

Genetic modification

/ QUESTIONS AND ANSWERS



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Working Group

Professor Rachel Ankeny

Dr TJ Higgins AO FAA FTSE

Professor Marilyn Anderson AO FAA FTSE

Associate Professor Judith Jones

Dr Owain Edwards

Dr Danny Llewellyn FTSE

Dr Liz Dennis AC FAA FTSE

Oversight Committee

Professor John Shine AC PresAA

Professor Matthias Hentze FAA

Professor Ian Dawes FAA

Professor Adrienne Clarke AC FAA FTSE

Professor Ian Small FAA

Consulting science writers

Craig Cormick

Sarah Tynan



**Australian
Academy of
Science**

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Foreword

The study of biological systems has revolutionised our understanding of life. For decades, scientists have studied the information encoded in the genes of living organisms, and how those genes can be modified. As our understanding increases, so does our ability to target and control these changes, allowing us great scope to change the properties of an organism. Genetic modification is a powerful tool that offers broad possibilities—and as such, must be used carefully, in a manner that is informed by a strong understanding of the science and of the ethical, environmental, regulatory and community context in which such possibilities may be realised.

The Australian Academy of Science strives to ensure the Australian community is guided by and enjoys the benefits of scientific endeavour. The purpose of this booklet is to provide a clear, concise description of genetic modification technology for Australians, including how it is used and how it is regulated. The booklet draws on the knowledge and expertise of the Academy's distinguished Fellows and of the Australian science community, to provide information about this important scientific issue.

I wish to thank the independent members of the Working Group and Oversight Committee for their expert and thorough work in the preparation of this booklet.

On behalf of the Academy, I am pleased to commend this information to all those who are looking for authoritative answers to the questions we all ask about the science of genetic modification.

John Shine

President

Australian Academy of Science

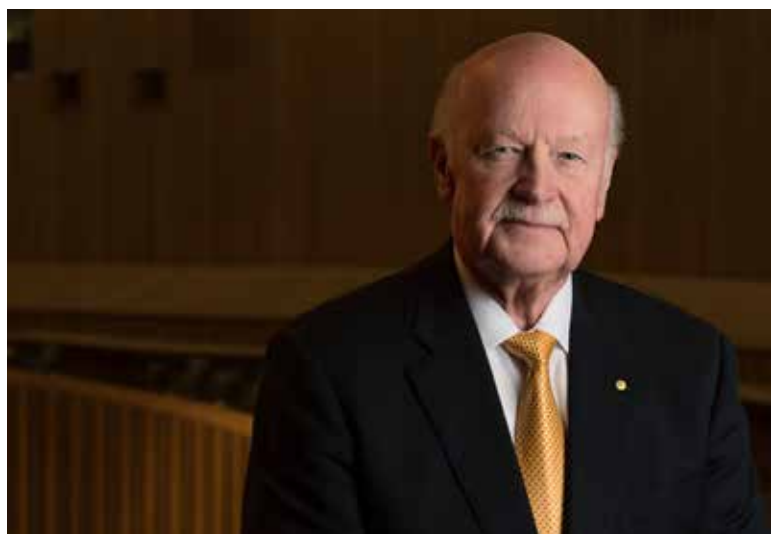


PHOTO: BRADLEY CLIMMINGS

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Key questions in brief

What is genetic modification?

Genetic modification (GM) is the process of altering an organism's genetic makeup. Molecular techniques can be used to add, delete, turn on or off or alter one or more genes to achieve desirable characteristics in the modified organism. **See Question 1, What is genetic modification? and Question 2, Where do we encounter GM products?**

A group of transgenic sheep, genetically modified with an extra copy of a sheep growth hormone gene. This work is still in the research phase and has not reached a commercial stage.

PHOTO: CSIRO

Why do we do GM research?

Humans have modified animals, plants and microbes by traditional methods such as selective breeding or crossbreeding for thousands of years. This was done to create crops or animals with better nutritional value or which are easier and cheaper to farm. GM techniques are more precise than traditional methods, but have similar goals. GM techniques have also opened up many new applications in medicine. **See Question 4, What are the benefits of GM products?**

Are GM foods safe to eat, and are GM medicines safe to use?

GM foods and medicines are safe, and no ill effects to humans from consuming them have been identified. The GM foods approved so far are no different to unmodified foods in terms of their safety and are digested normally. This conclusion is supported by the World Health Organization, the US National Academy of Sciences and the Royal Society of London. **See Question 3, Are GM products safe?**



Do GM crops harm the environment?

No. The scientific consensus is that GM products released to date pose no greater risk to the environment than similar organisms produced by traditional breeding processes. **See Question 3, Are GM products safe?**

Are GM products regulated?

Yes. In Australia, live GM organisms are regulated by the Office of the Gene Technology Regulator (OGTR). Other GM products are regulated by Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA) or the Therapeutic Goods Administration (TGA). GM products are subject to at least as much scientific scrutiny as other foods and medicines. **See Question 3, Are GM products safe?**

Soybeans are the largest GM crop globally with over 77% of the world's 121 million hectare soybean crop being GM in 2017¹

PHOTO: CSIRO / AMY WILSON

What are the risks posed by gene technologies?

The potential risks of gene technologies are that the introduction of new genes into an organism may have unexpected adverse impacts on human health or the environment, particularly if the introduced gene affects existing genes or biology in unexpected ways. Extensive testing is carried out on GM products before release, and in Australia the potential risks of GM are addressed with strict and appropriate regulation of GM technologies. **See Question 3, Are GM products safe?**

Doesn't gene technology only benefit big companies?

