Key points

Biotechnology, the use of living things to make products, has existed in various forms for over 8000 years, ever since yeast was first used for brewing beer and making bread. In 1953, the double helix structure of DNA was discovered, and modern biotechnology was born. From the development of the first genetically modified (GM) plant in the early 1980s, modern biotechnology has been used as a tool to develop new varieties of plants with desirable characteristics.

The current generation of GM crops commercialised worldwide mostly have production-enhancing characteristics such as herbicide tolerance and insect resistance. Plants with GM versions of these two characteristics made up 99% of the 81 million hectares of GM crops commercialised globally in 2004.

There are many GM crops under development in Australia and overseas. Knowing what is in the pipeline is needed to ensure a balanced debate and informed decision-making on GM crops. This booklet identifies a selection of GM crops within 15 years of commercialisation and discusses the factors that are considered when deciding whether to develop a new crop variety using GM methods or using conventional methods.

For delivery of some characteristics, conventional breeding programmes facilitated by modern biotechnology techniques other than GM may be the most promising approach. However, for other characteristics the scope for conventional breeding is limited, and GM may offer the most effective method for developing new crop varieties.

Not all GM crops in the pipeline will reach commercialisation. There are exit points along the pipeline where decisions have to be made about the potential of a product, and the value that the product will hold, balanced against the costs.

Did you know?

**Biotechnology** is a broad term used to describe the process of using living things to create products or do tasks for human beings.

**Genetic modification (GM),** in the context of this booklet, means modifying organisms by the direct incorporation (or deletion) of one or more genes to alter or introduce new characteristics using gene technology.
Background
Humans have utilised biotechnology for over 8000 years, ever since yeast was first used for brewing beer and making bread. Rather than just gathering wild plants, animals and fungi for food, humans began to explore how living things could be used to make products that could be used for food, and later, fibre.

In agriculture, plant varieties were created using the simple technology of selective breeding which, over many generations and sometimes hundreds of years, produced varieties that are now modified to such an extent that they sometimes little resemble the wild form from which they originated. Plant breeders traditionally relied on natural genetic variation within species or on naturally occurring mutations, and still do, to produce varieties matched to local growing conditions or the products required.

Hybridisation, or cross-breeding methods, continued to develop and over time it was found that the genes of closely related species could be mixed to produce plants with desired characteristics.

- Triticale, a grain crop used for stockfeed, was first produced in the 1930s by crossing two different species, wheat and rye.
- Canola, an oilseed crop widely used as a food ingredient, was developed through the intensive breeding of a previously inedible industrial oilseed crop in the 1970s.

In the early 1900s, breeders were able to artificially increase the genetic variation available with technologies such as gamma radiation and chemical mutagenesis to induce many random mutations, of which a tiny fraction might have practical commercial applications in food and agriculture. Around 1800 commercial varieties produced using gamma radiation are still in use around the world today.

In 1953, the double helix structure of DNA was discovered, and modern biotechnology was born through a new understanding of the expression of characteristics through genetic material. From the development of the first genetically modified (GM) plant in the early 1980s, the use of gene technology as a tool to develop new varieties of plants with desirable characteristics has grown rapidly. GM technology has appealed to plant breeders because it offers more precision than random mutagenesis. More importantly, it allows the transfer of genes from less closely related and totally unrelated species to the crop, which would be impossible using traditional hybridisation methods.

GM crops can be categorised as having either first, second or third generation characteristics:

- first generation characteristics provide benefits on the farm;
- second generation characteristics provide benefits to the producer and consumer; and
- third generation characteristics allow the plant to be used as a ‘factory’ to produce pharmaceuticals or industrial products (Table 1).

Table 1 lists the most commonly developed characteristics in crop plants, as represented in the reviewed literature. Most are still in the technology discovery stage, but some, like herbicide tolerance and pest resistance, are widely commercialised.

