

AusBiotech submission to the House of Representatives Standing Committee on Agriculture and Industry's inquiry into Agricultural Innovation

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24 September 2015

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<u>Introduction</u>

AusBiotech is pleased to submit to this consultation regarding Australian agricultural innovation. The submission represents a collation of comments and submissions from AusBiotech members engaged in delivering agricultural innovation to Australian agriculture either through research and development activities and/or pathway to market commercialisation activities in agricultural biotechnology.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology, food technology, industrial and agricultural biotechnology and food technology sectors. The industry consists of an estimated 900 biotechnology companies and employs in excess of 45,000 Australians.

AusBiotech welcomes the government's recognition of the importance of primary producer access to advanced technologies such as plant and animal genetics to increase farming productivity. One of the key drivers of long-term productivity growth implicit in the terms of reference for this review is the development and adoption of new production technologies (innovation).

AusBiotech has made a number of recommendations based on feedback from its members. Most recommendations hinge upon increased investment in the sector in order to at least maintain a competitive position amongst international counterparts. All contributors to this submission, including the large multinational agricultural-products organisations, would like to see greater investment from both the Commonwealth and the private sectors (domestic and international). Several key factors are acting as barriers to achieving greater net public investment in Australian agricultural biotechnology, the most important of which is the regulatory uncertainty that faces organisations investing in the commercialisation of GM crops.

Many of the examples used in this submission related to GM crops and the benefits resulting from agricultural innovation. This is in part because GM is a contemporary breeding technique that is providing present-day regulatory and social challenges. However, the rapid evolution of molecular biology and the life sciences in general has meant that many of these challenges are becoming dated purely because the emerging gene editing methodologies avoid the current definitions of GM.

As the Committee considers the submissions to this inquiry into Agricultural Innovation it should ensure that:

- A long-term strategy for innovation is used to guide recommendations. Many of the
 contemporary challenges will resolve or fade as new techniques emerge and food security
 issues become more prominent. Modern breeding techniques (plant and animal) along with
 advances in precision agriculture and data management will be critical if we are to address
 the future food security and sustainability challenges.
- Australian regulators remain strong, and flexible. The application of good regulation is
 critical to build confidence and certainty and underpins public investment in agricultural
 innovation. Ambiguous or absent regulation elevates risk and is a strong barrier to
 innovation.

¹ Commonwealth of Australia 2015, Agricultural Competitiveness White Paper, Canberra

² Commonwealth of Australia 2009. Promoting productivity in the agriculture and food sector value chain: issues for R&D investment. ABARE

Summary of Recommendations

- 1. Federal engagement with the State Governments to develop stable and consistent application of policy and regulation covering farmer's right to grow and sell GM crops.
- Federal engagement in international regulatory harmonisation talks such as the APAC initiatives to support the development and global adoption of science-based risk assessments and increased participation in international engagement on agricultural bioscience developments.
- 3. Ensure Australian regulators such as the OGTR, FSANZ and the APVMA do not duplicate activities, and have integrated approaches to policy frameworks and related definitions pertaining to agricultural biotechnology.
- 4. Engage and provide the resources and support through the Department of Agriculture to facilitate the necessary changes to the APVMA regulatory system that will provide certainty and confidence in agricultural biotechnology dealings with Australian regulators.
- 5. Through strategic Federal Government investment, develop an Australian focused commercialisation 'fast track' pathway for agricultural biotechnology innovation that can contribute to Australia's competitive advantage in global agricultural production.
- 6. Support initiatives that build science and business-management literacy in the agricultural sector including specialised education initiatives and support for industry events that inparticular target translation of agricultural biotechnology into commercial outcomes in Australian and global agricultural production systems.
- 7. Increase support for the Research and Development Corporations (RDCs) reinforcing their role in directing resources towards agricultural research, development, extension and adoption (R, D, E & A) and greater engagement and collaboration with industry and the private sector. Reviewing the focus and efficiency of the RDCs aught to be done in a transparent manner with publically accessible reporting by the RDCs.
- 8. Ensure that plans for adoption of innovations from agricultural biotechnology are a key part of any initiative funded by the Department of Agriculture and/or the Department of Industry and Science. Funding should be made available specifically for translation of R&D results (national and international) into outcomes for Australian agricultural producers and where appropriate global opportunities.
- 9. Engage and provide the necessary resources and support through the Department of Industry and Science and the Department of Agriculture for Australian based small and medium sized enterprises that are focused on the translation of agricultural biotechnology research into outcomes for the various Australian agricultural sectors and where appropriate global opportunities.
- 10. Encourage the best and brightest of Australian public and private sector scientists to form internationally competitive R, D, E & A consortiums to develop and commercialise innovative solutions which maintain Australia's competitive advantage in global agricultural production in crops and livestock systems of interest.