Big agricultural or life science companies have been major players in the research and development of gene technology. This has primarily been because of the high costs and long time frames involved. In Australia, public research institutions also

conduct significant gene technology research, especially in medical and agricultural research. As the technology has developed costs have reduced, allowing smaller companies and public research institutions to become more involved and increasing the range and application of GM research. **See Question 4, What are the benefits of GM products?**

What things are most likely to be GM?

GM products currently available in Australia include insulin to treat diabetes, chymosin used in the production of cheese, cotton fibre used in textile manufacture, soybeans used in a variety of imported processed food products, and cooking oils derived from GM cotton and canola. No GM whole fruits or vegetables are available in Australia, nor are GM livestock. GM food products are more common in other parts of the world. **See Question 2, Where do we encounter GM products?**



BOX 1 / A NOTE ON TERMINOLOGY

This publication only uses the terms 'genetically modified organism' or 'GMO', where discussing the operations of the Office of the Gene Technology Regulator. This is because these terms have a precise legal definition as set out in the *Gene Technology Act 2000* (the Act) and can have different meanings in common use.

Instead, this publication talks about GM crops, GM animals, GM insects or GM microorganisms. These terms are commonly used by the media and the general public, and include broad applications of genetic modification technologies.

The term 'GM product' is used in this document to refer generally to the outcomes of gene technology, usually in the form of

foods and materials. Again, this is meant to include broad outcomes as found in common usage, rather than the precise meaning as defined in the Act.

The term 'GM technologies' is used to encompass all applications of GM, including the GM organisms themselves as well as the outcomes, such as GM foods and materials.

What is genetic modification (GM)?

BOX 2 / CRISPR/CAS9—NEW AND MORE PRECISE MODIFICATION OF GENES

The CRISPR/Cas9 system is one of a number of new genome editing techniques which enable researchers to make precise, targeted changes to the genome of a living cell. The name stands for 'Clustered Regularly Interspaced Short Palindromic Repeats/CRISPR associated protein 9' (see Figure 1.1).

CRISPR/Cas9 is very precise because it uses an RNA construct to accurately target specific DNA sequences. Once aligned with the targeted sequence, it can introduce specific or random DNA changes in a gene, delete a gene, or modify the gene's expression. In particular, it can effectively 'cut' the DNA of any genome at a specific location, enabling precise modification of one or a small number of the nucleotides in a gene.

CRISPR/Cas9 is only one of many different genome editing tools developed during the past decade, but is probably the most widely used because of its simplicity and accuracy.

More on CRISPR can be found on the Australian Academy of Science website.

People have been modifying the genes of plants, animals and microbes for thousands of years, using traditional breeding and selection methods to produce desirable traits. Selective breeding methods have produced such things as higher yield and drought- and pest-resistant crops, docile livestock, and low-allergenic fur in dogs.

Genetic modification (GM) draws on this type of approach but involves controlled manipulation of an organism's genes using modern technology to add, delete, or turn on or off a gene function. Specific genes that determine particular traits are identified, isolated, and manually transferred into another organism. The final organism is described as 'genetically modified' (also shortened to 'GM'). The transferred gene functions successfully to produce the associated trait in the GM animal, plant, insect or microorganism.

In traditional breeding using sexual crossing, entire chromosomes from the parents are introduced and their genes randomly re-assorted within the offspring. Achieving the desired combination of traits is not assured. Successful breeding depends on sufficient numbers of offspring obtaining the right combination of genes, a process that can take decades.

Through the ability to target specific genes rather than relying on this random genetic mixing, gene technology allows greater precision and speed in the process of gene transfer. Genes are modular in their structure and function, and can be manipulated to be active at the right time and place in the target organism to successfully achieve a particular trait.

Gene technology has been used in many countries since it was pioneered in the

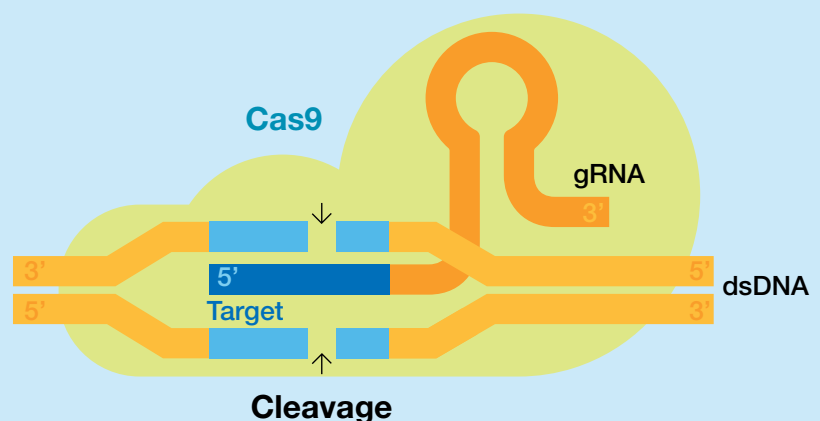


Figure 1.1 / A schematic diagram of the Cas9 enzyme (yellow) and the guide RNA (gRNA) that directs the enzyme to cleave double-stranded DNA (dsDNA) at specific sites. IMAGE ADAPTED FROM SOURCE: MARIUS WALTER.

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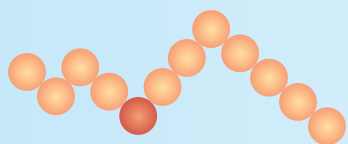
Methods of plant breeding

Traditional

Plants produced by traditional plant breeding receive a mixture of genes from both parents. These genes may include the gene responsible for the desired agronomic trait, as well as genes responsible for unwanted characteristics.

