CropLife AUSTRALIA

SUBMISSION IN RESPONSE TO

DEPARTMENT OF INNOVATION, INDUSTRY, SCIENCE AND RESEARCH

ENABLING TECHNOLOGIES ROADMAP STUDY

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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 agricultural biotechnology products. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are essential to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $1.5 billion per 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, an application of modern agricultural biotechnology, are just another step along the same path of technological improvement that led to Australian agricultural inventions such as the combine harvester and Federation wheat varieties. The utilisation of these innovations has delivered safe and affordable food to the nation and the world. Despite a proven record of safety, every GM crop is subjected to intense global regulatory scrutiny. Globally, government regulators have independently reached the same conclusion - that cultivation of GM crops pose no greater risk to human health or the environment than cultivation of conventional (non-GM) varieties.

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. The current regulations in Australia already 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.

Further threats are posed by inflexible, unworkable and unscientific standards. For example, those set by the Australian organic industry, which are at odds with the more realistic organic standards set by our important trading partners. This has resulted in an artificially created conflict between organic farmers and GM farmers, one that could easily and amicably be resolved by setting adventitious presence thresholds similar to those in all other forms of agriculture.

If Australia fails to properly exploit the opportunities that are offered by agricultural biotechnology, the results will be profound. ABARE modelling in 2005 indicated that a failure to commercialise GM crops then and in the near future could cost Australians $3 billion by 2015 in forgone gross national product[1]. Agriculture has the earliest and best opportunity to exploit the many opportunities offered by biotechnology, and the plant science industry is at the forefront. The Australian Government needs to encourage continued research and development in agricultural biotechnology and there **is a need for a paradigm shift in thinking from regulating the science** (as it has been proven safe) **to facilitating the growth of the Australian economy by driving the agricultural biotechnology industry to its full potential**.

[1] Apted S, McDonald D and Rodgers H 2005, 'Trangenic Crops: Welfare Implications for Australia'. Australian Commodities, Vol 12 no 3.

The world's population is predicted to increase to 9.2 billion by 2050, requiring an increase in global food production of 70 per cent. Providing enough food in the context of production constraints, volatile consumption patterns and a changing climate will be an unprecedented scientific, political and financial challenge. 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 agricultural biotechnology, then the sector and the regional communities that rely on it will be strengthened. If, however, we allow government regulations to unnecessarily stagnate the industry, these opportunities will be missed.

CropLife Australia commends the Australian Government for having the foresight to examine the potential for enabling technologies to address Australia's major national challenges. CropLife views the Enabling Technologies Roadmap as vital for guiding the development of national investment in agricultural biotechnologies to help sustain Australia's global competitiveness and commercialisation of value-added goods and services.

This submission focuses on those parts of the Roadmap that relate to the opportunities, barriers and risks of agricultural biotechnologies. It also takes the opportunity to provide some updated data where available.

COST AND DURATION OF DEVELPMENT OF A NEW GM TRAIT

As it currently stands, the Roadmap neglects to account for the investment the plant science industry makes in bringing a new genetically modified (GM) crop trait to market.

To determine the relative cost and duration of this process, CropLife International commissioned consultancy firm Philips McDougall[2] to survey six of the industry's largest GM crop developers. The survey found that the cost of discovery, development and authorisation of a new plant biotechnology trait introduced between 2008 and 2012 is **US$136 million**. This total cost is comprised of:

- Discovery: US$31 million (22.8 percent)
- Development: US$69.9 million (51.4 percent)
- Regulatory process: US$35.1 million (25.8 percent).

The average time from initiation of a discovery project to commercial launch is 13.1 years. The time associated with the regulatory process has increased to 5.5 years and accounts for the longest phase in product development.

The cost and duration of new trait development, particularly navigating the regulatory process, highlights the need for a transparent and workable regulatory system based on good science and harmonised risk assessment. Improvements to regulatory systems (discussed further below) will help remove unnecessary barriers to innovation and trade, assisting to achieve goals of food security and sustainable agriculture.

The high level of private sector investment in agricultural research and development in Australia demonstrates the industry's commitment to supporting sustainable agriculture and the extent necessary to bring innovation in enabling technologies to the market.

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

OPPORTUNITIES

CropLife welcomes the Roadmap's position that biotechnology enables better and more targeted scientific research. However, we believe that there are specific opportunities presented by the agricultural biotechnology sector that have not been captured in the current draft.