Overview

The ability of Australian agriculture to meet the potential for growth in demand for food, feed, fibre and energy, for a burgeoning global population through to 2050 and beyond will depend on the industry's capacity to embrace innovation, engage investment and bring new technology to market in a manner that allows a realisation of the intended benefits of that investment by all supply chain participants.

The success of Australian agriculture has been built on innovation. Innovation has come from both the development of Australia's own technology and from the rapid adoption of world best practices, including the freedom to evaluate and adopt new technology.

The need for Australian agriculture to continue to innovate and have the freedom to evaluate and adopt new technology was reinforced in the findings of the *Creating Our Future — Agriculture and food policy for the next generation* report, which identified the foundations of long-term success for Australian agriculture and food.³

"Biotechnology is transforming agriculture and food production. Its benefits — agronomic, environmental, nutritional, human health and economic — can strengthen the Australian agriculture and food sector's competitive position in world markets. Other farmers around the world are rapidly adopting crop varieties that are genetically modified for traits such as insect resistance and herbicide tolerance. Many other traits are in the pipeline for a wide range of crops and livestock. If Australia falls behind in this rapidly developing area of innovation, it will lose ground to competitors whose investment in, and adoption of, biotechnology is racing ahead...As Australian agriculture and food businesses strive to remain competitive, GM and other biotechnologies offer ways to reduce costs, drive innovation and maintain sustainable industries."

As outlined in this seminal report, biotechnology offers a set of innovative tools that will create new and improved food and fibre products, more efficient and resilient farming systems with farreaching agronomic, environmental, nutritional, human health and economic benefits. Such benefits will strengthen Australia's competitive position in global food and fibre markets and provide increased surety of supply for domestic consumers. However, to achieve these benefits significant changes in public and private sector policy and incremental investment in agricultural biotechnology R, D, E & A, the commercialisation pathway to market and the regulatory landscape will be required.

In view of the potentially significant human health, environmental and economic benefits from applying biotechnology in agriculture and contributing to global food security, when compared to the costs to Australian agriculture of failing to capture these benefits, the authors of the *Creating Our Future — Agriculture and food policy for the next generation* report put forward the following recommendations:

 "Governments must give higher priority to communicating the benefits of current and emerging agrifood biotechnology, and to publicising the robustness of the regulatory regime for the safety of research and the resulting products.

³ Corish, P. et al. 2006 Agriculture and Food Policy Reference Group 2006, *Creating Our Future: Agriculture and Food Policy for the Next Generation*, Report to the Minister for Agriculture, Fisheries and Forestry, Canberra, February.

- Agriculture and food businesses should work with governments to facilitate the rapid uptake
 of agrifood biotechnologies that will contribute to better health, a cleaner environment and
 more globally competitive industries.
- State governments should lift their moratoriums on the commercial use of GM crops immediately, and work with the Australian Government, industry and researchers to achieve nationally consistent traceability and tolerance protocols, and to clarify legal liability surrounding the use of GM organisms in agriculture and food products."

The importance of agricultural biotechnology to Australian agriculture and the broader economy is likely to come less from the size of the sector, and more from:

- the use of agricultural biotechnology across various sectors within agriculture
- the way in which agricultural production systems are being reworked to take advantage of newly-developed agricultural biotechnology processes and products
- the outputs emanating from the various stakeholders that are either developing or using agricultural biotechnology.

Australian Agricultural Industry Innovation

Australia has a proud history of agricultural innovation and it is critical for the competitiveness of our industry that Australia maintains both the capability in research skills and capacity to deliver its outcomes (i.e. commercialisation) to ensure that Australia maintains its global leadership in developing technology that will benefit Australian and where appropriate farmers in countries with similar production systems.

Australia has a strong history of agricultural biotechnology research. Australian agricultural biotechnology publication citation rates rank highly in comparison to United States and the EU15 with 3.5% of the publication in the area.

Australian agricultural plant biotechnology has attracted significant investment from both the private and public sectors during the early part of the new millennium. The investment has primarily been focused on the basic science of gene discovery and the development of platform capabilities in agricultural sectors ranging from grains, sugar, cotton, pastures and horticulture through to the livestock industries including sheep, beef cattle, pigs, poultry, dairy and aquaculture. In Australia an increasing number of targeted technologies have progressed to initial proof of concept, however, few have progressed to commercialisation.