TABLE 1 Classification of GM crop characteristics used in this brief

<table>
<thead>
<tr>
<th>Category</th>
<th>Specific characteristics</th>
<th>Also called</th>
</tr>
</thead>
<tbody>
<tr>
<td>First generation</td>
<td>Environmental (abiotic) stress tolerances</td>
<td>Input characteristics</td>
</tr>
<tr>
<td></td>
<td>Improved pest and disease control</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post-harvest pest protection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Improved nutrient use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increased yield</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Herbicide tolerance</td>
<td></td>
</tr>
<tr>
<td>Second generation</td>
<td>Enhanced nutrition and flavour</td>
<td>Output characteristics</td>
</tr>
<tr>
<td></td>
<td>Improved oil quality</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Longer post-harvest life</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Improved feed and pastures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Improved ease of processing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Functional (fortified) foods</td>
<td></td>
</tr>
<tr>
<td>Third generation</td>
<td>Pharmaceutical</td>
<td>Plants as factories</td>
</tr>
<tr>
<td></td>
<td>Industrial crops</td>
<td></td>
</tr>
</tbody>
</table>
What is the ‘pipeline’?

The ‘pipeline’ in this context refers to the product development processes for GM crops, illustrated in Figure 1.

Predictions of the time taken to commercialisation of a GM crop depend on many factors, including the crop, complexity of the desired characteristic, type of product, marketing negotiations, and the regulatory regime. In the United States, the time span from initial discovery to commercialisation of GM crops developed to date has been between eight and twelve years.

The state of play

Currently, most public discussion and publications on agricultural biotechnology have focussed on the release of GM crops with production enhancing characteristics such as herbicide tolerance and insect resistance. These two characteristics, in four main crops – maize, soybean, cotton and canola – are the most common throughout the world, accounting for 99% of the 81 million hectares of GM crops grown commercially in 2004 (Chart 1).

For further information see the ISAAA website www.isaaa.org

In Australia, GM organisms are regulated by the Gene Technology Regulator (the Regulator) supported by the Office of the Gene Technology Regulator (OGTR) under the Gene Technology Act 2000 (Cth). The role of the Regulator is to protect human health and safety and the environment by identifying and managing risks posed by the use of this technology. The OGTR has developed a risk analysis framework which describes how the Regulator approaches risk assessment and risk management for GMOs.

The Regulator liaises with other regulatory agencies, including Food Standards Australia New Zealand (FSANZ), Australian Pesticides and Veterinary Medicines Authority (APVMA), and the Therapeutic Goods Administration (TGA) to coordinate the approval of GM products for use and sale.

For further information see the OGTR website www.ogtr.gov.au

There are currently only two GM crops grown commercially in Australia: cotton, which has been modified for herbicide tolerance, pest resistance, or a combination of the two (Box 1); and carnations, with modified flower colour. Herbicide tolerant canola was the next crop expected to be grown commercially in Australia, with licences being granted by the Regulator in 2003. However, the instigation of State and Territory moratorium legislation has prevented commercial plantings of GM canola crops and stalled its progression to market (Table 2).
As of June 2005, FSANZ had approved twenty-five GM foods/food ingredients from six crops – soy, canola, corn, potato, sugar beet and cotton. Most of the GM foods currently available in Australia come from GM crops which have been grown and processed overseas.

For further information see the FSANZ website

**TABLE 2 Status of Australian Commonwealth, State and Territory GM bans**

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commonwealth</td>
<td>No ban on GM crops</td>
</tr>
<tr>
<td>New South Wales*</td>
<td>Ban on commercial cultivation of all GM food crops (including GM canola) until March 2008. Exemptions permitted for field trials.</td>
</tr>
<tr>
<td>Victoria</td>
<td>Ban on commercial cultivation of GM canola until February 2008. Exemptions permitted for field trials.</td>
</tr>
<tr>
<td>South Australia</td>
<td>Ban on commercial cultivation of GM food crops to be reviewed by April 2007. Exemptions permitted for field trials.</td>
</tr>
<tr>
<td>Tasmania</td>
<td>Ban on commercial cultivation of all GM crops (including GM canola) until June 2008. Exemptions permitted for field trials of non-food crops.</td>
</tr>
<tr>
<td>Western Australia</td>
<td>Ban on commercial cultivation of all GM crops (including GM canola) to be reviewed by December 2009. Exemptions permitted for small scale field trials.</td>
</tr>
<tr>
<td>Australian Capital Territory</td>
<td>Ban on the commercial cultivation of GM canola until July 2006. Exemptions permitted for field trials.</td>
</tr>
<tr>
<td>Queensland*</td>
<td>No ban on GM crops.</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>No ban on GM crops.</td>
</tr>
</tbody>
</table>

* Large scale growth of GM cotton in these States

As of June 2005, FSANZ had approved twenty-five GM foods/food ingredients from six crops – soy, canola, corn, potato, sugar beet and cotton. Most of the GM foods currently available in Australia come from GM crops which have been grown and processed overseas.

