

# Factsheet

## 16. Genetically modified organisms

*Genetic modification is a technique that enables the transfer of genes between related and unrelated organisms, even across species barriers. Introducing these new combinations produces genetically modified organisms (GMOs) with specific purposes (for example, introducing them into existing crop plants might produce insect resistance). The release of GMOs has environmental, social and economic impacts, many of which are unknown as yet.*

*This fact sheet outlines the regulatory regime which applies to genetically modified organisms in Western Australia. The principal legislation applying to GMOs is the Commonwealth Gene Technology Act 2000 (the GT Act). The Western Australian Genetically Modified Crops Free Areas Act 2003 (the GMCFA Act) relates only to crops.*

*The WA Parliament is considering the Gene Technology Bill, (GT Bill) which will ensure that the same law applies to all dealings with GMOs, including any that cannot be covered by the GT Act because of Constitutional limitations.*



### What is a GMO?

A GMO is defined in the GT Act and the GMCFA Act as an organism that has been modified by gene technology or has inherited a particular genetically modified trait from such an organism. The GT Act defines an "organism" as any biological entity that is viable, capable of reproduction or capable of transferring genetic material.

The GT Act does not regulate matters which are concerned with products containing GMOs (as opposed to GMOs themselves), as such matters are covered by other agencies. Specifically, the GT Act does not deal with:

- Food safety and labeling (which is dealt with by the Australia New Zealand Food Authority);
- Medicines and drugs (dealt with by the therapeutic goods administration); and
- Registration of chemicals (which is dealt with by the Australian Pesticides and Veterinary Medicines Authority).



### What authorities are responsible for regulating GMOs?

Under the GT Act, a Gene Technology Ministerial Council makes policy decisions about the Act. This body is made up of Ministerial representatives from each of the Commonwealth, States and Territories.

The GT Act establishes the independent office of the Gene Technology Regulator ("the Regulator"). The Regulator is a single person. However, that person is assisted by the Office of the Gene Technology Regulator. The Regulator is responsible for authorising dealings with GMOs and collecting and providing information about GMOs.

The GT Act established a Gene Technology Technical Advisory Committee, a Gene Technology Community Consultative Committee and a Gene Technology Ethics Committee. These are expert committees from which the Regulator and the Ministerial Council may request advice.



### How are GMO's regulated?

The GT Act prohibits all "dealings" with GMOs unless an authorisation applies to that dealing. "Dealings" with a GMO are defined under the GT Act to include:

- (a) conducting experiments with a GMO;

#### Important disclaimer:

This Fact Sheet is for general information purposes. Important legal details have been omitted to provide a brief overview of this area of the law. If you require legal advice relating to your specific circumstances you should contact the Environmental Defender's Office WA (Inc) or your solicitor. The EDO takes no responsibility for any loss or damage resulting from any error in this Fact Sheet.

- (b) making, developing, producing or manufacturing a GMO;
- (c) breeding a GMO;
- (d) propagating a GMO;
- (e) using the GMO in the course of manufacturing a thing that is not a GMO;
- (f) growing, raising or culturing a GMO;
- (g) importing a GMO;

and includes the possession, supply, use, transport or disposal of a GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (g).

### What authorisations are available for dealings with a GMO?

Dealings with GMOs may be authorised in one of four ways:

#### *Exempt dealings*

The *Gene Technology Regulations 2001* set out various “exempt” dealings, including dealings with “gene-knockout” mice (those mice whose genetic modification involves deletion or inactivation of a specific gene). Any exempt dealings which do not involve an intentional release of a GMO into the environment are authorised, and do not require any further approval under the GT Act.

#### *Notifiable Low Risk Dealings*

The *Gene Technology Regulations 2001* set out “notifiable low risk” dealings, including any dealings involving a genetically modified flowering plant which does not involve the plant being grown to flowering stage. Any notifiable low risk dealings which do not involve the intentional release of a GMO into the environment are authorised, and do not require any further approval under the GT Act.

