CropLife AUSTRALIA

SUBMISSION IN RESPONSE TO

REVIEW OF THE GENE TECHNOLOGY ACT 2000

14 JUNE 2011

CropLife Australia Limited
ABN 29 008 579 048
Level 2 AMP Building
1 Hobart Place Canberra ACT 2600
Locked Bag 916 Canberra ACT 2601

Tel 02 6230 6399
Fax 02 6230 6355
www.croplifeaustralia.org.au

Executive Summary

The current Gene Technology Act as administered by the Office of the Gene Technology Regulator is working well for approvals sought by the developers of genetically modified (GM) crops. However, there are some problems with the legislation because of state government intervention and the involvement of other regulators, such as the Australian Pesticides and Veterinary Medicines Authority creating regulatory duplication. CropLife also believes that it is now time to increase the use of the GMO Register for genetically modified crops that have been sold commercially for several years without evidence of adverse effects. The GMO Register could also be used to list crops that are no longer commercially sold in Australia.

CropLife strongly urges the Federal Government and all of Australia's state governments to recommit to a national approach to regulation. This recommendation was made during the last review of the Gene Technology Act but to date, has not been acted upon. This is a critical goal if Australia is to remain at the leading edge in modern agriculture.

After a decade's experience with the Gene Technology Act it is clear that its effect is to make some clauses of other federal legislation redundant. CropLife requests Ministers to recommend that the Intergovernmental Regulators' Forum review this and any other federal regulatory overlaps to streamline federal regulations. The Regulators' Forum should also introduce improved intellectual property protection for data that is submitted for regulatory assessments.

CropLife believes that it is important that regulation is commensurate with risk. Understanding of the risks associated with GMOs has been significantly improved through a decade of practical experience since the Act was originally drafted. CropLife urges the Australian Government to consider the costs and benefits of the current regulations in order to identify and remove areas of regulation where the risk is negligible.

The current Gene Technology Act is written to include all new crops bred using modern crop breeding technologies, unless specially excluded by regulation. This approach restricts the introduction of new crops that use new technologies that do not include transgenic DNA. This regulation is not commensurate with risk because many new breeding technologies mimic naturally occurring processes and pose much lower risks than other historically unregulated breeding technologies.

Looking forward, it is likely that future GM crops will possess health and environmental benefits that should not be unnecessarily delayed from reaching consumers. It is also likely that there will be many new crops developed by companies and institutions that have not previously brought GM crops to market, particularly those that are based in India and China. This will pose new challenges for regulators in Australia and around the world. CropLife recommends that in order to minimise future trade disputes, the Australian Government consider a system involving mutual recognition of regulatory approvals when the modified DNA present in a GM crop is detected at very low levels. This could be based on the Codex Annex on Low Level Presence that was adopted in the Codex guidelines in mid-2008.

1. INTRODUCTION

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, formulators and registrants of crop protection and agro-biotechnology products. 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 $1.5 billion a year to the Australian economy and directly employs thousands of people across the country.

CropLife member companies spend more than $13 million a year on stewardship activities to ensure the safe use of their products on the environment and human health. CropLife ensures the responsible use of these products through its industry code of conduct and has set a benchmark for industry stewardship through programs such as ***drum****MUSTER*, ChemClear® and Agsafe Accreditation and Training.

Genetically modified (GM) crops are just another step along the same path of technological improvement that led to Australian agricultural inventions like the combine harvester and federation wheat varieties. The utilisation of these innovations has delivered safe and affordable food to the nation and the globe. Despite a proven record of safety, every GM crop is subjected to intense global regulatory scrutiny. None of the regulators anywhere in the world has found any safety issues associated with these genetically modified crops.

One threat to the potential success of this important agricultural innovation is unnecessary and overly stringent regulation that brings an equally unnecessary cost burden. CropLife believes that all regulation should be commensurate with the associated risk, cost and benefit to the community. Science and experience have established that there is no health or safety risk differential between approved GM and non-GM crops. However, already the current regulations in Australia impose 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.