For further information see the FSANZ website

**chart 2** Area of conventional and GM cotton grown in Australia since the 1996/97 growing season

Uptake of GM cotton in Australia has been rapid, as indicated by Chart 2 above, which shows the estimated area planted to both conventional and GM cotton since the 1996/97 growing season.

For further information about cotton research see the Cotton Research and Development Corporation website

**box 1**

In 1996, Australia’s first GM cotton – Ingard® – was commercially released. Ingard® cotton contained a single insecticidal gene from the bacterium Bacillus thuringiensis (Bt). On average, Ingard® cotton reduced overall pesticide use on the crop by 50% and the use of toxic chemicals such as endosulfan by up to 90%. Ingard® cotton has recently been phased out of commercial production and replaced with Bollgard® II cotton, a line containing two different Bt genes to provide improved pest resistance. The advantage of having two different Bt genes in the Bollgard® II cotton varieties is the reduction in the threat of development of insect resistance to the toxin as it is less likely that an insect would have resistance to both proteins. In the future, inserting a third Bt gene would offer even more protection for cotton crops. Interestingly, Australian cotton farmers already had experience managing the application of Bt toxins on their crops. This is because preceding their use in GM plants, Bt toxins in a crystallised form were used as a spray-on pesticide to control insect pests.

In addition to pest resistance, cotton has also been genetically modified to be tolerant to the herbicides glufosinate ammonium (i.e. Liberty®) or glyphosate (i.e. Roundup®) and varieties have been developed which combine both the pest resistance and herbicide tolerance characteristics.
New crop varieties are needed

Continuing challenges face the Australian agriculture and food sector, for example the declining terms of trade, protectionist international trading policies, climate extremes, and in some areas significant land and water degradation. New challenges are emerging that will also impact on Australian agriculture and these are being explored by a high level reference group appointed in March 2005 by the Australian Government Minister for Agriculture, Fisheries and Forestry.

For further information
www.agfoodgroup.gov.au

To help meet these future challenges, research into new crops and varieties suitable for the Australian agricultural environment is needed now, particularly because of the years taken to develop new varieties for commercialisation, both by traditional breeding and GM.

Traditional breeding or GM?

Traditional breeding mainly involves the crossing of plants of the same species, although genes can also often be transferred between closely related species. As all the genes in the parent plants go through the breeding process, desired changes come about over generations. This may also result in a large change in the next generation’s characteristics, as there is limited control over which genes are contributed by each parent and which are not. It is often difficult to keep all the desired characteristics together, and a significant amount of time in traditional breeding is spent selecting out unwanted characteristics.

There is no formal regulatory approval required for release of a new variety of crop plant bred by traditional methods, although it may be subject to internal industry standards, for example in regard to grain quality or disease resistance. This is because the kinds of changes that can be made to the plant are nearly always within the usual range of variation of the naturally occurring species or close relative. However, if a crop is bred to have a new food use, an example being linola, a high quality oilseed crop developed from the linseed plant by CSIRO, regulatory approval from FSANZ is required.

The GM approach allows desirable genes to be altered within an individual or transferred between very different organisms, for example from bacterium to plant. Changes using the GM approach involve genes whose activity and expression has been thoroughly studied, and can be introduced relatively quickly in just a few generations. The GM approach is to target and change or introduce a single characteristic by manipulating when and where the novel gene(s) is turned on or off. However, because it is a new technology and genes can be transferred between species that would not be possible in nature or using conventional methods, it is stringently regulated by the Regulator and other Government agencies to ensure that any risks posed to human health or the environment are identified and safely managed.