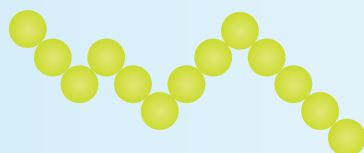
Donor DNA from one parent

DNA strands contain a portion of an organism's entire genome



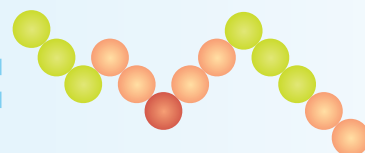
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Desired gene

Recipient variety DNA strand from the other parent



New variety DNA strand

Many genes are transferred with the desired gene



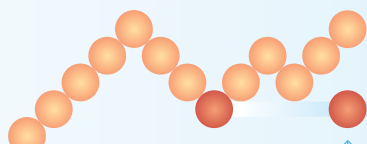
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Potentially unwanted genes

Genetic engineering

Genetic engineering enables the introduction into the plant of the specific gene or genes responsible for the characteristic(s) of interest rather than a mixture of desired and unwanted genes from the donor genome. By narrowing the introduction to one or a few identified genes, scientists can introduce the desired characteristics without also introducing genes responsible for unwanted characteristics. This saves years of plant breeding to remove the unwanted genes.

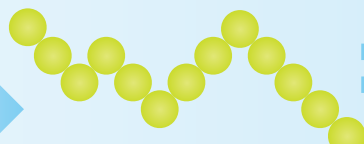
Donor organism DNA strand

The desired gene is copied from the donor organism's genome



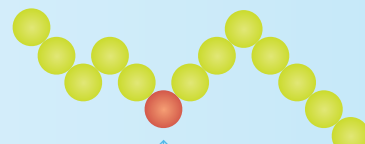
↑
Desired gene

Recipient variety DNA strand



New variety DNA strand

Only the desired gene is transferred to a location in the recipient genome



↑
Desired gene

IMAGE ADAPTED FROM SOURCE: U.S. FOOD AND DRUG ADMINISTRATION

1970s, and our knowledge and methods have advanced considerably over the past four decades. Some of the new methods enable scientists to modify or 'silence' existing genes without a substantial change in the organism's

genetic structure, in a process called genome editing. For examples, Arctic apples developed in Canada have been modified to turn off the enzyme that causes the fruit to quickly go brown when it is bruised, sliced or bitten.

This makes the apples more appealing to consumers and protects flavour and nutrition. These apples have been on the market in the USA since 2017.

2

Where do we encounter GM products?

BOX 3 / LABELLING OF GM FOODS

Clear labelling of foods helps consumers to make informed decisions when purchasing or consuming a product. The labelling requirements for GM foods are covered under Standard 1.5.2 of the Food Standards Code.

GM foods and ingredients must be labelled with the words 'genetically modified' if they contain novel DNA or protein. However, labelling of GM products is not required in the following cases:

- where food is highly refined and the resulting novel DNA or proteins are removed during processing (such as canola or cotton oil from GM plants), except where the food has an altered characteristic (such as lysine-enriched corn and high-oleic acid soybeans)
- where GM is used as a processing aid or food additive and no novel DNA or protein remains in the final food
- where the final concentration of a GM flavour additive is less than 0.1 per cent of the food
- unintentional presence of approved GM ingredients, where the ingredient is less than 1 per cent of the food
- any foods consumed at the point of sale (such as in restaurants or cafes).

In addition, labelling is not required for food from animals that have eaten GM feed—animals that consume GM feed are not GM animals, so the GM labelling laws do not apply.

GM crops

The only GM plants approved for commercial cultivation in Australia are cotton, canola, safflower and carnations. There are moratoria (temporary suspensions) on growing any commercial GM crops in South Australia, Tasmania and the Australian Capital Territory. New South Wales and Victoria also have moratoria in place, but GM cotton and GM canola are exempt, and both are grown in these states. Western Australia and Queensland grow GM cotton and GM canola. The Northern Territory does not grow cotton or canola, so GM varieties of these crops are not farmed. GM safflower grown for industrial applications is exempt from current moratoria, and is grown in

Victoria, New South Wales and Western Australia.

A significant proportion of Australian canola and nearly all Australian cotton is GM, so most people will likely have consumed canola oil that came from a GM canola plant. People may also have consumed foods fried in cottonseed oil from a GM cotton plant. These oils are extracted from seeds, and have no remaining genetic material. They are compositionally identical to oils from conventional canola and cotton. After these products have been scientifically assessed as safe for human consumption, Australian regulations do not require specific labelling, unless they have an altered characteristic such as a different fatty acid or amino acid



Canola crop near Ardlethan, New South Wales

PHOTO: CSIRO / WILLEM VAN AKEN

composition (see Box 3 Labelling of GM foods).

Other GM plants being grown or trialled overseas include drought-tolerant corn plants in Africa,² insect-resistant eggplants in Bangladesh and the Philippines,³ and bacteria-resistant bananas in Uganda.⁴ None of these are grown in Australia. Processed foods containing GM ingredients are much more common internationally, particularly in the USA, and GM products might be present in processed foods that are imported into Australia.

Many GM crops approved for use as food are actually only grown for animal feed. The main global GM crops, corn and soybean, are often used for animal feed and may be imported into Australia in bulk to feed livestock. If a product is not approved to be grown in Australia, any imported seeds must be rendered non-viable to prevent them from being cultivated.

Other GM plants are only used for the efficient production of hybrid seeds that provide better yields than non-hybrids. This is the case with some types of canola grown in Australia.

Food Standards Australia New Zealand (FSANZ) has approved food derived from nine GM crops—soybeans, potato, canola, sugarbeet, rice, corn, cotton, safflower and lucerne (alfalfa)—for use in Australia. Most of these foods are imported as ingredients in processed food. Fresh, whole GM foods such as potatoes or corn would require additional approval from the Office of the Gene Technology Regulator (OGTR) before they could be sold as food in Australia. A separate food approval is required from FSANZ for each genetic modification event. The approval of soybeans that are resistant to the herbicide glyphosate or have higher oleic acid content does not mean that other genetic modifications in soybeans are also permitted.