If Australia fails to properly exploit the opportunities that are offered by this technology, the results will be profound. The world's food producers are currently facing the sobering challenge of needing to increase global food production by 70 per cent in 40 years, with dwindling resources, in a challenging and changing climate. This situation presents opportunities for Australia to both assist in the global food security effort and also to profit from increased demand for our agricultural products. If we can produce more with less, through efficient use of technology, then the sector and the regional communities that rely upon it will be strengthened. If, however, we allow our regulations to unnecessarily slow the adoption of modern crops in Australia, these opportunities will be missed.

The Gene Technology Act is transparent and the assessments that are conducted under it are based on science. However, the Act overlaps with other legislation and was based on an understanding of risks of GMOs that are now superseded by 15 years of commercial experience. The biggest issue with the Gene Technology Act relates to its interaction with state based legislation. Initially, the Gene Technology Act was envisaged to be the fulcrum in a nationally consistent scheme. However, the interference in functioning markets by state governments has completely undermined this intent.

2. INTERACTION OF THE GENE TECHNOLOGY ACT WITH OTHER REGULATORY SCHEMES

The agricultural biotechnology industry faces often unnecessary regulation at every level of government. At the federal level, regulation is often not commensurate with risk and there is duplication in the responsibilities and assessments conducted by the regulators. At the state level, governments intervene in perfectly functional markets and provide no certainty to business investors as to whether they will ever be able to commercialise their product, regardless of the regulatory hurdles that they clear. CropLife also notes that several local councils have attempted to regulate the use of GMOs, however, this submission will focus on the federal and state levels of government.

2.1 National Regulations

The two major problems with the current regulation of gene technology in Australia at the Australian Government level are duplication between regulatory agencies and the fact that a number of regulatory requirements no longer correlate with the realistic risk posed.

The national system also has a number of positive features. Risk assessments are based on science and this means that the system is as predictable as possible. As discussed in other sections of this submission, predictability is vital if private investment is to fund any significant part of technology development in Australia.

The publishing of the risk assessment and risk management plans underpins one of the most transparent regulatory systems in the world. Transparency is important because it increases the trust of the regulator in the Australian community and provides industry with a better understanding of regulatory decisions.

A core strength of the system is in the broad consultation process. The Office of the Gene Technology Regulatory (OGTR) consults widely with technology providers and with other stakeholders and the public about its data and regulatory requirements, and changes in these are communicated promptly through a range of communication methods.

Another positive is the outreach of OGTR expertise and experiences to other countries in the region. This is important because many of these countries' regulatory systems are still being finalised. Australian experiences can assist these countries develop science-based regulation of biotechnology. It is also true that many nearby countries are important trade partners to Australia. Finally, as the world moves towards more integrated regional areas it will be beneficial to have regional partners that have similar regulatory systems to ours.

2.1.1 Regulatory Duplication

Key Points

- The Gene Technology Act is not currently operating in a seamless manner with other pieces of legislation.
- An example of this is the regulation of insect resistant GM plants by both the OGTR and the APVMA - the APVMA assessment essentially duplicates the OGTR assessment.
- CropLife encourages the Ministerial Council to direct the Intergovernmental Regulators' Forum to review this duplication and any other areas of regulatory overlap with a view to streamlining relevant processes.

Unnecessary duplication of regulation is undesirable because it increases regulatory costs with no associated reduction in risk. This is recognised by Recital B(b) in the Gene Technology Agreement, which states that the scheme should:

> "Operate in a seamless manner in conjunction with existing Commonwealth and State regulatory schemes relevant to genetically modified organism and products derived from such organisms (for example, the schemes that regulate food, therapeutic goods, agricultural and veterinary chemicals and industrial chemicals);"

GM insect resistant crops are regulated by the OGTR and the Australian Pesticides and Veterinary Medicines Authority (APVMA). The Gene Technology Act requires the regulator to consult with the APVMA and take that advice into account during the preparation of a risk assessment and risk management plan. Over time, it has become increasingly clear that the roles of the OGTR and APVMA overlap. Only one aspect of the APVMA assessment of insect resistant GM plants is unique – the efficacy assessment. All other issues are either waived for GM plants or duplicate assessments undertaken by the OGTR in its risk assessment.