Biotechnology applications are not always GM

Not all biotechnology applications result in GM products. It is possible to create varieties of crop plants with desirable characteristics by using traditional breeding methods combined with modern biotechnology techniques. For example, in recent years traditional breeders have linked up with biotechnologists to develop ‘molecular markers’ associated with desired characteristics.

Did you know?

Molecular markers are short fragments of DNA already present in a species that can be used by breeders to quickly and accurately identify and track the inheritance of a desired characteristic in a breeding programme. Molecular markers allow better control over which genes are retained during plant breeding and can be used to facilitate traditional breeding programmes without necessarily resulting in a GM product.
For the delivery of some characteristics, traditional breeding programmes facilitated by modern biotechnology techniques such as molecular makers, rather than GM, may be a feasible approach. However, for others the scope for traditional breeding is limited because the characteristics can only be sourced from related species and GM may offer the only effective method for the development of new crop varieties with specific characteristics. Barriers to the development of a GM crop that must also be considered are discussed later in this booklet.

**First generation characteristics**

**Environmental stress tolerance**

Environmental (abiotic) stresses, caused by salinity, drought, acid soils or temperature extremes pose serious threats to the successful cultivation of crop plants in Australia.

- There are 5.7 million hectares of land in Australia with a high potential for developing dryland salinity;
- the direct effect of the recent drought on Australian agricultural production in 2002-03 was equivalent to over $6.5 billion dollars;
- acid soils are Australia’s most serious land degradation issue, costing $1 billion in lost production each year; and
- spring frosts cost growers millions of dollars in direct yield losses annually.

Some plant species can cope more readily with these harsh conditions than others. By transferring the genes that confer environmental stress tolerance in these plants to crops or by modifying the expression of related genes already present in crop plants, it may be possible to increase crop yield on marginal land or under adverse conditions, retain land in productive use and rehabilitate land.

There are a large number of crops under development with environmental stress-tolerant characteristics that have been bred using a traditional approach assisted by modern biotechnology. One example is varieties of wheat with improved water-use efficiency, which will allow them to produce more grain than existing varieties in dry years.

**Did you know?**

Engineering of stress tolerant crops is not simply a matter of creating plants which can survive stress. To be of use to agriculture, a worthwhile stress tolerant plant must be able to produce yields comparable to its non-stressed counterparts, or be more cost-effective than traditionally bred varieties under the same stresses.

There are a large number of crops under development with environmental stress-tolerant characteristics that have been bred using a traditional approach assisted by modern biotechnology. One example is varieties of wheat with improved water-use efficiency, which will allow them to produce more grain than existing varieties in dry years.
For individual crops, the decision to take a GM or a non-GM approach depends on many factors. For example, many important crop and pasture species lack sufficient acid soil tolerant genes within their hereditary material (germplasm) for traditional breeding to be effective. The GM approach provides a method by which the acid soil tolerance of these sensitive species can be improved through the introduction and expression of tolerance genes from other plant species or organisms.

**Pest and disease control**

It is estimated that insect herbivores are responsible for a 10-20% loss of yield in major crops worldwide, and far more in developing countries. For example, caterpillar pests have the potential to destroy a cotton crop if not properly managed.

Every day, plants are constantly challenged by viruses, bacteria, fungi and nematodes, however significant disease is comparatively rare. This is because plants have evolved different layers of defence to cope with pathogen attack. Defences range from structural barriers and production of compounds toxic to micro-organisms, to adaptive defence mechanisms.

Pathogens and parasites of plants pose a threat to crop production in Australia and worldwide. Traditional breeding has had only limited success at controlling outbreaks of pests and disease. This is due in part to modern agriculture’s reliance on the cultivation of huge areas of crops bred from a relatively narrow range of genetic material. Therefore protection from pests and disease is limited to dependence on a small number of inbred resistance genes and the widespread application of chemical pesticides. Pests and disease are often able to overcome plant resistance genes and/or pesticides used by a simple genetic mutation.

As pests and diseases become increasingly resistant to the existing control methods it is necessary for scientists and breeders to look outside the limitations of a crop’s existing germplasm and towards modern biotechnology for a solution. Box 1 highlights the success of transferring pest-resistant genes from a bacterium to a crop plant using a GM approach.