Effective translation of research outcomes into farm productivity requires strong science, knowledge of the pathway to market and business management literacy across the paddock to plate supply chain. The prosperity of Australian agriculture cannot be sustained in the absence of a community of inquiring and capable people, a steady pipeline of specialist science, technology, engineering and maths (STEM) skills in the workforce, and general science and mathematical literacy in the community.

The level of formal education in the agricultural sector is still relatively low but is growing in response to a focus on the needs of the modern agricultural practices. Inadequate business management, innovation and cultural competence skills have been identified as industry training

priorities for participants in the Australian agricultural sector if farmers are to take advantage of advanced technologies and if Australia is to have a globally competitive, profitable and environmentally sustainable agrifood industry. Farm business managers that have a sound understanding of business and financial management principles are better able to improve the financial performance and productivity of their businesses through better understanding of the economic implications of adoption of new technology.

One of the major reasons for Australia's dominance in agricultural biotechnology research is the existence of the fifteen Research Development Corporations (RDCs). Australia has a long tradition of the various agricultural industries collectively investing in RD&E through their different levy schemes, with the government matching these funds. This has provided long term stability and significant funds to CSIRO, DPI's and University groups to tackle the problems industry faces and develop the innovative solutions that have helped to maintain our ability to produce crops and livestock in an increasingly international competitive market place. In various economic reviews of these RD&E investments, the returns have been shown to be greater than \$10 for every dollar invested.⁶

Initiatives that support consolidation, cooperation and/or collaboration between sectors will help to both reduce duplication and enhance synergies where familiar challenges and barriers exist to the adoption of innovative technologies. The development of long-term sector priorities such as the Primary Industries RD&E Framework (the Framework) that was endorsed by the Primary Industries Ministerial Council in 2009 have led to a national approach to developing sector priorities, and have helped align RD&E activities with sector priorities. Whilst in general the Framework led to the development of good sector-specific strategies, the performance of some strategies was found by the Allan Consulting Group to be disappointing. Many of the sectors have not published updated strategies since their initial commissioning in 2010.

The Framework had mixed success with enhancing cross-sector cooperation despite this being a primary objective in the Framework's statement of purpose. The reasons for limited success of cross-sector cooperation will be complex but probably relate to the relative benefit to sector leaders in implementing activities that directly benefit their stakeholders (e.g. levy payers) compared to those that may indirectly benefit their industry by creating benefits to the broader agricultural sector. Irrespective of the reasons for the past failings, the principles supporting the enhancement of cross-sector cooperation remain as relevant as they were when the Framework was first proposed and will be important to any future national innovation strategy.

Existing successful cross-sector initiatives such as the Australian Biotechnology Council of Australia⁸ (ABCA) that acts as a national coordinating organisation for the Australian Agricultural biotechnology sector should be encouraged and supported as an industry-led model that is successful.

⁴ Agrifood Skills Australia 2014, Environmental scan of the agrifood industry.

⁵ National Rural Advisory Council 2013, *Report on the workforce planning capabilities of agricultural employers.*

⁶ Council Rural R&D Corporations (CRRDC) 2009 *Impact of investment in research and development by the Rural Research and Development Corporations*. www.ruralrdc.com.au

Allan Consulting Group 2012. Evaluation of the National Primary Industries Research Development and Extension (RD&E) Framework. www.acilallen.com.au

⁸ <u>www.abca.com.au</u>

ABCA's vision is:

...that the current and potential benefits of agricultural biotechnology are fully recognised to ensure that the Australian farming sector can access and adopt this technology for the benefit of national and global food security, the nation's farming sector, and the environment, thus helping to deliver a more sustainable and prosperous future for Australian agriculture.

Governments can support initiatives such as ABCA either directly or by encouraging government-supported organisations such as RDCs and CRCs to participate and then by recognising participating organisations efforts to support cross-sectoral initiatives.

Agricultural Biotechnology - Global Context

From the time that GM cotton was first released in 1996 through to the release of GM canola in 2008 and up until today, agbiotech within Australia has been primarily focused on pest and pesticide resistant plants, the development of plants with improved abiotic and biotic stress tolerance and the development of grain or pasture with improved nutritional profiles. However, within the global context the scope of agbiotech has expanded and broadened to include:

- Bio-based energy production
- Industrial enzyme production
- Microbe-based pest control and growth enhancers
- Aquaculture improvements e.g. diagnostics
- Human and animal therapeutics and vaccines
- Industrial materials and fibres
- Environmental restoration
- Animal diagnostics
- Marker assisted plant and animal selection

Therefore, as a platform for innovation in agriculture to meet the increasing demand for food, feed, fibre and energy, the influence of agbiotech into the future will be significant as many of the current crops which serve as the delivery platform for these next generation of technologies are approved and introduced into agricultural production systems.

