AusBiotech submission to the Productivity Commission regarding the regulation of Australian agriculture

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12 February 2016

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Introduction

AusBiotech is pleased to submit to this issues paper regarding the regulation of Australian agriculture. The submission represents a collation of comments and submissions from AusBiotech members engaged in delivering economic benefits to Australian agriculture through the commercialisation of 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 sectors. The industry consists of an estimated 900 biotechnology companies and employs in excess of 45,000 Australians.

Within AusBiotech, the agriculture, food and industrial biotechnology sectors are represented by the Agriculture Food & Industrial Biotechnology Committee, a special interest industry group dedicated to support AusBiotech with its mission to:

"…foster a growing, strong and profitable biotechnology and life science industry in Australia through representation, advocacy and the provision of services and benefits to its members to help the industry realise its nationally important economic potential"

AusBiotech members recognise that the application of good regulation is critical to build confidence and certainty; it underpins public investment and ensures the competitiveness of Australian agriculture. Ambiguous or absent regulation elevates risk and is a strong barrier to innovation and as a result undermines economic benefit.

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

Inconsistencies within, and uncertainty of agricultural regulation is the single most influential factor impacting the decision of major agricultural research providers to invest in Australia. This uncertainty is being exasperated with the development and introduction of new breeding technologies at a time when policy and regulation has not kept pace with these developments. New breeding technologies have demonstrated that when adopted by plant breeders they have the potential to facilitate greater efficiency, effectiveness and economies of scale associated with producing high performance plant varieties that will be required to address the increasing demand to feed the world.

Agricultural Biotechnology – Global Context

From the first release of GM cotton in 1996 through to the release of GM canola in 2008 and up until today, agricultural biotechnology 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 agricultural biotechnology has expanded to include:

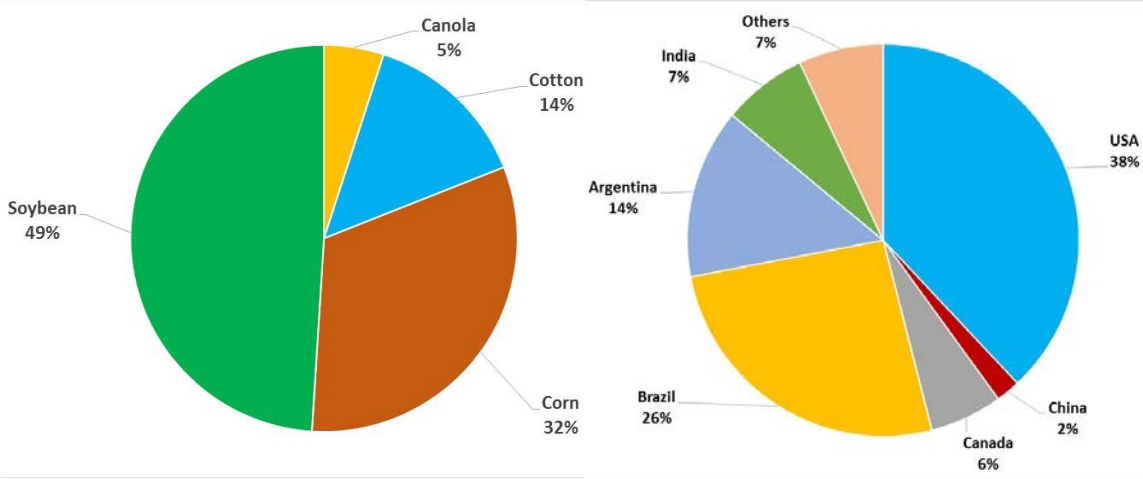
- Bio-based energy production
- Industrial enzyme production
- Microbe-based pest control and growth enhancers

- 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 the influence of agricultural biotechnology into the future will be significant as many of the current crops that 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.[1] 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.

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



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.

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).

[1] www.isaaa.org

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 competitive advantages that these crops bring. However, given Australian agriculture reliance on exports and the economic value that these generate for the Australian economy it is imperative that Australia continue to overcome the barriers to adoption of agricultural biotechnology in Australia and seek competitive advantage through innovation in agricultural production systems.

Barriers for the development and contribution of agricultural biotechnology to the Australian economy.

The rapid global adoption of agricultural biotechnology serves to highlight the challenge that the Australian agriculture industry and in particular the agricultural biotechnology industry faces to attract private investment, especially when companies weigh the opportunity and risks associated with investing in Australia versus competing regions of the world.

