necessary resources are available.

All relevant industry bodies including CropLife Australia, the Plastics and Chemicals Industries Association and Accord Australasia (the hygiene, cosmetic and specialty products industry organisation) have opposed the changes since consultation began in 2009. CropLife is aware that the Department of Agriculture and Water Resources and the APVMA have also repeatedly expressed their opposition to SWA. Despite this, SWA has belligerently pushed ahead with the unnecessary, confusing and potentially dangerous duplication of agricultural chemical labelling regulations.

All state governments except for Victoria and Western Australia have adopted SWA's Model Regulations, with compliance mandatory by 1 January 2017. Agricultural chemical products, however, are supplied nationally and can be in the market for over twelve months after production. The previous recognition that APVMA labels comply with WHS regulations must be reinstated urgently to avoid the unnecessary cost to manufacturers and therefore Australian farmers, as well as the inherent increased risk to worker health and safety.

3.5 Inefficient poison scheduling

The delays and unpredictability associated with poisons scheduling are resulting in substantial additional and unnecessary delays to the introduction of new and innovative crop protection products to the Australian market. In some specific cases, poisons scheduling alone has delayed the introduction of crop protection tools that farmers desperately need by in excess of eight months. Revisions to scheduling arrangements to increase the number of delegate-only decisions were meant to streamline this process, but technicalities appear to have completely undermined that promised efficiency.

Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules according to the level of regulatory control over the availability of the medicine or chemical required to protect public health and safety. It is an inefficient and unpredictable process that not only delays the introduction of new and innovative products into the Australian market, but is also out of step with Global Joint Reviews (GJRs). Agricultural chemical products associated with GJRs are registered and available for use in all involved international jurisdictions other than Australia, solely due to unnecessary delays associated with scheduling. These embarrassing situations will continue until the scheduling system significantly improves its timeliness and predictability.

The *Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009* provided for revised scheduling arrangements that commenced on 1 July 2010. This included the conferral of the power to make amendments to the Poisons Standard (the Standard) to the Secretary of the Department of Health or their delegate. Decisions not deemed sufficiently straightforward to enable a delegate-only decision are referred to the Advisory Committee on Chemicals Scheduling (ACCS), a statutory committee under the Therapeutic Goods Act 1989, for advice and to make recommendations to the Secretary of the Department of Health (or delegate) on the level of access required for medicines and chemicals.

These amendments had the laudable intention of increasing the number of delegate-only scheduling decisions, allowing straightforward scheduling decisions to occur outside of the regular ACCS process and thereby markedly improving the timeliness and predictability of the process. It has, however, come to light that delegate-only decisions do not at all expedite the process. This is due to delegate-only decisions not being legally enforced until the Standard is amended. The Standard only gets amended after ACCS has met at one of its three meetings a year to finalise proposals to amend the Standard, following its exhaustive and time consuming public consultation process. Missing a deadline for an ACCS meeting can lead to delays to new and innovative products entering the Australian market by up to, and sometimes in excess of 8 months.

CropLife has regularly expressed concern to the Office of Chemical Safety within the Department of Health and the Department of Agriculture and Water Resources about the time taken for poisons scheduling decisions to be made and the impact this has on the availability of new and innovative tools that Australian farmers desperately need. The revised scheduling arrangements have not achieved the improvements in timeliness and predictability that were expected and it is crucial that this unnecessary regulatory burden and internationally embarrassing situation is corrected urgently.

3.6 Minor use and specialty crops program

CropLife has long advocated for the introduction of a comprehensive, publicly funded minor use and specialty crops program to alleviate the market failure resulting from the mandatory regulatory system. Crop protection products are only registered in circumstances where there is a direct financial incentive for registrants to do so, irrespective of the financial and economic benefits to the farming sector or the broader economy other uses of these products may be able to deliver. This problem is directly caused by the inability to recover the significant costs of the mandatory regulatory system in a relatively small market. It is important from a public policy perspective, to recognise that bringing a new crop protection product to market in Australia is the same on a dollar basis as it is in the United States, yet the market is one tenth the size.

The current Government's initial funding of $8 million over four years to the development of a Minor Use and Speciality Crops agricultural chemical program is significant and welcomed by CropLife, the plant science industry and the nation's farming sector. Such a program is crucial to the nation's agricultural productivity and our international competitiveness, and it is imperative to ensuring Australia's farmers have access to the tools and products essential for meeting the food security challenges of the future.

The Government's initial $8 million commitment, if utilised properly, will be a profitable investment in Australia's agricultural sector. Similar programs in the United States were established over 30 years ago and have demonstrated that every dollar invested in a minor use program generates a net return to the US economy of US$550. Targeted investments would also leverage complementary and collaborative investments from users and registrants. However, CropLife estimates that total funding of $45 million (including the initial $8 million allocation) spread over four or five years would be the likely requirement for crop protection products for the program to deliver the full and genuine economic benefits to Australia.