Furthermore, the APVMA system appears to recognise this duplication. "*Guidelines for the Registration of Biological Agricultural Products*" states that prior to the APVMA assessing a GMO a 'record of approval' from the OGTR is required. This means that an OGTR Risk Assessment has been conducted for every application to register a GM insect resistant crop active ingredient or product through the APVMA. The applicant is also required to provide a summary to the APVMA of any information that has been given to the OGTR, again highlighting the awareness of the overlapping assessments.

Section 14 of the Agricultural and Veterinary Chemicals Code Act 1994 establishes that the APVMA is required to register an agricultural chemical product when it is 'satisfied' that a range of issues have been addressed. CropLife believes that the APVMA can be satisfied that all of its considerations, with the exception of efficacy in some cases, are effectively addressed by regulation under the Gene Technology Act 2000 and the Australia New Zealand Food Standards Code. Food Standards Australia New Zealand (FSANZ) is also required to approve a food derived from a GM crop and consequently, addresses food residues, but not animal feed residues. The APVMA can be satisfied that all other considerations were adequately addressed by the assessments undertaken by the OGTR and FSANZ.

CropLife proposes that the APVMA develop specific guidelines for dealing with insect or fungi resistant GM crops. These guidelines should specify that the APVMA only requires information on the efficacy of the insect or fungi resistant GM plants and all other traditional agricultural chemical data modules are not relevant.

Alternatively, the Agricultural and Veterinary Chemicals Code Act could be amended to specifically remove the duplicated assessments from the APVMA's remit in the case of GM crops. CropLife suggests that the Ministerial Council directs the Intergovernmental Regulators' Forum to consider this regulatory streamlining, and any other regulatory duplication that can be identified.

2.1.2 Risk Based Regulation

Key Points

- The risks of GMOs are now better understood than they were in 2000, due to fifteen years of commercial cultivation in many different countries and environments.
- There is no evidence that currently approved GM crops pose any additional threats to the environment or human health when compared to conventional crops.
- A cost-benefit analysis of existing regulations should be undertaken to identify areas where regulatory burden no longer corresponds to any meaningful risk.
- GM crops that have been safely cultivated for a period of five years should be added to the GMO Register.

When the Gene Technology Act was drafted, genetically modified organisms were relatively new and as a result there was a much higher degree of uncertainty relating to effects of these organisms on human health and the environment. Today, there are fifteen years of commercial experiences with GM crops, along with decades of research that indicates very few unique risks posed by GM crops to the environment or human health – this evidence will be discussed in the next two sections of this submission.

CropLife believes that the Government should conduct a cost-benefit analysis of existing regulation on biotechnology in Australia, in order to incorporate the global experiences with the technology in the last fifteen years. The analysis should identify areas where there is negligible risk and remove the regulation of these areas accordingly. One way to achieve this is to increase the list of GM crops that are listed on the GMO Register. Currently, the only GMOs that are listed on this are the different varieties of GM carnations that have been developed by Florigene.

The listing of additional GM crops on the GMO Register would not only reflect the reduced risk of products that have been safely used for many years, it would also address a potential future problem with the existing system. Currently, the licence holder for a GMO is responsible for reporting on several aspects of the risk management plan and is also responsible for providing annual reports to the OGTR. As these crops become generic (ie. the patents expire) the number of providers is likely to increase dramatically. When this happens, it will be impossible for one company to provide reports on all of the uses of that crop. If GM crops that have a demonstrated record of safety are included on the GMO Register before the patent expires, then this problem will be solved. There may also be other regulatory approaches to address generic GM crops and CropLife would be willing to discuss these with the authors of the Review.