Investment

Existing barriers to public investment in the implementation of emerging technologies include restrictive, inconsistent and uncertain regulatory processes governing the commercialisation of these technologies and, uncertainty in market and consumer acceptance. AusBiotech members suggest that market acceptance has been negatively influenced by poorly supported, mandatory-labelling requirements and a public perception that if GM products require special labelling and are banned in some states then there must be uncertainty regarding the safety of these foods.

AusBiotech suggests that by addressing the current regulatory burden imposed on agricultural biotechnology, particularly, but not limited to, GM crops, governments can:

- Positively address the issue of food security
- Improve the competitiveness of Australian agriculture through the accessibility of new technologies to farming practices
- Reduce consumer anxiety about the safety of agricultural biotechnology
- Increase investor confidence in Australian agriculture
- Stimulate private investment in agricultural biotechnology research and facilitate the translation of research that benefits Australian agriculture.

Regulation

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.

Australia has one of the worlds leading regulatory systems for genetically modified organisms, including GM foods. At a Commonwealth level, policy and regulation governing the role of the OGTR and FSANZ is evidence based, risk assessed and transparent, in line with world's best practice. The statutory timeframe for technology applications to be assessed and granted is its greatest strength and compares favourably to many other countries. It provides certainty to technology developers and investors. AusBiotech would regard any weakening of the regulators as a regressive step. Good regulation is an essential asset both domestically and for international trade.

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 causing the erosion of business investment into agricultural biotechnology which harms the whole Australian economy. Bayer CropScience and Monsanto each invested over $20 million to develop GM varieties suitable for the Australian agricultural environment prior to the introduction of the State moratoria. Despite obtaining approval from the OGTR for commercial release of new crops, the persistence and threat of State moratoria mean that companies lack the confidence to make further investments and are unsure that the return on their Australian investment will be realised. While there are indications that, for example, the WA Government will repeal the GM Crops 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 negative impact on public investment in agricultural biotechnology in Australia than the uncertainty created by changeable State moratoria against GM crops.

AusBiotech recommends to the Australian government that it work with appropriate State and Territory governments and industry to implement appropriate processes to discontinue the moratoria that remain in place and thereby removing a barrier to economic growth through investment and adoption of innovation from agricultural biotechnology.

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 potential applicants to apply for regulatory advice prior to the submission of an application to register both agricultural chemical and veterinary medicine products. Whilst the APVMA is to be commended for attempting to streamline processes, when the performance of the PAA was reviewed none of the veterinary 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 previously been sold in Australia. 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.

AusBiotech recommends to the Australian Government that 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 and all regulatory authorities.

iii. *Policy and regulatory uncertainty with the introduction of New Breeding Technologies (NBT's)* Innovation in plant and animal breeding is necessary to meet the challenges of global changes such as population growth and climate change. Agriculture has been able to cope with these challenges until now. However, further efforts are needed and therefore plant and animal breeders search for new and improved breeding techniques.

AusBiotech supports the need for continuous progress in plant and animal breeding techniques, which can help to overcome some limitations of traditional breeding and enlarge the portfolio of high quality products developed in Australian agriculture.

Australian legislation regulating genetically modified organisms (GMOs) goes back to the year 2000 (OGTR Act, 2000). The GMO legislation has been revised during recent years. However, the definition of GMOs remains the same as in 2000. New breeding techniques that have been developed since this time create new challenges for regulators when applying the GMO definition from 2000.

New breeding technologies which have been developed in recent years that require regulatory clarification include, but are not limited to, the following:

- Genome editing technologies
- Oligonucleotide directed mutagenesis (ODM)
- Cisgenesis and intragenesis
- RNA-dependent DNA methylation (RdDM)
- Grafting (on GM rootstock)
- Reverse breeding
- Agro-infiltration (agro-infiltration "sensu stricto", agro-inoculation, floral dip)
- Synthetic genomics.

The main driver for the adoption of new breeding techniques is the technical potential of these techniques. Most of the techniques can be used for producing genetic variation, a critical step in breeding. They aim at, for example, targeted mutagenesis (genome editing and ODM), targeted introduction of new genes (genome editing, cisgenesis and intragenesis) or gene silencing (RdDM). Agro-infiltration can be used for the selection of plants with specific traits, the second step in plant breeding.

The new breeding techniques show technical advantages when compared to 'older' techniques: some (genome editing and ODM techniques) allow site-specific and targeted changes in the genome. For many of the techniques the genetic information coding for the desired trait is only transiently present in or stably integrated only in intermediates. Therefore, the commercialised product will not contain an inserted transgene.

The second main driver for the adoption of new breeding techniques is its economic advantages. The use of new breeding techniques makes the breeding process faster, which lowers the production costs. For example, cisgenesis uses the same gene pool as conventional cross breeding, but is much faster as it avoids many steps of back-crossing.