In 2013 it was estimated that 18 million farmers in 27 countries planted biotech crops, increasing the overall area planted to GM crops from 1.7 million hectares in 1996 to over 175 million hectares in 2013. Brooks & Barfoot (2015) reported that in 2013 almost all of the global GM crop area was derived from soybeans, maize/corn, cotton and canola (Figure 1). In 2013, GM soybeans accounted for the largest share (49%), followed by corn (32%), cotton (14%) and canola (5%). There were also additional GM crop plantings of papaya (395 hectares), squash (2,000 hectares), sugar beet (467,000 ha) and alfalfa (about 750,000 ha) in the US. There were also 5,000 hectares of papaya in China and 15,600 hectares of sugar beet in Canada.

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⁹ www.isaaa.org

Others Canola India 7% Cotton 14% USA Argentina Soybean 14% 49% Brazil Corn China 32% 2% Canada

Figure 1: Global GM crop plantings 2013 by crop and country (base area of the 4 crops: 168.5 million hectares)

Sources: Various including ISAAA, Canola Council of Canada, CanolaUSDA, CropLife Canada, CSIRO, ArgenBio, National Ministries of Agriculture (Mexico, Philippines, Spain), Grains South Africa.

Of the share of total global plantings to these four crops, GM traits accounted for the majority of soybean plantings (74%) in 2013. For the other three main crops, the GM shares in 2013 were 29% for maize/corn, 71% for cotton and 22% for canola (Figure Three).

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The US had the largest share of global GM crop plantings in 2013 (38%), followed by Brazil (26%). The other main countries planting GM crops in 2013 were Argentina, India, Canada and China (Figure 1, Table 1).

In terms of the GM share of production in the main adopting countries, Table 2 shows that, in 2013, the agricultural crops, GM crops accounted for significant shares of total production in several countries, many of which are major exporters of grain and compete with Australia in the global export market.

Table 1: Global GM crop growth 2013 - top 10 countries

No.	Country	Area (million hectares)	Crops	
1	USA	70.1	Corn, soybean, cotton, canola, sugar beet, alfalfa	
			(lucerne), papaya, squash	
2	Brazil	40.3	Soybean, corn, cotton	
3	Argentina	24.4	Soybean, corn, cotton	
4	India	11.0	Cotton	
5	Canada	10.8	Canola, corn, soybean, sugar beet	
6	China	4.2	Cotton, papaya, poplar, tomato, sweet pepper	
7	Paraguay	3.6	Soybean, corn, cotton	
8	South Africa	2.9	Corn, soybean, cotton	
9	Pakistan	2.8	Cotton	
10	Uruguay	1.5	Soybean, corn	
13	Australia	0.6	Cotton, canola (and carnations)	

Table 2: GM share of crop plantings in 2013 by country (% of total plantings)

Country	Soybeans	Maize	Cotton	Canola
USA	93	90	90	93
Canada	79	96	n/a	95
Argentina	99	80	93	n/a
South Africa	92	87	95	n/a
Australia	n/a	n/a	99	10
China	n/a	n/a	86	n/a
Philippines	n/a	31	n/a	n/a
Paraguay	93	50	50	n/a
Brazil	89	82	65	n/a
Uruguay	99	96	n/a	n/a
India	n/a	n/a	95	n/a
Colombia	n/a	15	85	n/a
Mexico	7	n/a	90	n/a
Bolivia	91	n/a	n/a	n/a
Burkana Faso	n/a	n/a	69	n/a
Pakistan	n/a	n/a	88	n/a
Myanmar	n/a	n/a	85	n/a

^{*} n/a = not applicable

In summary, Australia is a small player in terms of the overall area of GM crop planting, and lags behind many of its competitors in the proportion and diversity of GM plantings. The reasons for these differences are complex but the figures serve to illustrate that GM crops are being adopted by our competitors conferring to farmers in these regions the advantages that these crops bring. The data also serve to highlight the challenge that the Australian agriculture industry faces to attract private investment in R, D, E & A when companies weigh the opportunity and risks associated with investing in competing regions of the world.

Challenges for the Australian Agricultural Biotechnology Industry

Increasing the efficiency and economic sustainability of agricultural practices will require increased investment in agricultural R, D, E & A. Growth in agricultural productivity fell dramatically in the early 2000s from 2.5% growth year on year to 0.8% growth – this has been attributed by ABARES almost entirely to cuts to R&D spending. Public R, D, E & A accounts for 63% of agricultural productivity growth of which 32% is from foreign investment.

