



# Gene technology regulation

**Australia's national gene technology regulatory system came into force in June 2001 as a result of the *Gene Technology Act 2000* legislation. It aims to identify and manage risks to human health and the environment posed by, or as a result of, gene technology.**

The Gene Technology Act created the regulatory office, the **Office of the Gene Technology Regulator (OGTR)** within the Australian Government Department of Health and Aged Care. This Office is overseen by an independent **Gene Technology Regulator (GTR)** — whose role it is to administer the laws and make decisions relating to gene technology research and development across Australia. The GTR must:

- assess any risks posed by genetically modified organisms (GMOs)
- inform and advise other regulatory agencies, states and territories and the public about GMOs and genetically modified (GM) products
- promote harmonised risk assessments of GMOs and GM products between regulatory agencies
- monitor and enforce the legislation
- report to Parliament annually and quarterly.

The Act also created a **Ministerial Council** comprising the Commonwealth Health Minister and ministers from each state and territory to provide broad direction and regulatory guidance to the regulator.

Several expert committees have been established to advise the GTR and the Ministerial Council on technical issues, ethical matters and community issues. The committees comprise of experts from a diverse range of areas such as agriculture, herbicide resistance, biology, medicine, immunology, ethics, religion, philosophy and public health as well as community representatives.

The *Gene Technology Act 2000* covers live and viable GMOs and the research, manufacture, production, breeding and import of GMOs. But it does not cover:

- cost/benefit considerations
- comparisons with alternative technologies
- marketing and marketability
- intellectual property
- human beings and cloning.



## Licensing

The legislation prohibits people from involvement with GMOs, unless they are licensed by the regulator, or listed on the GMO Register. The GMO Register allows some dealings with GMOs to be undertaken without a license. To be listed on the register a GMO dealing must have been licensed for a certain period of time and demonstrated the absence of risk.

### License conditions

Conditions that are applied to all licenses include:

- notifying all people covered by the license that they are handling a GMO
- allowing the regulator or a person authorised by the regulator, access to the premises for auditing and monitoring purposes
- informing the regulator of any breaches, or any additional information that becomes available regarding public or environmental health and safety.

Further license conditions may include notifying neighbouring property owners that a GM crop field trial is to be conducted on neighbouring land, annual reporting, and transport conditions.

## Monitoring and enforcement

Penalties for unauthorised dealings with GMOs also exist, ranging from fines between \$55,000 and \$1.1 million, and imprisonment. Penalties for breaches of licence conditions, such as those mentioned above also exist.

## The assessment process

When the OGTR receives an application by an organisation interested in undertaking gene technology research an **initial screening** is undertaken to ensure that all the necessary information has been provided, and that the proposed research does not go against any policy principles set by the Ministerial Council. Following this, the assessment process then begins.

Firstly, the regulator **assesses any potential risks** the GMO research may pose to the environment or to the health and safety of people. The regulator assesses all GMOs on a case-by-case basis. Factors considered here include the effect of the modification, provisions for limiting the persistence of the GMO in the environment, the extent of the proposed release, and the likely impacts of the research on human health and safety.

Secondly, if the regulator considers that the GMO may pose significant risks to the health and safety of people or the environment, the regulator must release the application for a formal round of **public consultation**—including advertisements in newspapers.

The regulator is required to provide a copy of the application (excluding any that has been deemed by the regulator as commercial-in-confidence) to anyone that requests a copy.

Following this, there is a **government consultation** period where advice on possible risks must be sought from the Commonwealth Environment Minister, the Gene Technology Technical Advisory Committee (GTTAC), the states and territories, relevant Commonwealth Government agencies and relevant local councils.

Next, before making decisions, the regulator may call public hearings, commission independent research, undertake literature reviews or consult with experts to gather further information about any potential risks posed by the GMO dealings.

The regulator must then prepare a **risk assessment and risk management plan**. This involves identifying any risks, and how these risks can be managed to ensure that they do not eventuate.

Once the risk assessment and risk management plan has been drafted, it is released for **public input**. This consultation occurs in the same manner as the previous public consultation. Finally, the regulator may issue a license subject to certain conditions, ask for further information from the applicant, or deny an applicant a license.