Not only will the Minor Use and Specialty Crops Program increase the productivity of Australian agriculture, it stands to enable more environmentally friendly pest management practices. Accessibility to modern, target-specific chemicals can reduce the excessive use of older, broader-spectrum chemicals. The Minor Use and Specialty Crops Program will also encourage more investment in developing these products.

A lack of pest and weed control options has a number of consequences. Farmers may be forced to rely on a permit system that is not ideally suited to facilitating the development of new uses on product labels. Should a farmer not have access to a registered or permitted product, they may be forced to rely on some state legislation that may in some circumstances allow 'off-label' uses, which are not risk assessed. Some off-label uses may therefore result in unacceptable risks to users, consumers, trade or the environment. As such, CropLife does not support off-label use of agricultural chemical products.

A lack of available pest and weed protection products provides a significant barrier to the development of new agricultural industries. New crops are less likely to be commercially cultivated for domestic and export markets if there are no options for pest control. Horticultural crops, in particular, face challenges as the smaller areas under production often make it uneconomic for registration of new chemical products.

The consequences are not limited to minor crops. Major commodities such as wheat and barley can still be susceptible to minor pests and diseases that are not significant enough to justify investment by registrants to extend labels or develop new control technologies. Pests may not always be a problem for a particular crop, or unusual and unexpected weather conditions in a particular season may lead to new pest and disease pressures.

The small size of Australia's crop protection product market on a global comparison means that the implementation of this initiative is vital so that Australian agriculture is assured access to the latest innovations from the plant science industry and their full range of uses.

Appropriately funded, the Minor Use and Specialty Crops Program can safeguard Australian agriculture by increasing its productivity and diversity. Ensuring that farmers have access to adequate crop protection technologies can also facilitate:

- Development of new industries growing new crops for domestic and overseas markets;
- Agricultural development of new regions for new crops as pest issues can be sustainably controlled; and
- Ongoing sustainable production within existing farming systems as new tools facilitate better, more effective and long-lived resistance management strategies.

Critically, support for minor uses can reduce risks to users, consumers and the environment from off-label use. It will also minimise reliance on APVMA issued permits increasing its capacity to provide high quality risk assessments and registrations.

If structured properly, such a program would attract further investment from crop protection product companies, grower groups and Research & Development Corporations that would deliver an even better value proposition for the Australian taxpayer, as well as even bigger returns to the Australian economy.

3.6.1 Use of International Decisions

To help alleviate the market failure caused by excessive entry to market regulatory burden in the short, medium and long-term, robust incentives for registrants to add minor uses to labels in the presence of difficult or poor business cases is a must. Minor use and specialty crop programs internationally, such as IR-4 in the US, the Canadian Minor Use Program, and more recently the Rural Industries Research and Development Corporation AgVet Collaborative Forum all categorically reinforce this view.

The incentive removed during recent reforms to the *Agricultural and Veterinary Chemicals Code Act 1994* was insufficient and therefore ineffective. Data protection remains a viable incentive for registrants to add minor uses to labels in the presence of difficult or poor business cases, however, it needs to align or better the additional data protection offered in other international jurisdictions such as the US or Canada to act as an effective incentive.

Introducing transferability of data protection achieved through adding minor uses to labels could also be an effective incentive, particularly for adding minor uses to older generic products for which there is currently very little incentive. Being able to transfer the data protection resulting from the addition of minor uses to older generic products to new and innovative products would provide significant incentive for registrants. It would help to improve the business cases for new and innovative products, improving the attractiveness of the Australian market internationally, resulting in the availability of key crop protection tools to Australian farmers of which only their international counterparts currently enjoy.

3.7 National harmonisation of control of use

CropLife promotes improved harmonisation of state control of use regulations in Australia to remove duplication and inconsistencies, and reduce unnecessary costs to industry. CropLife members find it difficult, confusing and costly to meet the multiple regulatory requirements of all the jurisdictions in Australia.

Some state legislation in certain circumstances allows 'off-label' uses that are not risk assessed. Some off-label uses may therefore result in unacceptable risks to users, consumers or the environment. For these reasons, CropLife does not support off-label use of agricultural chemical products. A comprehensive, publicly funded program for minor uses of agricultural chemical products would enable registration of chemical products for use on minor and specialty crops, reducing the need for off-label uses and providing a platform for which national harmonisation could occur.

4. COST RECOVERY BY REGULATORY AGENCIES

CropLife supports regulatory cost recovery where it is justifiable, appropriate and proportionate to undertaking core business, and not used to subsidise budget shortfalls.

Unfortunately, all too often we have seen attempts by regulatory agencies to use regulatory cost recovery as a means to balance budgets or make applicants pay for work not related to the regulatory risk assessment of a particular product.

4.1 Cost recovery for crop biotechnology products

For example, in June 2012, Food Standards Australia New Zealand (FSANZ) released an industry consultation paper indicating they intended to increase their existing cost recovery fee for assessment of applications by an average of 57 per cent (a cost increase that would have amounted to twenty-five times inflation). Such an exorbitant and unprecedented increase, should it have proceeded, would have had an immediate negative effect on the competitiveness and productivity of Australia's food sector. This proposal would have made the regulatory cost in Australia, on a per capita basis, over five times more expensive than any other country in the world to seek regulatory approval for a GM food or food ingredient.