Existing barriers to public investment in the implementation of emerging technology include uncertainty in market acceptance, restrictive state government regulation, limited access to pathways to market and the availability of skilled technology translation researchers and extension officers.

AusBiotech suggests that by addressing these barriers the Department of Agriculture can dramatically improve the translation and adoption of new technologies including and beyond GM and attract significantly more private industry investment into the implementation of advanced agricultural practices.

a) Regulatory Environment

Australia has one of the worlds leading regulatory systems for genetically modified organisms, including GM foods. At a Commonwealth level, including the OGTR and FSANZ, regulation is evidence based, risk assessed and transparent, in line with world's best practice. The statutory time frame for technology applications to be assessed and granted is its greatest strengths, as compared to many other countries it provides certainty to technology developers and investors. AusBiotech does not want to see any weakening of the Regulators as good regulation is an asset domestically and for international trade.

However, for Australian and/or international investors and technology providers to invest in developing and commercialising agricultural biotechnology for Australian crop and livestock production systems they must be able to gauge the level of risk associated with the commercialisation of the technology. Several areas of regulation continue to retard domestic and international investment into Australian agricultural biotechnology research and commercialisation.

i. State moratoria against the planting of genetically modified crops. The existence of state moratoria have had, and continue to have a profound impact on the erosion of business investment into agricultural biotechnology. Bayer CropScience and Monsanto each invested over 20 million dollars to develop GM varieties suitable for the Australian agricultural

environment prior to the introduction of the State moratoria. Despite getting approval for the commercial release from the OGTR the existence or threat of State moratoria mean that companies lack confidence that the return on their Australian investment will be realised. Whilst there are indications that the WA Government will repeal the GM Corps Free Areas Act 2003, the WA Shadow Minister for Agriculture has stated that if elected the opposition would reintroduce a ban on planting GM crops. It is unlikely that any single factor has a greater impact on public investment in agricultural biotechnology in Australia than the uncertainty created by indecisive State moratoria against GM crops.

ii. Regulator inconsistencies. While the industry has seen significant improvements in regulatory agencies, such as the OGTR and FSANZ in relation to providing certainty and confidence in the regulatory compliance and approval process, concerns remain about the lack of performance of the Australian Pesticide and Veterinary Medicines Authority (APVMA). In July 2014 the APVMA implemented a new Pre Application Assistance (PAA) arrangement to allow a potential applicant to apply for regulatory advice prior to the submission of an application to register a veterinary medicine product. Whilst the APVMA is to be commended for attempting to streamline processes, when the performance of the PAA was reviewed none of the industry participants indicated that they were satisfied with the administrative requirements, timeliness, cost or quality of the response they received. In fact they felt that the new arrangements provided a lower level of service that what was available before 1 July 2014. While Industry was encouraged by the APVMA's willingness to respond to its needs, its execution of these changes fell well short of industry expectations (ACIL report Jan 2015).

Another example helps to illustrate these concerns. A major international vaccine manufacturer submitted a change of site of manufacture variation for a vaccine that had been sold in Australia for many years. The vaccine for Bovine Ephemeral Fever virus is used in the northern regions of the cattle industry. After two years this submission had not been dealt with and all existing vaccine supplies had either been sold or reached their expiry date. This situation left the cattle industry exposed to this disease with no treatment available. Unfortunately this is not an isolated example and urgent reforms are needed within the APVMA.

Industry believes that the Australian Government through the Department of Agriculture, should more actively engage in, and provide the necessary resources and support to facilitate the necessary changes that will provide certainty and confidence in agricultural biotechnology dealings with the APVMA.

iii. Synchronicity and mutual recognition between regulatory agencies when approving food, feed and environmental approvals could make an important difference to Australia. The commercialisation of GM crops is a regulated activity and different countries have different authorisation procedures, hence new GM crops do not get simultaneously approved worldwide (asynchronous approvals). In addition, increasingly technology providers are not necessarily seeking regulatory approval outside of the producing country (asymmetric approvals).

The lack of alignment in regulatory strategy implementation (i.e. asynchronous and asymmetric approvals) is of growing concern for its potential impact on international trade, in particular where countries operate a "zero tolerance" policy that may result in rejections of imports that contain only traces of such GMOs. A similar problem of "low-level presence" (LLP) of unapproved GM material in imports arises when developers of new GM crops do not seek approval in export markets, i.e. when there is "isolated foreign approval" in their home countries only.