Modern biotechnology has led to an increase in knowledge about inbuilt plant defence mechanisms and has facilitated sophisticated approaches to enhancing resistance through the use of GM. Candidate genes of interest can come from either the plant itself, from other species of plant, from a pathogen, from unrelated organisms or can even be novel ‘synthetic’ sequences.

### TABLE 3 Some GM crops with first generation characteristics being developed in Australia

<table>
<thead>
<tr>
<th>Environmental stress tolerance</th>
<th>Crop</th>
<th>Stage in pipeline*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid soil tolerance</td>
<td>Pasture species</td>
<td>Technology discovery</td>
</tr>
<tr>
<td>Acid soil tolerance</td>
<td>Barley</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Salt tolerance</td>
<td>Wheat</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Drought tolerance</td>
<td>Wheat</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Frost tolerance</td>
<td>Wheat</td>
<td>Proof of concept</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pest and disease control</th>
<th>Crop</th>
<th>Stage in pipeline*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virus resistance</td>
<td>Barley</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Resistance to canegrubs</td>
<td>Sugarcane</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Fungus resistance</td>
<td>Cotton</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Insect pest resistance – new Bt and Bt/Ht</td>
<td>Cotton</td>
<td>Field trial</td>
</tr>
<tr>
<td>Insect pest resistance – Protease inhibitors</td>
<td>Cotton</td>
<td>Field trial</td>
</tr>
<tr>
<td>Virus resistance</td>
<td>White clover</td>
<td>Field trial</td>
</tr>
</tbody>
</table>

*Bt* Insecticidal genes from the bacteria *Bacillus thuringiensis*  
*Ht* Herbicide tolerance  
*Not all field trials are an indication of imminent commercial release. Some are more accurately described as large-scale proof of concept experiments and are classified as such in this table.
Second generation characteristics

Second generation crops aim to produce food and feed with increased nutrition, enhanced quality or better processing characteristics. Increasing the nutritional quality of food is of particular significance in developing countries where nutritional sources are lacking, but market demand also exists for higher quality and fortified plant foods to improve human health and life expectancy in the developed world. Output characteristics that modify the nutrient content of plants to increase protein and energy content together with the availability for animal feed are also being developed.

Improving oil composition and quality is also an important priority for food and feed production. For example, long chain polyunsaturated fatty acids belonging to the Omega-3 and Omega-6 classes are nutritionally beneficial oils usually sourced from fish consumption. Research is underway in Australia and worldwide to develop crop plants as alternative sources of these healthy oils without further increasing the pressure on wild-harvest fisheries.

Increasing the value of agricultural products by the use of new technologies is a major goal of industry. Certain industries (for example the grains and sugar industries) have already made strategic steps in this direction. CSIRO’s Food Futures Flagship, the Cooperative Research Centre for Sugar Innovation through Biotechnology and the Grain Foods Cooperative Research Centre are just some of the initiatives pursuing high value crops as a priority. However, only a subset of research in these initiatives is directed towards GM products, most projects are using traditional breeding enhanced by modern biotechnology techniques. Competition from overseas is significant, with huge investment in this by food giants such as Unilever and Nestle, in addition to venture capitalists. It is predicted that larger companies will focus on large-scale products, and the potential exists for Australia to position itself in the niche market for supplying high-value products.

Third generation characteristics

Third generation characteristics are where GM plants are used as a factory to produce industrial or medical compounds, this is often referred to as plant molecular farming. Such compounds could include pharmaceuticals such as hormones, antibodies, vaccines or enzymes, or industrial compounds such as biofuels, biodegradable plastics, enzymes or lubricant oils. There is scope for crop plants to be used as biofactories for a broad range of products.