The Australian agricultural industry has the earliest and best opportunity to capture the opportunities presented by biotechnology. As an existing industry and one that has been harnessing the power of modern biotechnology in the form of GM crops since 1996, it is at the forefront of encouraging and capturing the R&D benefits from the plant science sector. Innovation through biotechnology will provide essential productivity improvements that ensure Australia is able to efficiently produce safe food for Australian consumers and overseas markets.

Meeting ongoing food security challenges will require Australian farmers to continue to improve their productivity. For example, innovation through the plant science industry has reduced the need for constant tillage of farm land to control weeds. Farmers now have the option to use agricultural chemicals to control weeds as effectively as tillage while improving the productivity of the land and minimising any potential environmental impacts.

GM 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. A report compiled by world leading agricultural economists Brookes and Barfoot[3], revealed that in 2009, GM crops saved globally around 18 billion kg of CO_2 gas emissions - the equivalent of removing 8 million cars from the road. The Brookes and Barfoot report revealed that the fuel savings associated with making fewer spray runs and the switch to conservation, reduced and no-till farming systems, resulted in permanent savings of more than 1,409 million kg of CO_2 in 2009 alone.

As noted in the Roadmap, GM crops that are in the innovation pipeline have the opportunity to further improve these environmental outcomes. For example, crops are being developed that use water more efficiently and these could greatly reduce the amount of water needed in agriculture. Crops are also under development that will utilise other nutrients more efficiently, including nutrients commonly found in fertilisers. These and other biotechnology innovations from the plant science industry will further improve the amount of food that can be grown using scarce and finite resources.

CropLife recommends the Roadmap also consult the 2009 European Commission report 'The global pipeline of new GM crops: Implications of asynchronous approval for international trade' for a comprehensive review of the global GM crop innovation pipeline[4].

The Roadmap needs to recognise the significant contribution made to date by innovation in agricultural biotechnology to the sustainability and productivity of Australia's food productions systems. It also needs to recognise that GM crops have the potential to maintain and increase yields into the future. Rather than engaging in a process of cherry picking, those future production methods that will be supported by government, the Roadmap needs to make it clear that farmers will be able to choose the methods, tools and production systems that best suit their particular circumstances.

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3 Brookes G and Barfoot P 2011, 'GM crops: global socio-economic and environmental impacts 1996-2009'. PG Economics Ltd, UK.

4 Stein A and Rodriguez-Cerezo E 2009, 'The global pipeline of GM crops: Implications of asynchronous approval for international trade'. JRC Scientific and technical Reports, European Commission.

Opportunities Lost

In 2005, ABARE reported that Australia's canola growers were suffering an economic loss as a consequence of the state moratoria on the commercial cultivation of GM canola. The report concluded that if the moratoria were to continue, it could result in a loss of $3 billion, in net present value terms, in the period to 2015[5]. While farmers in New South Wales, Victoria and Western Australia now have the opportunity to choose if they want to grow GM canola varieties, farmers in South Australia and Tasmania are still denied this choice.

Transgenic cotton, soy, maize and canola with productivity enhancing input traits have all been rapidly adopted globally[6]. This rapid adoption of these GM crops can be expected to force downward pressure on their prices in international markets. Given that Australian farmers also compete in these markets, barriers to future Australian commercialisation of GM crops will mean that Australian farmers will receive a reduced benefit from their crop, and a concomitant reduction in profit[7]. By facilitating a clear path to market for future crop biotechnology traits, the Australian Government is in the best position to ensure that Australian farmers can remain competitive on the world stage.

A more recent ABARE report in 2008 indicated that the estimated economic benefit to Western Australia from adopting GM canola from 2008-09 for the following ten years would be $180 milllion in 2006-07 dollars. Over the same period, the benefit to New South Wales farmers (excluding those in the Murray Catchment Area) was estimated to be $273 million and South Australian farmers would benefit to the tune of $115 million (yet it is dumbfounding that South Australian farmers are **still** denied access to this technology!)[8].

5 Apted et al 2005, *Op. Cit.*
6 James, Clive 2010. Global Status of Commercialized Biotech/GM Crops: 2010. ISAAA Brief No. 42. ISAAA: Ithaca, NY.
7 Apted et al 2005, *Op. Cit.*
8 Acworth W, Yainshet A and Curtotti R 2008, 'Economic impacts of GM Crops in Australia'. Prepared for the Australian Government Department of Agriculture, Fisheries and Forestry, Canberra, May.