The likelihood of LLP occurring and the impact it has on global grain trade is likely to increase as the global area planted to biotech crops continues to increase and while importing countries maintain "zero tolerance" policies on GM on one-hand and exporting countries with increasing GM commercialisation on the other. In addition, there is increasingly sophisticated and sensitive testing equipment escalating the risk of non-compliance with existing legislation through the accidental LLP of non-approved GMOs. This is causing a higher level of "destination risk", i.e. the official testing for unauthorised material only in the port of destination.

There are a number of factors that are contributing to the lack of alignment in regulatory strategy implementation:

- Increasing volume of GM crops produced
- Increasing volume of GM crops traded (movement)
- o Increasing diversity of traits that are used for GM crops
- Increasing number of countries adopting GM crops
- Increasing inclusion of the presence/absence of GM traits in trade agreements
- o Different timing of GM trait regulatory approvals (asynchronous approvals)
- o Diverse LLP policies in importing and export countries
- o Diverse levels of implementation and enforcement of the relevant regulations

Harmonisation between international regulators that govern existing and developing crops will serve to stimulate innovation in Australia and internationally. Given that Australia's international trading partners such as Canada, USA, India and Brazil lead in the development of GM research and at the same time also engage in active collaborations with Australian research institutes Australia is well placed to be an early adopter of these crops. However, as a relatively small market the threat to this opportunity is that without active engagement in the international regulatory discussions Australia's regulatory system will continue to present a barrier to companies seeking to engage with Australia.

It is essential that the Australian Government provide regulators such as the OGTR, FSANZ and the APVMA, the resources and policy support which will allow the respective agencies to provide proactive support to global and, in particular, APAC initiatives that facilitate the trade of GM products.

iv. The Australian National Standard for Organic and Biodynamic Produce (National Standard) is inconsistent with Australian Government policy regarding food labelling and with the regulations of Australia's key trading partners. Australia's Food Standard Code allows for up

to a 1% threshold for the accidental presence of an approved GM food ingredient whereas the National Standard states that GM products are not compatible with organic and biodynamic management practices and are not permitted under a parallel production system.

Organic certifiers have interpreted the National Standard as a 'zero tolerance' to the presence of GM materials on the farm or in the produce. This interpretation was recently the subject of the damaging WA Supreme Court case of *Marsh v Baxter*¹⁰ in which an organic farmer, Mr Marsh, who lost his farms organic status due to the accidental presence of GM material from a neighbouring farm, sought a permanent injunction to restrain his neighbour Mr Baxter from ever again growing a GM canola crop in paddocks adjacent to Mr Marsh's property.

The consequence of the internationally-inconsistent National Standard has been the unjustified personal and public costs that resulted from the WA Supreme Court case that followed. The high-profile case also has broader implications by undermining confidence amongst growers who are balancing the adoption of new technology that may provide an on-farm productivity improvement, with the uncontrollable risk that through adventitious or accidental means a contamination may occur leading to protracted and highly-public litigation.

AusBiotech recommends that the Department of Agriculture review the requirements of the National Standard for Organic and Bio-Dynamic Produce and request the Organic Industry Standards and Certification Committee introduce reasonable thresholds for GM materials into the standard that are in harmony with international benchmarks.

b) Lack of Government and Industry Alignment on the Role of Agricultural Biotechnology

Australia was the first international country outside of the US to commercialise the first GM crop in 1996 (i.e. Insect Tolerant Cotton – Ingard© Cotton). The introduction of GM cotton has revolutionised growing cotton in Australia, not only in terms of saving the industry from potential disintegration due to the threat of insect resistance to pesticides, but also by enhancing crop yields through the adoption of herbicide tolerant technology for weed control. By 2015, GM cotton was being grown over 98% of the total cotton area in Australia. This adoption rate is higher than any other GM crop in any other region of the world where GM crops are grown.

By contrast, Australia has been slow to adopt any other GM crops which it may have access too. For example despite GM herbicide tolerant canola being approved by Federal Regulators in 2004, it was not commercially released until 2008 in Victoria and New South Wales and 2010 in Western Australia, and remains unavailable to farmers in South Australia and Tasmania due to state government imposed moratoriums. Despite the delay in release, by 2015 the adoption of GM herbicide tolerant canola had reached approximately 25% of the Australian canola market. This is well below that achieved in Canada, where within five years of release in 1996, GM herbicide tolerant canola had achieved 75% market share. Australia is also well below the adoption rates for the various GM crops which have been introduced across a range of countries globally.

While there are many reasons for the difference in adoption of GM canola between Australia and Canada, one of the key reasons is the inconsistency and lack of alignment between and within Federal and State governments, as well as between and within the agricultural sector and the respective layers of government.

While this remains, it acts as a disincentive for domestic and international investment by investors and technology providers to develop agricultural products for the Australian market.