According to the Food and Agriculture Organization (FAO) of the United Nations, 973 approvals were granted for 24 GM

crops in 2014, and GM crops were approved to be grown or imported in 59 countries.⁵ The FAO lists GM foods and plants in accordance with the guidelines of the international food safety standards, known as the Codex Alimentarius. The FAO lists several GM fruits, vegetables and crops as safe for consumption, including GM papayas, apples, tomatoes, squash, beans and potatoes, along with the field crops approved by FSANZ for food use in Australia listed above. Despite this, there are few GM whole foods on the market anywhere in the world, although GM papaya, squash and non-browning apples are currently available in the USA.

Most GM crops grown today have enhanced agricultural traits that make them more beneficial for farmers and the environment. New-generation GM crops are now being developed that can be used for medicines and industrial products.

GM medicines

GM techniques are also used to produce some vaccines, antivenoms, immunoglobulins and antibodies. Insulin used in the treatment of diabetes is synthesised using GM bacteria. In this process, large quantities of bacteria modified to produce human insulin are grown in a bioreactor, an industrial

apparatus for conducting biological reactions at large scale. The insulin is extracted and purified for medicinal use. This is significantly more efficient than the previous method, which involved extracting animal insulin from cows or pigs.

Medicines that contain or are produced by GM technologies are regulated by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989* and its amendments, and the Biologicals Regulatory Framework,⁶ while those used in veterinary medicine are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Any medicines that contain live genetically modified organisms, such as vaccines, are also regulated by the OGTR.

Other GM applications

There are several approved and widely used food processing aids produced using GM microorganisms. These include chymosin used as a starter in cheese manufacturing, amylases for starch processing, and lipases for modification of fat composition. Asparaginases are also used to reduce the amount of the amino acid asparagine in starchy foods such as potatoes to decrease production of acrylamide during frying.



PHOTO: ISTOCK.COM / BPAZZO

3

Are GM products safe?

The general scientific consensus, supported by scientific organisations such as the World Health Organization,⁷ the US National Academy of Sciences⁸ and the Royal Society of London,⁹ is that after more than 20 years of commercial use, the GM technologies used to date pose no greater risk to human health or the environment than similar products derived from traditional breeding and selection processes.

GM products are usually predictable in their qualities and properties. Nevertheless, GM technologies and products continue to be treated with caution by governments and regulatory bodies, and their impacts on human and animal health and the environment are closely scrutinised.

In Australia, the government regulators overseeing the use of GM technologies and products (see Box 7 Regulation of GM in Australia) have a mandate to base their decisions on the best available scientific evidence. Assessments are conducted on a case-by-case basis, and the regulators are confident that any organisms and products approved are as safe as their conventional counterparts.

Australia has a rigorous, open and transparent regulatory system for GM technologies, with similar systems being implemented in other countries. This allows the relatively free movement of GM products in global commerce, although some countries still have restrictions in place for many GM technologies.



BOX 4 / IS EATING 'FOREIGN' DNA SAFE?

Yes. 'Foreign' DNA contains the same chemical building blocks, or 'nucleotides', as all other DNA, and is not inherently unsafe. We consume foreign DNA every time we eat raw or cooked food. Our digestive system breaks down DNA without transferring any of the traits of that DNA into our bodies, so eating a food with modified DNA is no different to consuming the DNA of unmodified food.

There are stringent testing requirements to ensure expression of the introduced DNA does not result in the production of a toxic or allergenic protein, or interfere with a biochemical pathway to produce an unusual level of a toxic or allergenic chemical. For this reason, a primary focus of GM safety assessments is to examine what introduced genes produce in GM products.

Banana plantation just north of Cardwell, Queensland.

PHOTO: CSIRO / WILLEM VAN AKEN

BOX 5 / THE SOYBEAN WITH A BRAZIL NUT GENE—EVIDENCE OF RISK OR SAFETY?

In the 1990s, researchers in the USA transferred a Brazil nut gene into a soybean to increase its nutritional quality. However, the gene encoded a protein that was one of the major allergens in Brazil nuts. This was detected in early laboratory tests and the research was not continued.¹⁰

This case is often cited as an example of the risks of genetic modification, but also as an example of how rigorous scientific practice can identify potential problems in the early stages of development, enabling researchers to decide to discontinue a project.

BOX 6 / CASE STUDY: BT-COTTON

Bt-cotton is a GM cotton plant that expresses insecticidal proteins derived from the soil bacterium *Bacillus thuringiensis* (Bt). These Bt proteins have been used for many decades as a sprayable biological pesticide to protect vegetable crops from caterpillars. However, sprayable biologicals are difficult to use, expensive and unreliable on large areas of field crops. By the mid-1990s, cotton production in Australia and the rest of the world was becoming uneconomic because of the large amounts of synthetic chemical pesticides required to protect the crop. GM cotton plants that produce the Bt insecticide protein are protected against the most destructive insect pest, the *Helicoverpa* caterpillar. Cultivation of Bt-cotton greatly reduced chemical insecticide usage, and almost certainly saved the industry from collapse.

As insects are able to develop resistance to Bt toxins, the industry was very cautious in its initial adoption of Bt-cotton, which contained only a single insecticidal gene. If the insects had quickly

developed resistance to the specific toxin in Bt-cotton, the technology would have become ineffective. To reduce exposure of the caterpillars to the toxin, growers voluntarily restricted Bt-cotton to one third of their crop.

The technology has been refined to include additional Bt-toxins that also control caterpillars but with different modes of action. This has dramatically decreased the probability of the caterpillar developing resistance. Since the introduction of Bt-cotton, cotton farmers have reduced their use of chemical pesticides by more than 90 per cent, and in many cases to no pesticides at all.