Biotechnology companies and plant and animal breeders are particularly concerned about the legislative uncertainty of the GMO classification of new breeding techniques. The registration costs will be low if a technique is classified as non-GMO or very high if classified as GMO. Therefore, the legal status of the new breeding techniques will influence the decision on whether to use these techniques only for the introduction or modification of traits in products with very high value or more extensively for a broad field of applications, and therefore will be of specific importance for small and medium enterprises.

This uncertainty of status is likely to have a detrimental effect on the market and may work against the national interest by restricting market-acceptable improvements of Australian design, negatively affecting the ability of Australian primary producers to compete globally. AusBiotech believes that Australian farmer should have the freedom to choose products that suit their particular business needs and would urge a 'light touch' for new technologies that do not pose a health or biosecurity risk.

AusBiotech recommends to the Australian Government that through the Department of Health undertake an independent review of NBT's for the purpose of clarifying and/or developing the policy and regulations which determine the status of individual NBT's for the industry and regulators such as the OGTR and FSANZ. The guidelines for the review would be based on an assessment of the final product derived from the application of NBT's (versus process) and be evidence based, risk assessed and transparent in line with world's best practice.

iv. *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, technology providers are increasingly not 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. Compliance with zero-tolerance policy is increasingly challenging international trade flow, particular where differing regulations are applied to the same type of product with asynchronous pre-market approvals.

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)
- 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
- Different timing of GM trait regulatory approvals (asynchronous approvals)
- Diverse LLP policies in importing and export countries
- 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.

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

v. *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 bio-dynamic 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*[2] in which an organic farmer, Mr Marsh, who lost his farm's 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 significant personal and public costs that resulted from the WA Supreme Court case that followed. The high-profile case has broader implications by damaging confidence amongst growers who are balancing the adoption of new technology that may provide an on-farm productivity improvement, with the risk that through adventitious or accidental means a contamination may occur, potentially leading to litigation.

The case may also establish a legal precedence regarding the interpretation of the National Standard having a zero tolerance of GM materials that is out of step with all equivalent international standards. This creates an unnecessary additional barrier to farmers considering organic farming practices for economic reasons, but are dissuaded because of the threat of loss of certification because of an unrealistic threshold of adventitious or accidental contamination.

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

Labelling of genetically modified foods

Food Standards Australia New Zealand (FSANZ) has approved a number of GM foods for sale on the Australian market. Their risk assessments for these foods conclude that they do not introduce any new or altered hazards into the food supply and that they are no different to the conventional foods already in the food supply. Every legitimate scientific and regulatory body that has examined the evidence has arrived at the conclusion that approved GM crops and the foods derived from them are as safe as their non-GM 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 Medicines, and many others.

The labelling of foods as GM therefore has nothing to do with the health or safety of food. AusBiotech believes that FSANZ's approach to the labelling of GM food is at odds with its otherwise best-practice, evidence-based approach to food-safety regulation.

Conclusion

AusBiotech is pleased to have the opportunity to respond to the Productivity Commission's issues paper on the regulation of Australian agriculture. AusBiotech believes that good regulation is critical to providing the certainty needed for private investment in advanced technologies, and more particularly agricultural biotechnology, which will be central to the future productivity

[2] [2014] WASC 187

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, in particular the uncertainty created by state moratoria against GM crops 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 investment in Australia.
- The resulting lack of investment in Australian agricultural biotechnology has led to the loss overseas of technology innovation that could otherwise have been directed to Australian farmers and the corresponding loss of investment in Australian research and development centres. Hence, there is a requirement for the Federal government to support initiatives that build the confidence required for greater domestic and international investment in Australian-directed agricultural technology translation, commercialisation and extension.
- Without increased 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.
- The lag and subsequent uncertainty that exists for industry and regulators (OGTR and FSANZ) in the absence of an Australian policy, and resulting regulation, relating to the status of new plant breeding technologies.
- 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 the APVMA, has led to confusion and frustration for technology providers and the industry and in some cases, such as the approval of vaccines, the potential for economic loss. 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.

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 and more efficient and resilient farming systems and supply chains. The benefits and value from the adoption of agricultural biotechnology will underpin future food security by delivering 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 there needs to be recognition that Australia is a small player in the global agriculture biotechnology sector. While in the short term there is the risk that regulation will slow the market uptake of new technologies, many Australian farmers will reap long-term rewards in the ability to trade with their counterparts in more 'technology-friendly' regions. Whist not all farmers will want access to these technologies those that see a commercial benefit should be afforded the choice, and enable to compete with their global competitors.