BARRIERS TO THE COMMERCIALISATION OF AGRICULTURAL BIOTECHNOLOGY IN AUSTRALIA

CropLife believes the Roadmap must explicitly recognise the major barrier to commercialisation of agricultural biotechnology in Australia—the lack of a clear path to market for GM crops.

- *A Clear Path to Market for GM crops*

  GM crops are intensively studied and rigorously regulated in Australia. CropLife believes that all regulation should be commensurate with the associated risk, cost and benefit to the community. CropLife supports the continued use of science-based risk assessment as the basis for sensible decision making.

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

  The *Gene Technology Act 2000* (Cth) was intended to establish a national system of regulating GMOs. Despite this intention, most states have implemented legislation to address "marketing concerns" that are neither consistent nor transparent. Some state governments have gone beyond marketing concerns and also have banned the transport through their state of sealed bags containing GM seed. This intervention 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 Office of the Gene Technology Regulator 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 food producers and consumers, with one analysis concluding that nationally, the bans on GM canola cultivation cost $157 million per annum[9].

  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 such failings.

  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 and acts 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. It does not, however, compel the Minister to grant a licence if an application meets these same conditions. As a result, there remains a very real possibility that a company would invest significantly in bringing a technology to market in Australia with data to address all the federal and state regulations and still be unable to sell its product commercially.

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

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 has created crippling uncertainty in the agricultural biotechnology industry in Australia and completely undermines the effective regulation of GM crops. Both of these issues need to be addressed if Australia is to continue to have safe and affordable food choices available to everyone.

CropLife believes that the Roadmap should clearly state that evidence to date has demonstrated that GM crops do not pose any unique risks to human health and the environment, and consequently the regulation of these crops is not commensurate with the risk. The regulation of GM crops could be reduced by undertaking an initial regulatory assessment followed by listing of the crop on the GMO Register[10] after a period of five years of commercial cultivation. By taking this step the Australian Government could facilitate growth in the agricultural biotechnology industry and maximise the industry's potential.

[10] Dealings with a GMO can be entered onto the GMO Register when the Gene Technology Regulator is satisfied that the risks posed by the dealings are minimal and that it is not necessary for anyone conducting the dealings to be covered by a licence in order to protect the health and safety of people or the environment - http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gmoregclass-2

RISKS

As discussed above, GM crops are intensively studied and rigorously regulated in Australia. With this in mind, CropLife is extremely disappointed that the Roadmap raises the case of Marsh v Baxter in this section, as this incident is not reflective of any risk of agricultural biotechnology, but rather represents an artificial conflict created by out-dated and unscientific standards set by the organic industry.

The coexistence of different crops, production systems and pest management practices in agriculture and the supply chain is not new. Different agricultural productions systems have been successfully practiced in proximity to one another for many years and in many parts of the world.

Australia's current National Standard for Organic and Biodynamic Produce (National Standard) does not align with international standards and is inconsistent with other Australian Government policies regarding food labelling and thresholds. This is both a policy and regulatory matter that needs immediate action by the Government.

The National Standard prohibits a number of things from use in organic systems, including pesticides and GM crops. The majority of prohibited products and techniques are permitted if they are accidently introduced at a low level. However, there is zero tolerance for GM crops being present on organic farms or in organic products. This is both out of step with the principles that the Government brings to other areas of regulation relating to biological systems and entirely out of step with regulations in other similar jurisdictions. By way of example:

- In the United States and Canada, organic certification is "process-based" and relies on organic growers having processes in place to meet the standard. The presence of prohibited residues/crops does not automatically invalidate the certification of an organic farmer.
- In Europe, organic standards are product based and permit up to 0.9 percent of approved GMOs in organic food products.
- Guidelines for organic production that have been produced by Codex are process-based as in the United States and Canada.

It is noteworthy that products approved under these international standards can be imported into Australia as "organic" products, despite the fact they could contain the adventitious presence of GMOs at very low levels.

Australian organic producers are being forced to certify their produce using an entirely product based system that has no threshold for adventitious presence. Thresholds recognise that there could be some accidental mixing of GM commodities and non-GM commodities due to the reality of agricultural supply chains and global trade.