Crops that are superseded by new varieties are likely to be discontinued in the future and it will also be problematic to find a reporting company once this occurs. The GMO Register could also be used to list crops that are no longer being commercially produced in Australia to avoid these problems. There are also several other regulatory approaches that could address discontinued crops and CropLife would be willing to discuss these with the authors of the Review.

2.1.2.1 GM Crops and the Environment

After fifteen years of experience, it is clear that current GM crops are beneficial for the environment and help our food producers to adapt to harsh environmental conditions. The ecological collapse that was predicted by anti-GM activists has not occurred. In fact, there has not been a single substantiated report of a GM crop damaging the environment in which it was cultivated. On the contrary, existing GM crops are already increasing biodiversity while conserving both water and fuel. Future GM crops will increase this trend.

Using GM cotton as an example, the amount of insecticide applied to each hectare of Australian cotton has been reduced by 65-85 per cent and yields increased by 48 per cent between 1998 and 2008. Importantly, most of the insecticide applications that were removed from the industry were broad spectrum insecticides that also affected beneficial insects, whereas the highly specific organic insecticide in GM cotton varieties only affects pest insects, allowing beneficial insects to assist in controlling the pest.

Australian cotton farmers are now able to better implement integrated pest management strategies like these. As a result, there is both greater biodiversity and greater biomass in a GM cotton field. Over 400 species of insects live in commercial Bollgard II® cotton, which is 15 per cent higher than the numbers of species found in commercial conventional cotton and up to 70 per cent more insects per square metre live in Bollgard II® crops compared to commercial conventional cotton[1].

Herbicide tolerant crops have allowed ploughing to be greatly reduced or eliminated, leading to increased moisture retention in better structured soils, increased carbon capture and reduced fuel consumption on farm. During 2009, this was equivalent to removing 17.7 billion kg of carbon dioxide from the atmosphere, or equal to removing 7.8 million cars from the road for one year[2].

GM crops also benefit the environment in another important way – by producing more yield per field, highly productive modern farms can reduce the pressure to convert wilderness and marginal areas into farmland in order to feed a growing global population.

1 Cotton Australia (2008) Cotton and Biotechnology – 10 Years of Improved Farming
2 Brooks and Barfoot (2011) GM crops: global socio-economic and environmental impacts 1996-2009

Future GM crops will assist farmers in producing food in a changing climate. Australia is leading the world in drought tolerant cereal research that will assist the production of wheat in dry years. In June 2008, Australian researchers announced that they had developed two GM drought resistant wheat varieties that produced 20 per cent yield increases over existing wheat varieties in drought conditions. This research is at an early stage, but these are exceptional early results that could reduce our reliance on water in agriculture and contribute to higher yielding food crops in the future.

2.1.2.2 GM Crops and Human Health

The safety of current GM food ingredients has been confirmed in numerous global and FSANZ food safety approvals. These approvals result from rigorous assessment of the extensive safety data that is provided to regulators and the fact that after fifteen years of commercial cultivation, and over a trillion meals consumed globally, there is yet to be a single confirmed case of a single health effect. It is clear, therefore, that the current system of GM regulations has been highly successful in ensuring safety of GM products and confirms the stringency of current systems.

In January 2011, the Blewett Review of Food Labelling in Australia and New Zealand was published. It made the following comments about GM food safety:

> "In relation to irradiation and genetic modification, the approved foods have been subject to stringent safety assessments and the science appears robust and has been peer reviewed… There is no evidence that consumption of either irradiated food or GM food produces any immediate detrimental effects in humans, nor has any convincing evidence been advanced to indicate potential, future harm to humans"

The consensus of opinion by scientific and legal experts for over a decade has been that food derived from GM crops does not present additional food risks when compared to conventional crops. It is also commonly agreed that the negligible risks that all foods share are regulated only for GM crops. Consequently, the scrutiny to which regulators submit GM crops is out of proportion to any realistic risk to human health.