Identification of the risks of using this GM technology and active research to address those risks enabled development of an agricultural product that is more sustainable and profitable than its conventional counterpart. The Australian cotton industry is now predominantly GM, and cotton is Australia's fifth largest agricultural export, worth more than \$2 billion a year.

PHOTO: ISTOCK.COM / ARTPHOTOCLUB



Unsprayed conventional cotton (left) and GM insect resistant cotton (right) in Australia.

PHOTO: CHERYL MARES



Addressing concerns

Despite a high level of precision, there may still be unpredictable outcomes from introduced modifications, and how modified organisms may influence or be influenced by their environment. Those with concerns about GM products often cite the possibility of long-term health or environmental effects of some GM products that may not become apparent during the required years of testing and evaluation.

These risks are dealt with during the regulatory assessment of a GM product prior to commercialisation. The safe consumption of GM products over the past 20 years supports the assessment processes used by our government regulators during the development and release of GM products.

Another concern is that the introduced gene(s) could encode a protein toxic or allergenic to humans or livestock. This is

unlikely, as toxins and allergens have well defined properties and any potentially unsafe genes can easily be identified, and would not be approved in a GM product. Many researchers are in fact using GM technologies to remove toxic or allergenic properties from some foods as well as from pollen from grasses responsible for asthma and hayfever.

Human testing is not usually required to determine the safety of GM food products. Isolated components of a GM food product, such as a new protein, may also be tested via animal toxicity studies. However, this is usually not necessary for proteins with a long history of safe use, no similarity to known protein toxins or allergens, and which have been shown to be readily digestible using laboratory studies.

Many genes introduced using GM technologies to produce desirable traits in crops, such as herbicide tolerance or

“...regulators are confident the organisms and products approved so far are as safe as their conventional counterparts.”

BOX 7 / REGULATION OF GENETIC MODIFICATION IN AUSTRALIA

Research and commercial applications using genetically modified organisms (GMOs) in Australia are overseen by the Gene Technology Regulator, established under the *Gene Technology Act 2000* (the Act). This legislation gives the Regulator strong compliance and enforcement powers and also defines:

- the types of facilities in which GM research and development can occur
- how to request permission to release a GMO for research or commercial use in a way that manages any potential harm to human health or the environment
- penalties for corporations, researchers or the public who do not abide by requirements. The Act includes offences attracting penalties of up to five years imprisonment or \$2.1 million fine per breach.

The Regulator is supported by the Office of the Gene Technology Regulator (OGTR), an Australian Government agency within the Department of Health. The aim of the regulatory system is to protect human health and safety and the environment through risk identification, assessment and risk management.

The Gene Technology Regulator has a range of statutory functions including:

- assessing applications for licences to work with GMOs
- commissioning research into GMO safety

- monitoring compliance with the *Gene Technology Act 2000*
- monitoring how other countries regulate GMOs
- promoting harmonisation of GMO risk assessments across Australia
- giving advice and information to the public on the regulation of GMOs in Australia.

The work of the OGTR is overseen by a Ministerial Council representing the states and territories. The OGTR also cooperates with federal agencies with responsibility for specific applications of GM technologies related to food (FSANZ), therapeutics (TGA), or pesticide and veterinary use (APVMA).

The Regulator focuses on the impacts of GM on human health, safety and the environment, and does not consider the economic or social impacts of GM technologies. These aspects may be considered by parliamentary committees, federal government departments, state and territory governments, research advisory bodies, industry associations and other groups.

Risk assessment and management plans for all GMOs produced in Australia can be found on the OGTR website (www.ogtr.gov.au), along with the field trial sites of GM crop research.

Oversight of GMO research by Institutional Biosafety Committees

The OGTR also has regulatory oversight of institutional biosafety committees, which must be consulted by every organisation—universities,

CSIRO, research institutes, commercial plant breeders or seed producers—that conduct research with GMOs. These committees, which are formally established under the legislation, augment the work of the OGTR to ensure organisations meet the safety provisions of the regulations. Biosafety committees conduct on-site scrutiny of GMO work, including for low-risk experiments that are contained in laboratories and are not being released into the environment.

Review of GM laws and regulations

As the science of GM can change rapidly, the legal framework for GM regulation in Australia is subject to frequent review. The most recent review of the gene technology regulatory scheme took place in 2017–18. This involved extensive consultation with researchers, industry and other stakeholders, with a final report and recommendations issued in October 2018.

In parallel to this, the Regulations for the Gene Technology Act were reviewed in 2018. This review focused on technical matters regarding the scope and interpretation of the Act. Among the changes resulting from this review, gene editing techniques such as CRISPR (see Box 2) were made explicitly part of the regulatory scheme, although certain minor applications are exempt.



Freshly harvested Bt Brinjal (Eggplant) in Bangladesh. PHOTO: ERIC HUTTNER, ACIAR

insect resistance, encode proteins that are already present in human diets and have a long and safe history of consumption or exposure. For example, the Bt insecticidal proteins in Bt-cotton or Bt-corn are the same proteins found in Bt insecticidal sprays that have been used in the horticulture industry for many decades. Even after washing the vegetables on which the insecticide spray has been used, the Bt proteins remain in significant amounts and are consumed safely. These sprays are promoted by organic growers as natural pesticides.

Detailed examination of the DNA around the gene insertion region is an essential

part of the analysis of all GM products intended for commercial use. This is to ensure an introduced gene does not affect the activity of existing genes, or result in the production of a completely new protein sequence with unknown and possibly toxic properties. If any toxic or allergenic proteins are identified at this stage of the research the product is not approved for use (see Box 5 The soybean with the Brazil nut gene—evidence of risk or safety?).