## Assessing and managing risk

The potential risks associated with GM crops are carefully managed. Some of the issues considered as part of the regulator's risk assessment process include those listed below.

- Can genes move from a GM plant to a weed?
- Can GM crops transfer genes to non-GM crops?
- Will GM crops create herbicide resistant weeds?
- Could insects become resistant to GM crops?
- Are there any unintended effects on insects?

## Field trials for GM crops

During the development of a GM crop, the crop undergoes extensive testing and assessment as outlined above. What begins as a scientific idea takes eight to 13 years to become a commercial reality. The field trial process is integral from a crop performance and risk assessment perspective. The crop will begin as a small plant in a laboratory, and from here, become several plants in a glasshouse. Once the plants have undergone assessment in the glasshouse, they then progress to a field trial, providing the regulator is satisfied that the crop poses no unmanageable risk to human health or the environment.

The first field trial for a GM crop is often only the size of an average backyard or suburban vegetable patch. The trial is established to assess how the crop will perform in its true environment, having spent several years of development in a glasshouse. It may take a few years or seasons before a field trial is actually the size of a paddock.

Field trials are conducted to assess the GM crop, develop management guidelines, and also to allow the developer to select the best variety to bring to market — the variety most suited to a particular region, or to certain environmental conditions.

### Field trials and regulation

For a field trial to go ahead, the product developer must have approval from the OGTR. When this approval is granted, a number of conditions and field management guidelines may also be imposed by the regulator.

All GM crops are judged on a case-by-case basis by the GTR to develop the necessary field trial management guidelines. Field trial management guidelines will differ between crops. This is not just because the commodity may be different (for example cotton and canola) but also because the genetic modification may be different (such as insect resistance and herbicide tolerance). Such management guidelines are not restricted to field trials, as commercial licence approvals may also be subject to certain management conditions being in place.

### Field management guidelines — an example

For a decade, GM insect-resistant cotton has been commercially available in Australia. Prior to 1996, Australian cotton growers spent approximately \$200 million annually on insecticides, and most of this expense targeted the heliothis caterpillar, the cotton industry's worst pest.

This first commercial insect-resistant GM cotton contained a gene from a soil bacterium — *Bacillus thuringiensis*, hence its common name Bt cotton. The cotton was marketed under the name Ingard®. The inserted gene produced a protein that killed the heliothis pests when they fed on the cotton plants.

Early in its development, regulators and scientists recognised the potential of heliothis to develop resistance to the Bt gene, thus reducing the cotton's effectiveness. For this reason, both during field trials and in the commercial production of the GM cotton, the OGTR, in conjunction with the cotton industry, established a number of field management and growing guidelines. These included:

- 'refuges' of non-GM cotton had to be grown around GM cotton to minimise the chance of the heliothis developing resistance to the introduced Bt protein.
- the industry 'capped' the use of the insect-resistant cotton to one-third of the entire cotton crop each season — further reducing the chance of resistant insects developing.

The introduction of this GM cotton resulted in a reduction in pesticide use by around 50 per cent per year. Since the introduction of Bollgard II (see below), Bt cotton has now been phased out. The use of Bollgard II by the cotton industry has reduced pesticide use by approximately 85 to 90 per cent over conventional varieties.

### Under constant watch

Field trials are under constant scrutiny by the regulatory body and are subject to random inspections. Also, should field management guidelines be breached for any reason, the organisation which applied to the regulator for the field trial and any person associated with the trials, including the grower, are required to report the breach immediately to the regulatory body - so that corrective action can be undertaken.

Post harvest monitoring of sites where field trials of GM crops have been undertaken is commonly required for several years as part of the risk management regime surrounding such trials.

Field trials are an integral component in developing a new crop — without field trials to assess how a product performs in the paddock, the crop will not progress to the commercialisation phase.

## Regulatory review

Two reviews of Australia's gene technology legislation have been undertaken since the Gene Technology Act came into force in 2001. The first review occurred in 2006, and the second in 2011.