TABLE 4 Some GM crops with second generation characteristics being developed in Australia

<table>
<thead>
<tr>
<th>Improved food and feed value</th>
<th>Crop</th>
<th>Stage in pipeline*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved oil quality</td>
<td>Cotton</td>
<td>Technology discovery</td>
</tr>
<tr>
<td>Omega-3 production in plants</td>
<td>Oilsed</td>
<td>Technology discovery</td>
</tr>
<tr>
<td>Starch modification</td>
<td>Wheat</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Improved digestibility</td>
<td>Wheat, barley, pasture species</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Altered sugar metabolism</td>
<td>Pasture species</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Reduction in pollen allergens</td>
<td>Ryegrass</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Improved oil quality</td>
<td>Canola</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Improved sugar content</td>
<td>Sugarcane</td>
<td>Proof of concept / Field trial</td>
</tr>
</tbody>
</table>

* Not all field trials are an indication of imminent commercial release. Some are more accurately described as large-scale proof of concept experiments and are classified as such in this table.

Did you know?

Plant molecular farming is a broad term used to describe the growing of plants to produce pharmaceutical or industrial compounds instead of food, feed or fibre. Crops producing pharmaceuticals are often called ‘pharma crops’ and cultivation of these crops called ‘pharming’ or ‘biopharming’.

Pharma crops

Commercial production of proteins for pharmaceutical uses has traditionally depended on isolation of products from animals or humans, or more recently the use of micro-organisms. Plants have potential to offer large scale, cheaper, safer and more efficient alternatives to these production systems. Pharming on a large scale still has technical and regulatory limitations, but a small number of GM plant-derived products are already commercialised overseas and others are approaching commercialisation.
**Industrial compounds**

Technology discovery in Australia and worldwide is being carried out on many GM crops engineered to produce industrial products. Examples include research into starch, fibre, forest products and natural polymers such as bioplastics. Biofuels are another potential area for investment in new technologies.

Research and development organisations recognise the huge potential in these areas and are keen to position themselves quickly to access technologies and assess applications for Australia. A prime example is the Grains Research and Development Corporation (GRDC) initiative ‘crops as biofactories’ that will focus resources on developing platform technologies for industrial crops, in particular monomer and polymer production from oilseeds.

Another example is the Australian sugar industry, which has been suffering from low world sugar prices over the past decade and has plans to diversify into other forms of value-added products to regain former levels of profitability.

**Third generation crops raise many regulatory and policy issues**

Debate continues about the advantages and disadvantages of producing pharmaceuticals and other industrial agents in food crops. The possibility of these products flowing into the food chain needs to be addressed. Factors required for the successful adoption of GM technology, and especially for transforming sectors of Australian agriculture into competitive and sustainable plant molecular farms include:

- capacity of supply chains to segregate pharmaceutical and industrial products from the food chain effectively;
- ‘freedom to operate’ and access to research tools;
- investment in this area;
- confidence of a clear path to market and consumer acceptance; and
- the regulatory environment.

The clear message for Australia is that researchers, product developers, consumer groups and regulators need to be engaged in two-way communication on these issues early in the product development pipeline.

**Barriers to GM crop commercialisation**

Not all GM crops in the pipeline will reach commercialisation. There are exit points along the pipeline where decisions have to be made about the potential of a product to reach commercialisation and the value and benefits that the product will deliver to end users, balanced against the costs of product development and market entry. Key barriers to the commercialisation of GM crops are discussed in the following sections.

**Technical barriers**

The control of a crop’s genetic makeup, or ‘genotype’, is very complicated and there are many examples, both in Australia and overseas, of GM crops which have reached the field trial stage but were not developed further because of technical barriers.

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**TABLE 5 Some GM crops with third generation characteristics being developed in Australia**

<table>
<thead>
<tr>
<th>Plant molecular farming</th>
<th>Crop</th>
<th>Stage in pipeline*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production of precursors of biodegradable plastics</td>
<td>Sugarcane</td>
<td>Technology discovery/ Proof of concept</td>
</tr>
<tr>
<td>Bioreactors – producing pharma proteins</td>
<td>Tobacco</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Alkaloid production</td>
<td>Poppy</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Alternative sugars for food ingredient and industrial applications – sorbitol</td>
<td>Sugarcane</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>Alternative sugars for food ingredient and industrial applications – isomaltose</td>
<td>Sugarcane</td>
<td>Proof of concept / Field trial</td>
</tr>
</tbody>
</table>

* Not all field trials are an indication of imminent commercial release. Some are more accurately described as large-scale proof of concept experiments and are classified as such in this table.
An example of a significant technical barrier to the development of next generation GM crops is the insertion and control of multiple genes, also known as ‘gene stacking’. It is likely that the engineering of most of the desirable first, second and third generation characteristics will involve coordinating the regulation of multiple genes.