CropLife noted at the time, that in spite of the fees charged by FSANZ, applicants receive nothing in the form of data protection in return. Studies submitted by applicants for use in the assessment process, other than those deemed confidential business information, become available for use by anyone, including overseas competitors.

It is clear to CropLife that on this particular occasion FSANZ had not considered the serious and significant impact that such increases in regulatory cost recovery fees would have had on both private and public sector applicants and the concomitant significant disincentive to innovation.

As a further example, in the 2013 Budget, the former Government announced the assessment and development of a cost recovery model for services provided by the Office of the Gene Technology Regulator (OGTR). On behalf of the sector, CropLife provided very clear and detailed feedback to the consultants undertaking the process outlining very serious concerns for significant negative impact on the plant science industry, public research and development, Australian agriculture and the operations of the OGTR itself.

Australia is already one of the most expensive markets in the world to bring a regulated GM crop product to market. The plant biotechnology industry is already subject to regulatory cost recovery via FSANZ, and also by the Australian Pesticides and Veterinary Medicines Authority (APVMA) (if there is an agricultural chemical registration required). As outlined in Section 2.4 of this submission, there is significant regulatory duplication for certain gene technology products between the OGTR and the APVMA, to avoid 'double charging' this overlap would need to be removed. If the OGTR were to also adopt cost-recovery mechanisms, a similar regulatory overlap between OGTR and FSANZ would need to be very closely examined to ensure double charging of applicants did not occur.

The cost of establishing, managing and signing-off on large scale, multi-year, multi-jurisdiction field trials to generate data for the OGTR is a significant cost already borne by the applicant. The cost of managing an Institutional Biosafety Committee is also already a significant cost borne by the applicant. The regulated gene technology sector in Australia remains a fledgling industry, with a very limited number of companies in the commercial agricultural biotechnology market. Other cost recovery schemes entitle the applicant, once successful, to access the market. Due to ongoing state moratoria (discussed in Section 2.3 of this submission) on commercial GM products, this is not the case for products approved by the OGTR, where a successful application can still be denied commercialisation by State Governments.

4.2 Cost recovery for agricultural chemical products

The Australian agricultural sector has been identified by the current Government as a significant contributor to both the national economy and local communities. Integral to the success of the sector is the access Australian farmers have to world's best agricultural chemical technology, including the latest developments of the most effective, safest and softest crop protection products.

Agricultural chemical regulation must be efficient to ensure it imposes the lowest possible cost to encourage investment and innovation by registrants to develop and register new products, uses and technologies for farmers. Inefficient regulation can prevent farmers from having timely access to the latest technology in new crops, new pesticides or new uses for existing pesticides. As the costs of the regulatory system administered by the APVMA all contribute in the end to on-farm costs, it is critical that the cost recovery system sets a structure that guarantees minimal and the most effective cost recovery principles that are drivers for low regulatory costs and regulatory efficiency. A properly constructed cost recovery framework should not impede this access to world's best products and should encourage and facilitate new technologies for use by Australian farmers.

Further, an assessment of the impact of cost recovery arrangements on the farming sector is essential, including whether the framework encourages or detracts from the ability of farmers and other users to have access to a complete suite of the latest technology in crop protection products.

CropLife is concerned an analysis of how the existing cost recovery framework may affect the agricultural chemical industry, particularly Australian farmers, has never been undertaken. All analysis on existing cost recovery arrangements appears on the surface to provide a somewhat effective way to fund the operations of the regulator. However, the broader public policy must be considered. That is, the Department of Agriculture and Water Resources must ensure the operations of the APVMA and how it is funded enables the best possible outcome for the Australian agriculture sector.

Given the relatively small size of the Australian market in global terms, if the cost of doing business in Australia becomes prohibitive, CropLife member parent companies may decide to pull out of the Australian market altogether (as has happened in the biotechnology sector in Europe), resulting in a major stifling of plant science innovation in this country and a concomitant loss in productivity for Australia's farmers. Maintaining the ability for Australian farmers to access the latest innovative tools in plant science will be essential if we are to secure a safe and nutritious food supply for both Australia and the rest of the world.

5. CONCLUSION

CropLife's submission has focussed on the use of regulation to create a stronger and more productive agriculture sector in Australia, specifically by improving access to new technologies and agricultural chemicals.

CropLife submits that a truly productive, competitive and sustainable agricultural industry in Australia that improves market returns at the farm gate is not achievable in the long-term without ensuring that regulatory oversight is efficient, effective and where necessary commensurate with the risks, costs and benefits to the broader community.

Crop protection products and crop biotechnologies are crucial to modern farming. It is essential that government works with industry to reduce unnecessary 'red tape' or regulation that is not commensurate with risk and creates nationally harmonised regulations and legislation to maintain the ability for Australian farmers to access the latest innovative tools in plant science.

Meeting the challenges presented by sustainably increasing food production to meet growing global demand will require science-based regulatory policies that support all farming production systems, including existing and future production tools.