



## Information Paper 2

# 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 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; and,
- 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 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; and,
- 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?**

The crossing of a modified gene to a weed can occur only if that GM crop has a local wild 'relative' capable of interbreeding. The process of interbreeding is known as outcrossing. Researchers planting GM crops that do have a local weed 'relative' must take

this fact into account when applying for permission to plant the crop. As part of the application process, the Regulator conducts a rigorous assessment of the outcrossing risk. If the risk is assessed as extremely low, the field trial will proceed, but only under conditions imposed by the Regulator.

As a part of the risk assessment process, scientific experts are involved in examining the key issues. For example, scientists have conducted research into the potential of GM canola outcrossing with its weedy relative. The researchers detected very low levels of outcrossing – one in 26 million.

The risk of outcrossing is managed on a case-by-case basis, taking into account the GM crop, the interbreeding potential and local weed 'relatives'.

#### **Can GM crops transfer genes to non-GM crops?**

Cross-fertilisation or gene transfer can occur between both non-GM crops and GM crops. A modified gene in a GM crop could possibly spread to a related, conventional crop by wind or insects to another crop.

If the GM and conventional crops flower at different times, cross-fertilisation cannot occur. Therefore there is no risk. If the two crops flower at the same time, they may be required to be kept separate. The Regulator requires such separation during field trials. This is based on studies that have shown that only very small amounts of viable pollen drift substantial distances from crops.

The risk of cross-pollination is further reduced by competition. If pollen from a GM crop drifts into a conventional crop that is also flowering, it must compete against the pollen from the conventional crop.

#### **Will GM crops create herbicide resistant weeds?**

Herbicide resistant weeds are an issue in both conventional and GM crops. Over time, weeds can develop a resistance to, or 'tolerance for' specific herbicides. As a result, increasing amounts of herbicide, or an alternative herbicide, must be used.

The risk of herbicide resistance can be limited by good farming practices such as rotating crops and herbicides as part of a weed management plan. Conventional weed control methods, such as maintaining stubble from previous crops can also be used. This reduces the number of herbicide applications and the amount of herbicide used, further reducing the risk of resistance.

Genetically modified crops incorporating insecticides or designed for use with a particular herbicide are also subject to regulatory oversight by the Australian

Pesticides and Veterinary Medicines Authority (APVMA).

### **Could insects become resistant?**

Insects can and do develop resistance to insecticides. This risk must be managed, regardless of whether the crop is non-GM or GM. For example, potential existed for insects to develop resistance to the first commercially available GM insect resistant cotton (known as Bt cotton and marketed as Ingard®) so management plans were implemented. Those licensed to grow the crop were required to plant refuges of non-GM cotton around the GM crop, in order to reduce the chance of the target pest developing resistance. These refuges provided a pool of non-resistant adults for any resistant heliothis to mate with, and, therefore, minimised the chance of a Bt resistant population building up. New insect resistant varieties are now being utilised which further reduce the incidence of insect resistance developing.

### **Are there any unintended effects on insects?**

Insect resistant GM plants produce their own insecticides to control particular insect pests. Field investigations by United States agricultural and university researchers suggest that GM crops actually preserve the 'good' insects - and reduce unintended effects - by lowering overall insecticide use.

In particular, a focus on the monarch butterfly in North America, resulted in a two-year study being undertaken and published in the Proceedings of the National Academy of the Sciences (PNAS) of the United States of America. The study suggested that the impact of Bt corn pollen on monarch butterfly populations was "negligible".

In Australia, the impact of Bt cotton on beneficial and non-target insects had to be thoroughly investigated prior to the crop being commercialised to prove that such an impact was not negative.

### **Why are antibiotic-resistant genes being used?**

Many GM crops contain antibiotic resistance 'marker' genes. Marker genes are used by researchers to identify when they have successfully introduced the new gene into a plant cell.

The risk issue in this case is whether the antibiotic resistance genes can transfer to human bacteria when the modified plant is consumed. Both the World Health Organisation (WHO) and the European Commission, Directorate General on Consumer Policy and Consumer Health Protection, concluded that there is no evidence that genes from plants have ever transferred to animal or human bacteria. They also concluded that the risk of transfer is

almost non-existent due to the number and complexity of the steps required for gene transfer.

Nevertheless, researchers are developing a better alternative to antibiotic-resistant 'marker' genes for GM crops, to address public concerns.

### **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.

### **What is a field trial?**

While it is called a 'field trial', 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 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, 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

After months of community consultation and consideration, a review of Australia's gene technology legislation was tabled in the Australian Parliament at the end of April 2006.

The 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, 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 regulatory changes resulting from this review became effective in July 2007, and are available from:

[www.health.gov.au/internet/ogtr/publishing.nsf/Content/regs-amend-1](http://www.health.gov.au/internet/ogtr/publishing.nsf/Content/regs-amend-1)

### Further information

Office of the Gene Technology Regulator (OGTR)  
[www.ogtr.gov.au](http://www.ogtr.gov.au).

Proceedings of the National Academy of the Sciences (PNAS) of the United States of America  
[www.pnas.org/content/98/21/11937.abstract?sid=e0182995-bd14-43a7-92c9-5e4d2580e5cb](http://www.pnas.org/content/98/21/11937.abstract?sid=e0182995-bd14-43a7-92c9-5e4d2580e5cb)

'Safety aspects of GM foods of plant origin'. Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology (2000).  
[www.who.int/foodsafety/publications/biotech/en/ec\\_june2000\\_en.pdf](http://www.who.int/foodsafety/publications/biotech/en/ec_june2000_en.pdf)