The first review concluded that the existing scope of the Act should be maintained, and that the aim of the Act — the protection of the health and safety of people and the environment — is being achieved. It found the Act to be rigorous, transparent, appropriate and effective. However, according to the review, the operational experience of the first four years has highlighted the need for some amendments to the regulatory system, such as improving the consultative structure and process, and providing clearer distinction between field trials and commercial releases of GMOs.

One review recommendation related to the extent to which state bans on the growing of GM crops had undermined the nationally consistent framework intended by the regulatory system by going against the federal regulator's decisions. The review noted that there was no evidence of adverse impacts on markets, and concluded that the bans were having detrimental rather than beneficial impacts. It recommended that all jurisdictions should reaffirm their commitment to a nationally consistent scheme and work together to develop a national co-existence framework.

The second review also had several recommendations relating to state governments. It recommended that 'those jurisdictions with GM moratoria that have not been reviewed in the last three years commit to reviewing them by the end of 2014', and it recommended 'governments in Australia maintain a science-based precautionary approach to the regulation of gene technology'.

## State governments and GM crops

There is provision within Australia's federal gene technology legislation to create zones free of GM crops. Under the *Commonwealth Gene Technology Act 2000*, the Ministerial Council, comprising of federal, state and territory ministers, has the opportunity to issue a policy principle, 'Recognising areas, if any, designated under state law for the purpose of preserving the identity of one or both of GM or non-GM crops for marketing purposes.'

## Introducing a policy principle

The Ministerial Council agreed in 2003 to issue a policy principle to recognise the rights of state and territory governments to designate zones for GM or non-GM crops for marketing purposes.

This means that the Federal Gene Technology Regulator's decision to grant a commercial release licence for a GM crop must recognise any laws the states and territories make in respect of preserving the identity of GM and/or non-GM crops for marketing purposes. For example, when a state government implements a policy principle recognising a GM-free area, in granting any GM crop licence, the regulator must respect this area as GM-free and exempt it from any licence approval.

As GM canola reached its final assessment for commercial release by the OGTR, some state governments expressed concerns about the market impacts of the new varieties, and proceeded to implement legislation to allow them more time to consider these issues.

## State governments — current status

The **Australian Capital Territory** (ACT) introduced a moratorium on the commercial release of GM food crops in the ACT in 2004. The latest legislation review occurred in 2011. The ban remains current. The ACT continues to support licensed, scientific research into genetically modified organisms (GMOs) being conducted in the territory.

The **NSW** Government implemented a ban on the cultivation of commercial GM canola in 2003. Since then, the legislation has been reviewed, extended and modified on several occasions. The latest version of the legislation was reviewed in 2011 and extended until 2021.

The change of relevance to commercial GM canola cultivation occurred in July 2007, when the NSW Government established an Independent Review Panel to re-examine the impact of the moratorium on the commercial cultivation of GM canola in the state. The review panel examined market acceptance of GM canola and found that the concerns about the impact of GM canola on markets and trade had largely been resolved, with strong evidence indicating that the introduction of GM canola to NSW would have minimal impact on market access or prices.

Following the panel review, the GM canola specific moratorium orders were replaced with a blanket moratorium on all GM food crops. The amended

legislation provides for the approval of the commercial cultivation of a specific GM food crop where the relevant industry makes an application which addresses criteria on industry preparedness to manage the GM food crop. The application is assessed by an expert committee which provides advice to the minister.

A representative of the canola industry made such an application in 2008 the minister announced the approval of the commercial cultivation of GM canola in NSW. Genetically modified cotton has been commercially produced in NSW since 1996.

Both the **Northern Territory** and **Queensland** governments support the national gene technology regulatory scheme and have not implemented any further legislation.