There is also good evidence, particularly in plants, that these types of gene insertions occur naturally and frequently, such as when plants are crossed sexually or are infected by certain

pathogens. Any newly developed crops, GM or otherwise, may contain inserted genes and we do not see frequent adverse consequences resulting from this type of gene movement in either GM or non-GM crops.

Broader environmental risks are unintended consequences such as insect resistance within a GM product acting on organisms other than crop pests, or the 'escape' of a GM crop into neighbouring environments where they may become 'super weeds' or spread their genetic modifications to other species. All such risk scenarios are evaluated as part of the regulators' formal risk assessment and they must be satisfied that risks are highly unlikely or can be managed through restrictions on the way the GM product is used commercially. GM products are very closely controlled during their early development and assessment phases, while any potential risks are fully evaluated. For plants, this is usually done in secure glasshouses, followed by trials in contained or confined fields with access limited to trained staff.

In Australia, approval for commercial use of a GM product can be withdrawn at any time if any unintended consequences become evident.

New genetic technologies such as gene drives are being designed to have an impact on whole populations of organisms, such as controlling mosquitoes that spread deadly human diseases. These technologies may pose different risks to those considered for the GM crops released so far, and will need to be carefully assessed on a case-by-case basis just as existing products have been assessed. The evidence so far is that the regulatory frameworks already in place will be sufficient to ensure they are developed and used safely into the future, particularly considering gene technology regulations are subject to regular review to ensure they remain relevant.

4

What are the benefits of GM products?

Gene technology is essentially an extension of traditional breeding technologies. It offers a more precise and targeted way to obtain the same kinds of outcomes that humans have been pursuing for millennia. GM applications also offer the means to be more responsible stewards of our environment, and respond to the significant environmental changes that have occurred during the course of human history. With the help of GM research, we can produce crops better adapted to changing environments.

Herbicide tolerance and insect resistance

The agricultural GM market has been largely dominated by two traits: herbicide tolerance for more cost-effective weed management; and insect resistance to minimise yield losses from insect damage. The dominant GM crops are corn, soybean, cotton and canola, which have produced considerable economic and environmental benefits across 24 countries.¹

Reduced use of insecticides and residual herbicides

The most obvious benefit from the adoption of these technologies has been the reduction in the use of toxic pesticides. Globally, farmers growing GM crops reduced insecticide usage by more than 8 per cent from 1996 to 2016,¹ and the environmental impact

“In Australia, adoption of around half a million hectares of GM cotton has reduced this industry’s insecticide use by more than 90 per cent during the past decade.”

associated with herbicide and insecticide use fell by 19 per cent, as measured by the indicator known as the Environmental Impact Quotient.¹¹

In Australia, adoption of around half a million hectares of GM cotton has reduced this industry’s chemical insecticide use by more than 90 per cent during the past decade. Decreased runoff of insecticides from irrigated cotton has also led to dramatic improvements in the water quality of waterways in cotton cropping areas. These waterways were previously routinely contaminated with insecticides such as endosulfan, but reports of contamination are now rare.

Use of herbicide-tolerant cotton in Australia has resulted in a 60 per cent reduction in the use of environmentally-damaging herbicides in favour of the use of glyphosate, a herbicide with a better environmental profile. In reducing the amount of soil cultivation required on cotton crops to control weeds, glyphosate-tolerant GM cotton has also facilitated healthier soils.

BOX 8 / WHEN GM CROPS DON’T MEET THEIR PROMISE

In some cases, GM experiments have not delivered on their promise to improve on traditional breeding methods. There are instances where higher yields have not materialised, expected insect resistance properties have not been observed, or herbicide tolerance has not been sufficient to improve farming practice. Sometimes properties observed under laboratory conditions are not observed in field trials.

These ‘failed’ experiments have still generated learning opportunities, such as investigating why the application did not work as expected. Instances of poorer-than-expected outcomes do not invalidate the technology as a whole—this is typical of many new scientific endeavours, not just GM technologies.

Given the potential scope of GM technologies, and the hypothetical ability to alter all aspects of an organism, it may also seem disappointing that current GM technologies do not yet extend beyond traits like herbicide tolerance or insect resistance. However, this reflects the understanding of gene function as it stood when GM technologies first began to be applied, 20 or more years ago. As with all scientific pursuits, progress is incremental. As our understanding of the genetic makeup of organisms improves, we become better placed to alter organisms through new advances in genetic improvement.

Increased yields

The combination of higher yields and lower production costs has directly benefited farmer incomes around the world, especially in developing countries. Between 1996 and 2015, use of GM insect-resistant corn increased yields by more than 13 per cent relative to conventional corn crops. Yields for GM insect-resistant cotton were 15 per cent higher.¹²

Improved yields have also been achieved through more efficient and cost-effective weed control. Furthermore, the herbicides that can be used with GM herbicide-tolerant crops are rapidly broken down in the soil allowing planting of additional crops in the same growing season. These yield benefits are even higher for farmers in developing countries who are often resource poor and farm small plots of land.

GM insect-resistant corn increased yields by more than 13 per cent relative to conventional corn crops.

PHOTO: ISTOCK.COM / SEASTOCK

Increased farm incomes

The global net farm income gains from growing GM crops for 1996–2016 was estimated to be \$233 billion. In Australia, farm income benefits from growing insect-resistant GM cotton (first planted in 1996), herbicide-tolerant cotton (first planted in 2000), and herbicide-tolerant canola (first planted in 2008), are estimated at about \$1.3 billion for 1996–2015.¹¹ Although cotton growers in Australia must pay a technology licence fee to use GM crop technology, farmers save on average \$186 – \$270 per hectare per year relative to growing non-GM cotton that must be extensively sprayed with pesticides.