‘Freedom to operate’ barriers
The global trend of increasing private sector investment in agricultural research has increased the importance of protecting both IP and tangible property rights. When developing a GM crop, from technology discovery to commercialisation, multiple property rights need to be considered.

These include those covering platform technologies such as the gene insertion process, marker genes and gene switches, as well as the specific characteristics involved. Ownership and origin of these processes and components must be tracked from the beginning to ensure that once an end product is obtained, the ‘freedom to operate’ has not been restricted by lack of a right of use for any of these components.

An insight into the complexity of gaining freedom to operate for a GM crop plant can be gained by looking at the much publicised development of ‘Golden Rice’, which has been genetically modified to produce beta-carotene (provitamin A). The rice was developed as one of many solutions needed to combat vitamin A deficiency in developing countries, responsible for 3000 deaths per day, and 500,000 cases of infant blindness per year.

Depending on the country where the rice was to be used, between zero and 44 patents have been identified which may apply to the product. For example, in the USA and most countries of the European Union, it is estimated that approximately 40 patents apply to the research. The complexity of the IP/TP landscape will only increase with the advent of ‘stacked’ or multi-gene characteristics and hence early identification of the barriers to commercialisation will become increasingly significant.

For more information visit the ISAAA website
www.isaaa.org/kc/bin/isaaa_briefs/index.htm

Did you know?

Freedom to operate refers to ensuring that the development, commercial production, marketing and use of a new product, process or service does not infringe the intellectual property rights of others.

Intellectual property (IP) refers to the legal rights associated with inventions, artistic expression and other intangible products resulting from intellectual effort. Patents, trademarks, designs and copyrights are the most common form of IP rights.

Tangible or ‘real’ property (TP) refers to actual physical property that can be touched or realised. A crop’s genetic material, or germplasm, that comprises the physical basis of its inherited properties is an example of TP in the agricultural sector.

New initiatives are being developed to address this issue of complexity of freedom to operate and restrictions to successful innovation. BIOS, the Biological Innovation for Open Society, has been developed by an Australian-based research organisation that builds on models of open source access to information technology and applies these concepts to innovations in biology, including agricultural biotechnology.

For more information see
www.bios.net
Regulatory barriers
Although two national licences to grow GM canola commercially in Australia were issued by the Regulator in 2003, bans on commercial plantings of these crops were instigated by various State and Territory governments due to concerns that export markets may potentially be adversely affected (Table 2). The biotechnology industry has the strong concern that, unlike the federal regulatory system, the State and Territory bans are not science-based and do not exhibit the transparency, predictability and clear path to market required of a regulatory system.

A recent report by the Australian Bureau of Agricultural and Resource Economics (ABARE) suggests that Australia’s canola producers suffer an economic loss as a consequence of these bans. The report shows that a continuation of the current bans on the commercial cultivation of GM crops may result in a loss of gross national product of $3 billion, in net present value terms, over the next ten years. As other nations commercialise oilseed crops with second and third generation characteristics this may further impact negatively on Australia’s international competitiveness.

For more information and to download the report visit abareonlineshop.com/ and follow the link to Crops.

Marketing uncertainties
Marketing uncertainties continue to be a key barrier to the progression of GM crops through the pipeline to commercialisation. The risk of developing a GM product with restricted markets or where the path to market is unclear, has had a huge impact on research and development investment decisions in Australia. Concerns have been expressed that the commercialisation of GM grains in Australia could pose market access problems for exports. However, trade data shows that Australian grains currently compete in export markets in which GM crops have a significant market share. In the case of some meat and dairy industries, certain markets reportedly require assurance that animals were raised on non-GM feed. For individual industries, monitoring of GM status of export markets and key competitors in these markets provides vital knowledge.

Some markets may require separate supply chains for GM and non-GM products, increasing the importance of segregation and identity preservation systems. The extra value of second and third generation crops would be a driver for implementing such systems and justify the extra costs involved.