Australia's agricultural productivity through the use of agricultural biotechnology, including governments and industry.

To progress and support agricultural innovation through the use of agricultural biotechnology will require significant collaboration, participation and investment by the Department of Agriculture in order to gain the alignment necessary to capitalise on the benefits and value that agricultural biotechnology innovation can deliver to Australian agriculture.

c) <u>Technology translation, commercialisation and extension</u>

Since the release of the first GM crop there has been a plethora of new GM events¹¹ which have gained food, feed and environmental approvals across a range of crops and countries.

A total of 2,833 regulatory approvals involving 27 GM crops have been issued in 36 countries (35 + EU-27): 1,321 for food use; 918 for feed use; and 599 for planting or release into the environment. As these approvals have progressed, there has been an increasing trend for regulatory approval of gene stacking.

It is estimated that a total of 43.7 million ha were planted to biotech stacks in 2012. This accounts for more than 26 percent of the 170.3 million ha of biotech crops planted worldwide with an average year-to-year increase of 31 percent. 12

The US Department of Agriculture estimated that stacked cotton and corn, respectively, reached 63 percent and 52 percent of total planted areas in the USA in 2012¹³.

There is an increase in research into second-generation attributes i.e. nutritional and consumer oriented traits. CropLife International ¹⁴ has recently released its 2015 Plant Biotechnology Product Pipeline which presents an overview of the research being undertaken by its members in the plant biotechnology arena. Products in the 'Advanced Development' category, which aim to hit the market within five to seven years, subject to regulatory approvals. (Table 3)

¹¹ Event: refers to the unique DNA recombination event that took place in one plant cell, which was then used to generate entire transgenic plants. If more than one gene from another organism has been transferred, the created GMO has stacked genes (or stacked traits), and is called a gene stacked event

James, C (2012) Global Status of Commercialized Transgenic Crops. ISAAA Briefs no. 44. ISAAA: Ithaca, NY.
 http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx

www.croplife.org.au/wp-content/uploads/2014/06/CropLifePlantBiotechPipeline-2015.pdf

Table 3: GM crop modifications due for release 2015 – 2022

Commodity	GM Modification
Corn	Herbicide tolerance
	Insect resistance
	Higher yielding
Soybean	Herbicide tolerance
	Insect resistance
	Omega 3
	Low saturated, zero trans-fat oil
Cotton	Herbicide tolerance
	Insect resistance
Canola	Herbicide tolerance
	Increased protein, higher nutrient density for feed
	Modified oil – Omega 3
Rice	Vitamin A enriched (Golden Rice)
Alfalfa	Reduced lignin
Bean	Virus resistance
Eggplant	Virus resistance
Potato	Virus resistance
Safflower	Modified oil – Super high oleic
Sunflower	Reduced saturates (oil profile)

Within Australia the adoption of GM canola has been modest when compared to the adoption of GM crops in other parts of the world. Despite the slow adoption of new plant biotechnologies Australian scientists have been at the forefront of researching and developing a range of GM traits across a range of crops. This has led to a significant increase in the number of international patents filed, together with an increase in the number of GM field trials planted in Australia across a range of crops including cotton, bananas, sugarcane, wheat, barley, safflower and canola. The range of GM traits being field tested includes nutrient use efficiency, abiotic and biotic stress, grain quality and modified oils such as super high oleic and Omega 3. The horizon for commercial release of some of these crops and traits in Australia is as close as 2018.

In the livestock industries, Australia is considered to be ahead of its competitors in the use of genetic markers for breeding in livestock and is on par with competitors in the use of DNA-based and protein-based diagnostic tests and disease treatments.

Despite these achievements, and having some of the world's top ranking universities and research institutes, Australia has very low levels of commercialisation innovators' (1.5%) compared to other OECD countries (between 10-40%). It is inevitable that much of the technology that will enable Australian farmers to remain competitive will be sourced internationally.

Australia is falling behind its competitors in many areas relating to the translation, commercialisation and extension of agricultural biotechnology innovation. Competitors that have been considered to be lagging behind Australia in the past, including Brazil and China, are catching up fast.

AusBiotech believes the Department of Agriculture has a strategic role to play in ensuring that appropriate policy and investment continues to be applied to developing biotechnology applications where domestic challenges are presented (e.g. high boron soils, salinity, drought, region-specific disease strains, and biosecurity). In addition it needs to take a pro-active role in ensuring that where there is potential market failure in commercialising international agricultural biotechnology developments, which are relevant to Australian agriculture (e.g. vaccines and diagnostic tests for diseases common elsewhere) it facilitates pathways for investment and commercial development and adoption of these technologies in Australia. Failure to do so will only further widen the gap between Australian agriculture and its major international competitors who are already aggressively pursuing and adopting these advances in agricultural biotechnology.