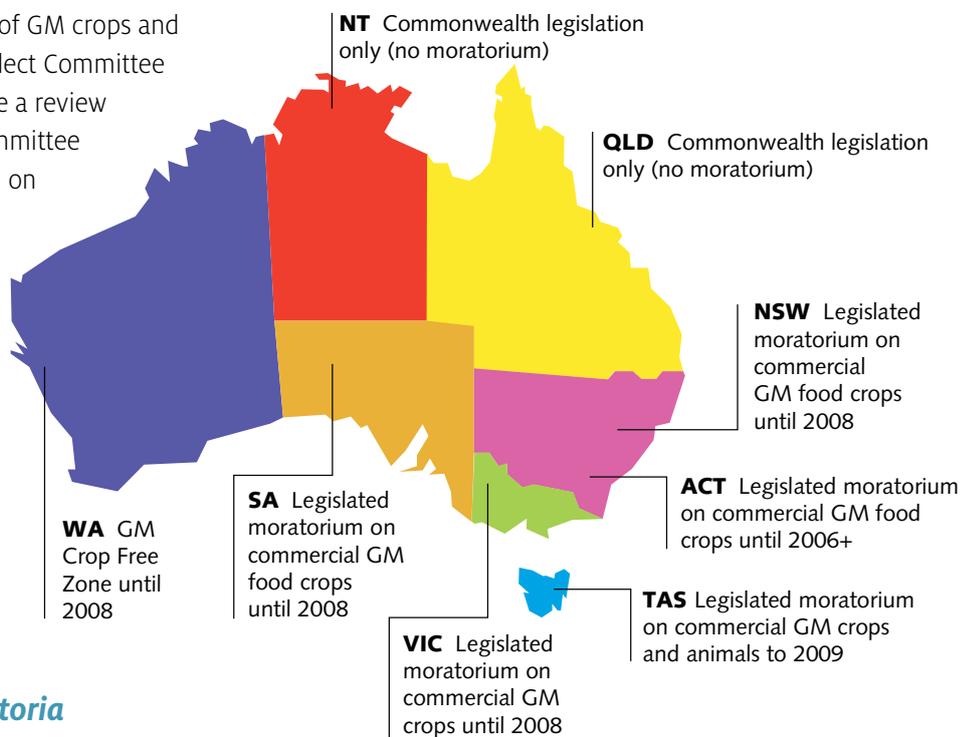
The **South Australian** (SA) Government implemented moratoria legislation in 2004 which designated the whole state as an area in which no GM food crops could be cultivated. The legislation was reviewed in 2007 by the Genetically Modified Crop Advisory Committee of SA. The committee prepared a report for the SA Minister of Agriculture, Fisheries and Forestry which examined any market and trade impacts on the introduction of GM crops. The committee recommended that the SA Government lift the moratorium except on Kangaroo Island. However, despite the review recommendations, in 2008 the SA Government extended the moratorium to September 2019. The legislation does provide for exemptions to allow field trials to continue under specific conditions.

The **Tasmanian** Government reviewed its moratorium on the commercial release of GM crops and animals in 2008. A Joint Select Committee was appointed to undertake a review of the moratorium. The committee recommended that the ban on the commercial production of GM food crops in the state be extended and reviewed after five years. The main reason for the recommendation was to allow Tasmania to stay 'GMO free' in order to gain a market advantage.

In 2007, the **Victorian** Government established an independent review panel to identify the impacts of the moratorium and any potential moratoria on the Victorian economy. The final report prepared for the Victorian Minister for Agriculture stated 'The panel finds no compelling market or price advantage that can be attributed to Australia's non GM status as a bulk canola exporter over the past four years.' Later that year, the government announced that it would let the moratorium on the commercial cultivation of GM canola expire in February 2008.

In December 2003, the *Genetically Modified Crops Free Areas Bill 2003* was passed by the **Western Australian** Parliament. In March 2004, the Premier designated the whole of the state as an area in which GM crops must not be cultivated. In November 2008, the newly elected Western Australian Minister for Agriculture and Food, granted an exemption under the *Genetically Modified Crops Free Areas Act 2003* for the commercial cultivation of GM cotton in the Ord River Irrigation Areas. More recently, following a successful trial of GM canola in 2009, the WA Parliament voted on 10 March 2010 to allow an exemption for the commercial cultivation of GM canola in the state.

In the future, it is likely that developers of each new food crop commodity approved by the Federal Gene Technology Regulator as safe to human health and safety and the environment will also need to consider how they approach each state's approach to commercialisations — in effect, navigating up to nine different systems.