Proposed Changes

CropLife believes that evidence to date has demonstrated that GM crops do not pose any unique risks to the environment or human health, and consequently the regulation of these crops is not commensurate with risk. The regulation of GM crops could be reduced by undertaking an initial regulatory assessment followed by a period of observation and concluding with listing of the crop on the GMO Register. Approved crops could be added to the GMO Register after a period of five years of commercial cultivation.

2.1.3 PROTECTION OF REGULATORY DATA FROM USE BY COMPETITORS

Key Points

- As patents expire on the first generation of GM crops, protection of regulatory data from use by competitors will become increasingly important.
- CropLife proposes that data that is submitted to regulators under the Gene Technology Act should be protected from unauthorised use by competitors for a period of fifteen years.

A major disincentive to private investment in developing agricultural biotechnology tools is that data that is generated for assessment by the OGTR 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.

There is potential to now combine GM traits that are out of patent in crops. The regulatory costs of doing this are large and there is a real possibility that competitors will be able to utilise the approval of non-patented 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 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 necessary 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 fifteen years from unauthorised use from competitors. The company that generates the data can choose to sell this data to competitors who wish to use it, or alternatively the competitor may choose to generate its own data for regulatory purposes.

2.2 STATE GOVERNMENT REGULATION OF GM CROPS.

Key Points

- The intervention in functioning markets by state governments undermines the intent to establish a national system for regulating biotechnology in Australia.
- State government moratoria on GM canola are estimated to have cost the Australian economy $157 million per annum.
- These bans remove certainty and transparency from the national system and act as a major barrier to private investment in the technology.

The Inter-Governmental Agreement contains several references to the need for a nationally consistent regulatory scheme for gene technology in Australia:

- Paragraph 3: “the purpose of this Agreement is to facilitate a national gene technology regulation scheme”.

- Paragraph 9: “Each State and Territory will submit to its Parliament as soon as possible a Bill or Bills to form part of the Scheme, for the purpose of ensuring that the Scheme applies consistently to all persons, things and activities within Australia. Each State and Territory will use its best endeavours to secure the passage of….any other State or Territory Bill that is subsequently required to ensure the Scheme remains nationally consistent...”.

- The entire text of Part 5 (Paragraphs 39-43) of the Agreement is aimed at “maintenance of a nationally consistent scheme over time and amendment of the scheme”.

Despite these intentions, there has been a clear failure to establish a nationally consistent scheme for regulating GM crops. Most states have implemented legislation to address 'marketing concerns' that are neither consistent nor transparent. Some state governments have gone beyond marketing concerns and have also banned the transport of sealed bags containing commercially-approved GM seed through their state. The diverse legislation means that there is no clear path to market for the developers of GM crops in Australia, even when licence applicants have satisfied the requirements of the Gene Technology Act and demonstrated that effects on trade are negligible.

This unclear path to market was well demonstrated in 2003 when the OGTR approved GM canola for commercial release and all the canola growing states 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 the economy a significant amount of money with one analysis concluding that nationally, the bans on GM canola cultivation were costing $157 million per annum[3]. The economic benefits of GM crops are also evident with GM cotton profits. It is estimated that cumulatively between 1996 and 2008, Australian growers managed to generate an extra $224 million from GM cotton. In added value terms, the effect of the reduced costs of production on farm income in 2008 was equivalent to an annual increase in production of 37 per cent (105,000 tonnes)[4].

It is a key principle of good governance that governments should only intervene in a market where there is demonstrated market failure. However, state government moratoria on commercial production of GM crops have never identified any market failures with OGTR approved GM crops. The argument that regulation is needed to ensure coexistence does not correspond with the fact that a wide range of crops that require separation throughout their life cycle coexist in the supply chain without regulation (eg. malting barley).

New South Wales, Victoria and Western Australia now allow the commercial production of GM canola. However, this introduction was only allowed after at least a five year delay following federal regulatory approval. It is not clear if these delays 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 the first GM crops were commercially grown in that state.