The current National Standard is also out of line with Australian Government policies regarding food labelling, which allow for a 1 per cent threshold for the accidental presence of an approved GM food ingredient. This threshold recognises that occasionally, accidental presence of a GMO will occur at very low levels and low level thresholds prevent this occurrence from becoming either a trade irritant, or a dispute between neighbours. Thresholds also exist in virtually every Australian grain standard for the unintended presence of a range of things, including insect legs, cracked grain, weed seeds and other crops.

CropLife believes it is critical for Australian agriculture and for the Australian agricultural biotechnology industry, that the National Standard is modernised to accommodate low level accidental presence of GMOs. The current situation undermines both organic and GM crop farmers, and the coexistence framework of the Australian farming sector.

NEW AND/OR UPDATED DATA

- *Global Area of GM crops*

  CropLife notes that there is more recent data available than that presented in the Roadmap on the current global area of biotech (GM) crops (Page 83).

  In 2010, 15.4 million farmers grew 148 million hectares of GM crops globally. Ninety percent of these were resource poor farmers in developing countries. Accumulated hectarage from 1996 – 2000 exceeded 1 billion hectares, indicating that on a global level at least, GM crops are here to stay[11].

- *Further applications of Plant Molecular Farming (Pharma crops)*

  The Roadmap highlights two applications of plant molecular farming [12] on Page 86. Further applications of this technology under development in Australia include production of[13]:

  - a human measles vaccines in lettuce
  - bioplastics in sugarcane
  - the protein vitronectin in tobacco – a high value human protein used in medical research
  - the elastic protein resilin
  - a poultry vaccine for Avian Influenza in tomato, tobacco or plant cell culture
  - antibodies in wheat for use in topical medical applications
  - pharmaceutical grade alkaloid compounds in poppies.

  The 2007 Bureau of Rural Sciences report on plant molecular farming also highlights plant molecular farming applications under development overseas. The report concludes that although plant molecular farming is still developing in Australia, it should provide opportunities for Australian farming to add value to existing cropping systems. In particular, GM plants that can produce industrial products such as bioplastics may help farmers on marginal land maintain their profitable, competitive and sustainable farming systems[14].

- *Contribution of Enabling Technologies to National Challenges Matrix*

  The matrix that commences on Page 160 of the Roadmap appears to have omitted a number of important developments in crop biotechnology that have been mentioned previously in the document. For example, the matrix appears to be missing any mention of: improved nitrogen use efficiency; tolerance to pests and diseases; cellulosic bioethanol production; control of flowering; photosynthetic efficiency; heterosis (hybrid vigour); plant vaccines; or biofortification.

  CropLife would like to see all innovations in crop biotechnology mentioned in the Roadmap captured in this matrix.

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11 James, Clive 2010, O*p. Cit.*

12 Plant molecular farming is the cultivation of GM plants as 'biofactories' to produce novel pharmaceutical or industrial products.

13 Mewett O, Johnson H and Holtzapffel R 2007, 'Plant molecular farming in Australia and Overseas'. Australian Government Bureau of Rural Sciences, Canberra.

14 *Ibid.*

- *Intellectual Property Rights*

The Roadmap (Page 176) currently refers to the *Patent Amendment – Human Genes and Biological Materials Bill 2010* and an associated Senate Committee report. CropLife notes that on 22 September 2011 the Constitutional and Legal Affairs Committee rejected the proposed Bill.

CropLife is aware of several expert inquiries on gene patents, including a report by the Australian Law Reform Commission in 2004[15], an Advisory Council on Intellectual Property[16] report and several IP Australia documents. These reports have all recommended that reforms should focus on the application of patentability tests rather than excluding certain fields of technology. CropLife encourages the Australian Government to instead look to ways to implement the recommendations in these expert reports.

CONCLUSIONS

The need to feed 9 billion people by the year 2050 will require the sustainable intensification of Australian agriculture. The innovations provided by crop biotechnology and the Australian plant science industry will not be a silver bullet, but will give Australian farmers extra tools to meet the global food security challenge in the face of a changing climate. The Australian Government can facilitate the growth of the Australian economy by driving the agricultural biotechnology industry to its full potential.

To do nothing is not an option.

[15] Australian Law Reform Commission 2004, 'Genes and Ingenuity—Gene Patenting and Human Health'.
[16] Australian Council on Intellectual Property 2010, 'Patentable Subject Matter'.