Allowing farmers to grow more without needing more land

As a result of the higher productivity GM crops achieve on existing agricultural land, it is estimated GM plants saved



183 million hectares of land from ploughing and cultivation from 1996 to 2016 and 22.5 million hectares in 2016 alone.¹

Improved productivity of existing agricultural land has helped reduce clearing and habitat destruction involved in creation of more arable land. A further benefit to biodiversity is the maintenance of beneficial insect populations through reduced insecticide use.

Reduced CO₂ emissions

Reduced use of insecticides associated with the adoption of GM crops also reduces aggregate fuel consumption from vehicles used to deliver insecticide sprays. It's estimated almost 10 billion litres of fuel were saved between 1996 and 2015, with a saving of 1056 million litres of fuel in 2015 alone.¹¹

A similar benefit is obtained from no-till or low-till practices enabled by herbicide-tolerant crops, where carbon that would otherwise add to CO₂ emissions is retained in the soil. Reduced nutrient runoff and soil erosion also represents a financial saving for farmers, and an environmental benefit for waterways.

Improved nutritional value

New agricultural applications of GM technologies include improved human nutrition from plants enriched with iron, vitamins A and E, essential amino acids, healthier oils and increased antioxidant levels,¹³ allergen-free nuts and turf grasses^{14,15} and gluten-free grains.¹⁶ Researchers are also developing more digestible lucerne (alfalfa) for livestock.¹⁷

Other applications

Male mosquitoes carrying a modified gene that inhibits mosquito reproduction have been released in Brazil to help control the spread of dengue fever. A field trial in the USA tested a pink bollworm modified to carry a heritable fluorescent marker to study the effectiveness of GM insects for insect control.

A fast-growing Atlantic salmon has been approved for use in aquaculture in Canada but currently is only farmed on a very small scale.

BOX 9 / FOOD SECURITY: FEEDING THE GLOBAL POPULATION IN A RESOURCE-CONSTRAINED WORLD

GM crops offer improved sustainability of food and fibre production even when farmed intensively. New traits that protect against environmental stresses, such as lack of water or exposure to salinity, will make production more sustainable.

GM has the potential to control disease that would otherwise wipe out a crop or even an entire industry. For example, GM bananas with resistance to bunchy top virus and *Fusarium* wilt (Panama disease) are being tested in Malawi and Uganda. Bananas are a staple food crop in Africa where they provide more than 25 per cent of the total food energy requirements for more than 100 million people. Sustainability of this crop is essential to meet the needs of the African population.¹⁸ Cowpea, rice and brinjal (eggplant) are other staples that have been modified to address food insecurity in different parts of the world.

BOX 10 / HUMAN AND ANIMAL HEALTH IMPACTS OF GM CROPS

There are several GM crops that have been developed to improve human health and nutrition. One of these is golden rice, which is enriched in provitamin A. The same technology is currently being applied to tuber crops and bananas. These plants will be introduced into developing countries to combat Vitamin A deficiency, which affects 250 million pre-school children every year causing blindness, illness and death.

In developed countries, applications with health benefits include oilseeds with reduced trans-fats, which are implicated in heart disease, and increased beneficial omega-3 oils. We may also see potatoes that produce less acrylamide, a chemical that can accumulate in starchy foods when they are cooked at high temperatures and is considered carcinogenic.

The most immediate impact of GM plants on human health has been reduced exposure of producers to noxious insecticides and residual herbicides enabled by GM insect-resistant or herbicide-tolerant crops. This is particularly the case for small-scale producers in developing countries.

The decrease in insect damage to insect-resistant Bt-corn had an added benefit in better control of fungal diseases that arise when pathogens enter the plant through insect-damaged sites. This led to a decrease in mycotoxins—toxic and carcinogenic compounds that are produced by fungi—in the corn.¹⁹ Developed countries have the resources to monitor mycotoxins in food and remove them from the food chain, but they are rarely monitored in developing countries, where they are associated with increased incidence of liver cancers.

Golden Rice grain compared to white rice grain in screenhouse of Golden Rice plants. PHOTO: (SAGANI SERRANO) – PART OF THE IMAGE COLLECTION OF THE INTERNATIONAL RICE RESEARCH INSTITUTE (WWW.IRRI.ORG)



5

What do people think of genetic modification and GM products?

Qualitative studies^{20, 21} show people's food choices and perceptions about food are not necessarily directly informed by knowledge about food science or agricultural practices and regulations, but result from a complex range of factors and values. Some people have strong opinions on GM foods and crops which may be related to the technology itself, but also may be related to views on the role of large multinational corporations and their participation

in agriculture. Many of these companies were prominent in the early days of GM research and development, and their names have become synonymous with GM technologies. Concerns about who will benefit from GM contribute to people's attitudes about its development and use.

When Australians are polled on what they think about GM foods, there are four key responses that have changed