The regulation of GM crops by state governments creates uncertainty that acts as a major disincentive for private investment, as well 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 Minister from granting a licence unless certain conditions are met. However, it does not 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 state and federal regulations and still be unable to sell its product commercially.

This sort of significant disincentive to private investment in Australian agricultural biotechnology is not sustainable if Australia wishes to have a modern 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.

In conclusion, the failure to implement the consistent national regulatory scheme that was envisaged in the Inter-Governmental Agreement has created crippling uncertainty in the agricultural biotechnology industry in Australia and completely undermines the effective regulation of GM crops. This is compounded by gaps in intellectual property protection that potentially allow competitors to utilise another company's regulatory data.

---

3 Norton R.M., Roush, R.T., (2007) *Canola and Australian Farming Systems 2003-2007*

4 Brooks and Barfoot (2010) GM crops: global socio-economic and environmental impacts 1996-2008

3. RECOMMENDATIONS FROM THE 2006 REVIEW OF THE GENE TECHNOLOGY ACT

Key Point

- The recommendation that the Commonwealth and States through the GTMC reconfirm their commitment to a nationally consistent scheme for gene technology has never been implemented.

The 2006 Review of the Gene Technology Act made a number of recommendations and CropLife would like to highlight the following two points for the purposes of this submission:

- Recommendation 7.1 – the establishment of a regulators' forum to ensure that duplication is minimised and the systems work seamlessly between each other.
- Recommendation 9.1 – the Commonwealth and States through the GTMC reconfirm their commitment to a nationally consistent scheme for gene technology.

CropLife supports both of these recommendations and notes that Recommendation 7.1 was accepted by governments and has been implemented. CropLife suggests that the regulator's forum consider the regulation of GM insect resistant crops, particularly the regulatory overlap between the OGTR and APVMA discussed earlier in this submission.

The response from governments regarding Recommendation 9.1 was not as supportive. The inter-governmental response states:

> Governments noted that the recommendation constitutes two separate elements:
>
> - All governments reconfirm their commitment to a nationally consistent scheme for gene technology.
> - Queensland, Tasmania, Western Australia and South Australia do not agree to a nationally consistent transparent approach to market considerations.

These statements are completely at odds with each other. It is hypocritical for a state government to claim to be committed to a nationally consistent scheme while simultaneously implementing inconsistent regulations that prevent commercial products being marketed. CropLife strongly believes that the various legislative approaches to 'market considerations' that are employed by some state governments undermines private investment and destroys any level of harmonisation that was achieved with the Gene Technology Act. This is undesirable for a number of reasons, not least because Australia is a small market even before it is broken up into individual states and small markets with costly regulations are not commercially attractive. When that small market has an uncertain and unpredictable regulatory system, then investment becomes even less likely.

If marketing considerations are considered essential by Australian governments, then these should be regulated nationally by the OGTR to provide consistency and regulatory certainty to technology developers. However, CropLife believes that governments should only intervene in a market when there is clear evidence of a market failure and this market failure has never been demonstrated in the case of GM crops.

4. THE EFFECT OF RECENT CHANGES IN AGRICULTURAL BIOTECHNOLOGY

Key Points

- GM crops that are currently being developed will include crops with significant health benefits. These crops are poorly regulated by a system that focuses exclusively on risk.
- The source of GM crops is changing and this increases the risk that new technology developers will not seek regulatory approvals in export markets in a proactive manner.
- If the Australian Government implemented the Codex Low Level Presence Annex, many of these risks would be removed.

The first generation of GM crops focussed on agronomic traits such as herbicide tolerance and insect resistance. Some of the GM crops that are currently being developed continue to focus on these traits. However, an increasing number of GM crops are looking to make existing foods healthier and more nutritious through the introduction of important dietary nutrients into staple foods.