## Local government and GM crops

Although local governments have no jurisdiction over GM food and crop regulation, a number of councils have considered the option of so-called Genetic Engineering (GE) Free Zones since the OGTR approved GM canola varieties for commercialisation in 2003.

### A zone free of GM crops — the reasoning

Some of the reasons councils wish to establish a zone free of GM crops include:

- uncertainty about the science behind gene technology, and the resulting GM crops, and how these are managed (including the field trial process)
- concern about the risks that such crops pose
- a belief that the local area can enhance its image and economic base by growing only non-GM crops
- a belief — based on ethics or religious grounds for example — that this technology should not be adopted.

### A zone free of GM crops — the establishment

In considering such a zone, councils must consider the wider implications of such a decision. Firstly, a national gene technology regulatory system is in place to ensure that gene technology is used appropriately in Australia, and that any commercial releases or trials of GM products take place under stringent conditions. Do councils have the expertise or resources to potentially duplicate or oppose such a science-based authority?

Secondly, councils do not currently regulate or determine what products can be grown on agricultural land. If councils intend to regulate GM crops, are they going to take on the regulation of all agricultural activities within their council boundary?

Thirdly, councils banning GM crops within their boundaries are effectively removing consumer and producer choice. Farmers need to select the method of agricultural production that best suits their needs and buying markets — be it organic, conventional or genetically modified. Will growers be compensated if the choices removed from them prove to be more economical?

**Legal considerations** — A number of councils have investigated the legal means by which they would establish a zone free of GM crops. Some councils, particularly in the eastern states of Australia, have considered including this within their Local Environment Plan (LEP) however, their investigations

have led to the general belief, that taking such an action, could place council in a position of liability if a GM crop, grain or seed were found within the council boundaries. Of course, councils seeking to establish such zones should seek independent legal advice.

**Logistics** — To establish a zone free of GM crops, the area would firstly need to be clearly defined. Councils would need to consider how they were going to achieve this, particularly where farmers' properties overlapped two shires. Once defined, many other logistical arrangements would need to be considered. These include:

- How will council administer and enforce such a zone?
- Will compliance/inspection officers need to be employed and provided appropriate training?
- Will council need to construct testing centres at major entry points to the shire to assess transport vehicles carrying grain, and agricultural machinery travelling through the shire?
- How will this new zone be communicated to local citizens, transport carriers and tourists? Will council need to invest in a broad communication and advertising campaign?
- If a GM crop, grain, seed or carnation is found within the council area, what action will be taken? Is one GM grain considered a 'breach' under the GM free crop zone?

**Economic considerations** — Establishing a zone free of GM crops has the potential to impose considerable economic costs. The potential costs involved were the subject of a report commissioned by Avcare, now CropLife Australia, several years ago. The report estimated that the cost of maintaining such a zone would be approximately \$2,260,250 per annum — including staff, infrastructure, testing equipment, communication and advertising, legal costs, and quality assurance programs for farms.

Of course, such a zone may also impact on issues beyond the shire. For example, if trucks carrying GM grain are required to travel around the shire or zone, than this may impact and deteriorate surrounding roads.

Australia's multi-million dollar grains industry is confident in allowing Australian growers access to a technology successfully being used by its global competitors. Local governments considering banning such crops need to consider if they are as confident and considered about removing such a choice?

## Gene technology — community consultation

In Australia, all gene technology work is regulated by federal regulatory bodies. This regulation extends from scientific laboratories, through to final products — including crops and food products. During the development of a GM product the key regulatory agency — the Office of the Gene Technology Regulator — provides one or more consultation periods, to allow relevant local governments and members of the community, the opportunity to provide comment and input. Interested individuals and organisations can also join the regulator's mailing list by visiting the website at [www.ogtr.gov.au](http://www.ogtr.gov.au).

Community views are also considered during the process, through the Gene Technology Ethics and Community Consultative Committee (GTECCC).

Before establishing a GE Free Zone, or zone free of GM crops, it is important for local government authorities to investigate all options and considerations, and to ensure that in making such decisions, wide consultation is sought. Councils should also seek independent legal advice.

## Further reading

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