Technologies such as genomic testing, marker assisted breeding, insect tolerant cotton and herbicide tolerant canola have already demonstrated the importance of the rapid adoption of innovation, however in these cases the technologies required very large markets to support the investments in R&D – usually US, Canada, Brazil and Argentina but increasingly China and other Asian block countries. Recognising this, Australia must ensure that it has the necessary translational research, commercialisation and extension skills to adapt and adopt technology from internationally developed research.

For example, by tailoring genomic testing of cattle DNA – which had been largely developed in the US and EU – to Australian farming conditions the Australian dairy industry has enable breeders to correct problems in Australian dairy cattle gene lines that would have otherwise taken many more generations of breeding to accomplish. Genomics confer to farmers and breeders the ability to select for traits that are either expensive or hard to measure commercially at young ages with relative accuracies equivalent to measurement at later life. Decreasing the generation time to target specific traits of interest to Australian farmers has a compounding impact on the productivity of Australian cattle in both the beef and dairy industries. However, in the absence of the technical capacity to develop Australian genomic breeding values, the genetic merit of the Australian herd would quickly fall behind its international competitors at the equivalent expediential rate. The economic impact of stagnation in the genetic merit of the Australian herd will be higher cost milk solids (relative to competing dairy nations), lower value of live cattle sales and lower investment in Australian dairy enterprises.

The primary industry RDCs are well structured, with appropriate governance and primary producer input, to support and direct government investment into the necessary development, extension and adoption of agricultural innovation. Whilst the RDCs already undertake varying levels of extension services, government could increase support for initiatives from the RDCs that lead to the on-farm adoption of advanced technologies such as digitisation, 'big data', genetics and precision agriculture. AusBiotech would like to see additional support linked to initiatives that foster greater cooperation between the RDCs and to measures ensuring transparency for the use of associated funding.

Conclusion

AusBiotech is pleased to have the opportunity to respond to the agricultural innovation inquiry. AusBiotech believes that innovation in advanced technologies, and more particularly agricultural biotechnology, will be central to the future productivity improvements of the agricultural sector, to industry's ability to compete on international export markets, and the enhancement of agriculture's contribution to the Australian economy.

The key hurdles to the adoption of these technologies are known:

- Inconsistent and unstable policy and regulation between the States, Territories and the Federal government has led to a lack of confidence by investors, technology providers and the agricultural sector in relation to supporting the pathway to market for agricultural biotechnology innovation in Australia.
- The lack of international harmonisation of regulation at a time when there is increasing trade of GM and non GM crops has led to a significant increase in risk exposure for the supply chain, and an escalation of the costs associated with gaining the necessary global regulatory approvals to ensure continuity of trade and market choice.
- Overlapping and inconsistent regulatory agencies particularly APVMA, has led to confusion
 and frustration for technology providers and the industry. Hence, greater alignment and
 improvements in cross agency policy, administration and communication is required in order
 to generate consistency and continuity within and between agencies.
- The lack of an Australian domestic agricultural investment sector to support
 commercialisation of Australian generated agricultural biotechnology innovation has led to
 the loss overseas of technology innovation which would have otherwise been directed to
 Australian farmers. Hence there is a requirement for the Federal government to support
 initiatives that build greater domestic and international investment in Australian-directed
 agricultural technology translation, commercialisation and extension.
- Australian agriculture lacks the skills required to support the future large scale
 commercialisation and adoption of agricultural biotechnology. There is a pressing need to
 accelerate investment in capability and capacity building in on-farm business and STEM skills
 to capitalise on the benefits and value from agricultural biotechnology.
- Without additional overall investment Australian agricultural will continue to see its
 innovators move off-shore to seek opportunities which will result in Australian farmers
 falling further behind in the levels of productivity required to be sustainable and competitive
 in expanding global markets for Australian agricultural products.

In summary, agricultural biotechnology offers a set of innovative tools for Australia's crop and livestock industries that will create new and improved food and fibre products, more efficient and resilient farming systems and supply chains. The benefits and value from the adoption of agricultural biotechnology will deliver far-reaching agronomic, environmental, nutritional, human health and economic benefits to Australian agriculture and consumers. Such benefits will strengthen Australia's competitive position in global food and fibre markets and provide increased surety of supply for domestic consumers. However, to achieve these benefits significant changes in public and private sector policy and incremental investment in agricultural biotechnology R, D, E & A, the commercialisation pathway to market and the regulatory landscape will be required.