In the developing world, crops like rice and cassava provide cheap food to billions but current varieties lack many of the nutrients that the human body needs to thrive. Currently, more than a million children die and 500,000 more go blind every year due to insufficient Vitamin A. This deficiency also lowers a child's immune system and makes them particularly vulnerable to a number of different infections. GM golden rice will supplement the diets of these children and conservative estimates are that it will provide enough Vitamin A to avert a quarter of these deaths and illnesses. These technologies have been developed by public institutions, will be provided at virtually no cost to farmers and they will save millions of lives.

Scientists in Nigeria and the US are working on improving cassava so that its current nutritional profile of starch and sugar is replaced by a crop that can provide all a person's nutritional needs in a single meal. This will obviously provide huge benefits to the 200 or 300 million Africans who survive on this crop, although it is unclear whether it will be commercialised due to the regulatory hurdles in front of this 'golden cassava'.

It is not only the developing world that could benefit from future GM crops. Oils from GM canola, soy and cotton plants will have healthier fatty acid profiles that improve the health of all consumers. These oils will also reduce pressures on global fish stocks because they will no longer be the only source of omega 3 fatty acids. The first of these crops is expected to be initially cultivated in North America in 2012.

GM crops that improve the health of consumers in this way are poorly supported by regulatory systems that only focus on the potential for negative risks. An important component of risk management is identifying benefits and the likelihood of their occurrence in different scenarios. CropLife believes that the current Gene Technology Act needs to be reviewed to consider how it regulates crops that offer major benefits to human health and the environment.

A 2008 report from the EU's Joint Research Centre found that not only are the types of GM crops changing, the source of these crops is also changing.

Table 1: Pipeline for GM crops[5]

	2008	2015
Number of GM crops commercialised globally	33	124
Proportion generated in USA/Europe	73%	54%

[5] European Union Joint Research Centre (2009) The Global Pipeline of New GM Crops. Implications of asynchronous approvals for international trade

CropLife member companies, the current developers of GM crops, have made extensive efforts to seek regulatory approvals in all markets where a GM crop may be sold once it is harvested. They have made these efforts even when it is very unlikely that the crop will be sold to that market.

The arrival of many new technology developers who are not CropLife members and reside in different cultures, raises the possibility that global regulatory approvals will not be sought for occasional markets. Consequently, there is a possibility that some food imports will contain low levels of GM material that have not been approved for sale in Australia, although they have received regulatory approval in a third country. As the number of crops and the sources of these crops explode globally, this possibility becomes more likely. This has implications for all imported biological materials whether they be food or seed. CropLife believes the Australian Government should implement a clear low-level presence policy based on the Codex Annex on Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food[6] so as to avoid these problems. This policy should consider all instances of low-level presence, whether they are in food or other imports, so that unnecessary trade disruptions are avoided.

5. CONCLUSION

It is clear when reviewing the establishment of the Gene Technology Act that its architects intended, quite correctly in CropLife's view, to establish a single transparent and efficient national regulatory system for biotechnology in Australia. Unfortunately, that goal has not been realised to date, due to the states retaining the right to regulate for trade. If these risks are to be regulated then it should form part of a nationally consistent scheme.

There are a number of improvements that could be made to the current legislation that regulates GM crops in Australia. The removal of duplication at the federal level, the introduction of data protection and listing of GM crops on the GMO Register after five years of safe commercial use, would all reduce the regulatory burden on the industry. By far the most important change is the re-establishment of a nationally consistent approach to regulating GM crops.

Agricultural biotechnology has much to offer the world - cleaner, cheaper, more secure and better food being produced on more sustainable farms that represent a smaller proportion of the global landscape. CropLife believes that in order for Australia to capitalise on these opportunities, federal regulation needs to be streamlined to take into account experience with GM crops over the last fifteen years and state government intervention in functioning markets needs to cease. This would remove the shackles from this field of agricultural innovation and allow Australia to join other countries that are global leaders in a technology that is going to be vital to all of our futures.

[6] Codex Alimentarius (2008) Alinorm 08/31/34 Report of the Seventh Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Annex III.