In the United States (US) and Canada, where GM crop uptake has been extensive, commercialisation of GM herbicide tolerant wheat was put on hold by the major developers in part because of concerns for domestic and export markets such as the European Union (EU). Significantly, however, research and development of first and second generation GM wheat characteristics is continuing in laboratories and glasshouses worldwide, including in the US, Canada, the EU and Australia. Research and field trials of many other GM food crops are also ongoing worldwide.

For more information on GM crops being developed overseas, download the report ‘International Agricultural Biotechnology Applications of Interest to Australian Crop and Forage Production’ on the Department of Agriculture, Fisheries and Forestry – Rural Policy and Innovation website www.daff.gov.au/agbiotech
Whether marketing barriers to GM crops are due to consumer or importer preferences, or whether they are actually being used as barriers to trade is questionable (Box 2). Many studies and surveys in Australia and overseas have explored consumer attitudes towards GM foods and crops and the results are often contradictory. This represents not only global differences in the attitude, design and objectives of individual studies but also the complexity of consumer opinion.

It has been predicted that the development of second and third generation GM crops will have positive implications for the uptake of GM technology. This is because GM crops with characteristics which offer obvious consumer and producer benefits, or have a more widely understood environmental benefit, may reduce market resistance to GM crops and may even drive adoption.

**Value capture**

Another significant element in the pathway to the commercialisation of a GM product is the development of business cases which identify how to capture value from the investment in research and development. Being able to define a problem in economic terms, and then describe the scientific solution and how value may be captured, particularly by investment returns, is increasingly important. Large development and regulatory costs coupled with the marketing uncertainties and lack of a clear path to market make this a significant barrier to GM crop development.

**For further information on Australian consumer attitudes see the Biotechnology Australia website**


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**BOX 2**

**Marketing barriers and the World Trade Organization**

Trade in GM products has been the subject of discussion in the World Trade Organization (WTO). WTO agreements on sanitary and phytosanitary issues, technical barriers to trade and trade-related aspects of intellectual property rights are all relevant to trade in GM crops, as with any other commodity. The United States, Canada and Argentina have mounted a WTO challenge asserting that the moratorium applied by the EU since October 1998 on the approval of biotech products has restricted imports of agricultural and food products (disputes DS291-3). Australia is a third party to these challenges. The WTO is expected to issue its final report on the GMO case in 2006.

**For more information about these disputes visit the WTO website**

www.wto.org/english/tratop_e/dispu_e/find_dispu_cases_e.htm
Conclusions

GM technology has the potential to help address current and future challenges facing Australian agriculture by breeding varieties better adapted to environmental stresses or with reduced susceptibility to pest and diseases. GM crops can also be developed that may provide new, high value crops and niche markets.

For crops with first generation characteristics, decisions on whether to develop a GM or conventional crop depend on many factors including the genetic complexity of the characteristic, the capacity of current crop varieties to cope with environmental challenges, and the presence of the characteristic within the species or in closely related plants. These factors will differ greatly depending on the crop itself, the desired characteristic and the nature of the challenge.

For some second and third generation characteristics, such as nutrient enhancement, conventional breeding approaches are feasible in some crops. However, for the majority, GM is the only route to obtaining these novel characteristics.

With a few exceptions, most third generation characteristics are in the technology discovery phase. Before the majority of the products can reach commercialisation, many technical, production and regulatory issues need to be resolved and addressed. For example, the logistics of scaling-up production, distribution and segregation need to be developed.

The GM crops in the pipeline discussed in this report represent only a proportion of Australian research and development in this area. There is huge breadth of ongoing high quality research and development in Australia that could lead to GM crop outputs. However what this BRS review shows is that the current regulatory and marketing environment in Australia has stalled many crops in the pipeline. Unless this environment changes, the capacity of breeding programmes to quickly develop GM varieties suitable for Australian agriculture is becoming questionable. The impact of Australia’s agricultural competitors adopting GM technology in other key export crops also needs to be considered.

For further information

If you found this summary booklet informative you can access the whole report at the BRS biotechnology website – www.daff.gov.au/brsbiotech

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