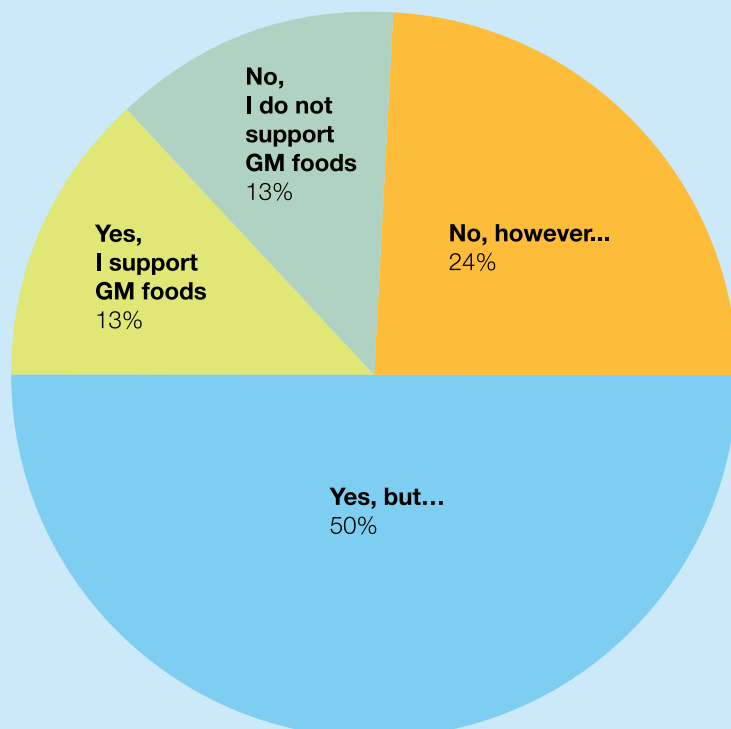


Figure 5.1 / Attitudes towards GM foods

little over several years. In 2017 the results of such a survey were (see Figure 5.1):

- Yes, I support GM foods (13%)
- No, I do not support GM foods (13%)
- Yes, but... (50%)
- No, however... (24%)²²

The conditional support of those who stated 'Yes, but...' relied on a desire to be assured GM products are regulated, or to know whether they have environmental or health benefits.

The conditions of those who stated 'No, however...' include 'not until science proves it is safe' and 'not if it is produced by a multinational company'.

Other surveys show people are generally slightly less concerned about GM foods than the presence of preservatives or pesticides in food.^{22, 23}

Australians are also much more supportive of gene technology in medical or industrial applications, as compared to agricultural purposes. People also have varying levels of support for different types of GM—they are generally more supportive of genetic changes within a plant, or insertion of gene(s) from a closely related plant.

Concerns about GM foods can be wide-ranging. They include issues such as GM foods being unnatural or unhealthy, having potential for adverse effects on the environment, a lack of assurance GM products are tested properly, or GM products do not have clear public or consumer benefits. Some also are concerned that the global multinational companies traditionally associated with GM have placed undue pressures on farmers and their practices

through their licensing and intellectual property claims, especially in developing countries. Due to the reducing costs and growing advancements in gene technology, there are now many small and large organisations researching and producing GM applications.

Those who are relatively unconcerned about GM crops show an awareness of other GM applications, such as GM synthesised medicines, which they are also happy to consume. People from both the concerned and unconcerned groups express frustration with the existing labelling regimes in Australia, which they view as being inadequate with reference to GM due to the focus on what is in the final product, and not the process involved in making the food.²⁴

Glossary

APVMA The Australian Pesticides and Veterinary Medicines Authority, the government organisation that regulates agricultural and veterinary chemical products in the Australian marketplace, including GM products.

Biochemistry The science of chemical processes and substances which occur within living organisms. When we talk about 'biochemical substances' or 'biochemical processes', we refer to the chemical components of living organisms and how they change.

Chromosome The biological structures that contain the majority of a cell's DNA.

Codex Alimentarius The international body established by the United Nation's Food and Agriculture Organization and World Health Organization that develops international food standards, guidelines and codes of practice for an international food code.

CRISPR/Cas9 The CRISPR/Cas9 system is used to make targeted changes to DNA. CRISPR refers to a family of DNA molecules characterised by particular sequences of nucleotides. Cas9 is a protein that 'cuts' DNA. The CRISPR sequences guide Cas9 to the section of cellular DNA that is to be modified. CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats. Cas9 stands for CRISPR associated protein 9, as it was the ninth protein associated with the CRISPR sequences to be characterised.

DNA Deoxyribonucleic acid, the long biomolecule that includes the codes for

proteins and other genetic information (see Gene). DNA forms long, stable, double-stranded helices (spirals).

FSANZ Food Standards Australia New Zealand, the trans-Tasman government agency that develops food standards for Australia and New Zealand, including for GM foods.

Gene A sequence of DNA that encodes a function or trait within a cell of an organism, usually in the form of a protein that performs the function. The gene is *transcribed* to a matching sequence of RNA, which is then *translated* to a protein.

Genetic modification (GM) The process of altering an organism's genes or DNA.

Genetic modification technologies (GM technologies) All applications of genetic modification, including biological entities and derived, non-living products.

Genetically modified organism (GMO) A live and viable organism whose genes have been modified. For the purpose of regulation by the OGTR, in Australia the term 'genetically modified organism' has a precise legal definition under the *Gene Technology Act 2000*.

Genetically modified product (GM product) The non-living outcomes of gene technology, usually in the form of foods and textiles.

Genome The total of the all the genes in an organism. This could refer to all the genes of an individual, or all the genes that characterise a species. The 'human genome' refers to all the genes possessed by humans.

Nucleotide Nucleotides are the fundamental units of the genetic code. There are five of them: adenine (A), cytosine (C), guanine (G), thymine (T) and uracil (U). These compounds are arranged in sequences along long biomolecules (see DNA and RNA).

OGTR Office of the Gene Technology Regulator, the Australian government agency that regulates activities related to genetically modified organisms.

Protein A sequence of amino acid 'building blocks' that is encoded by a gene. Proteins perform a wide variety of functions within biological organisms and are responsible for most identifiable traits.

- **Expressing proteins** When a gene is *transcribed* and *translated* to form a protein, we say that the gene has *expressed* the protein. The protein has been produced from the gene.

RNA Ribonucleic acid. A biomolecule similar in structure to DNA, but somewhat less stable. A common form of RNA is messenger RNA, which is a single-stranded sequence of RNA copied from a section of double-stranded DNA—a gene—to be translated into a protein.

TGA Therapeutic Goods Administration, the Australian government agency responsible for the regulation of medicines and other therapeutic goods.

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