#### *GMOs listed on the Register*

If the Regulator is satisfied that any risks posed by a particular dealing are minimal, and that it is not necessary for persons undertaking that dealing to have a licence in order to protect the health and safety of people or to protect the environment, the Regulator can list that dealing on the GMO Register. That dealing will then be authorised and, subject to any conditions of the dealing being met, the dealing will not require any further approval under the GT Act.

#### *Licensed dealings*

Any other dealings, regardless of whether or not they involve the intentional release of a GMO into the environment, will only be authorised if they are the subject of a licence issued by the Regulator.



### What penalties apply if someone deals with a GMO without an authorisation?

It is an offence under the GT Act to deal with a GMO without one of the authorisations listed above. An offence will be an “aggravated offence” if the unauthorised dealing causes significant damage to the environment and the person either intended to, or was reckless as to, whether that conduct would cause such damage. The maximum penalties under the GT Act are:

- \$220,000 or five years jail for an aggravated offence,
- \$55,000 for an offence involving some knowledge about, or recklessness as to, whether the dealing was authorized,
- \$22,000 for an offence where there is no evidence of any intention or recklessness.

The latter is a strict liability offence. No element of knowledge or intention needs to be established, so it is possible to be liable without being aware that anything is wrong.



### How are the environmental impacts of a proposed GMO licensed activity assessed?

Before issuing a licence to authorise a dealing, the Regulator must prepare:

- ♦ a risk assessment and
- ♦ a risk management plan in relation to the dealings proposed to be authorised by the licence.

In preparing the risk assessment, the Regulator must take into account the risks posed by that dealing to the health and safety of people or risks to the environment, any previous risk assessment (whether in Australia or overseas), whether the applicant is a suitable person to hold the licence, and any submissions or advice received about the proposal. The Regulator must also consider the long and short term potential of the GMO to:

- a) be harmful to other organisms;
- b) adversely affect any ecosystems;
- c) transfer genetic material to another organism;
- d) spread, or persist, in the environment;
- e) have, in comparison to related organisms, selective advantage in the environment (such as an advantage which would increase the growth rate or resistance of the GMO); and
- f) be toxic, allergenic or pathogenic to other organisms.

In preparing the risk management plan, the Regulator must take into account the means of managing any risks posed by those dealings in such a way as to protect the health and safety of people and the environment, as well as any submission or advice received about the proposal.

The Regulator may not issue a licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in such a way as to protect the health and safety of people and the environment.



### Can conditions be placed on a licence?

It is a condition of every licence that the licence holder must allow the Regulator (or a person authorised by the Regulator) to enter any premises where a dealing is being undertaken for the purposes of auditing or monitoring that dealing. It is also a condition of every licence that the licence-holder inform the Regulator if they become aware of additional information as to any risks to the health and safety of people, or to the environment, or of any unintended effects of the dealings authorised by the licence.

The Regulator has broad powers to impose other conditions as the Regulator thinks appropriate.

Licences are valid for the period specified in each individual licence – there is no maximum period for a licence.

It is an offence for a person who has a licence to breach a condition of their licence.



### Can a licence be cancelled?

The Regulator may suspend or cancel a licence if the Regulator:

- believes on reasonable grounds that the licence holder has breached a condition of the licence or otherwise committed an offence against the Act;
- is satisfied that the licence holder is no longer a suitable person to hold the licence; or
- becomes aware of risks associated with the continuation of the dealings authorised by the licence, and is satisfied that the licence holder has not proposed, or is not in a position to implement, adequate measures to deal with those risks.



### How can the public be involved in decisions under the GT Act?

Once the Regulator has prepared a risk assessment and risk management plan in respect of a licence application, the Registrar must advertise this fact in a State newspaper and on its website: [www.ogtr.gov.au](http://www.ogtr.gov.au) The public must be given at least 30 days to make submissions on the risk assessment and risk management plan.

In addition, if the Regulator receives an application for a licensed dealing which may pose significant risks to the health and safety of people or the environment, the Regulator must advertise the licence application in a State newspaper and on its website before it prepares a risk assessment and risk management plan. The public must be given at least 30 days to make submissions on the licence application.

The public does not need to be consulted about other matters under the GT Act and the GT Bill. Specifically, they do not require that the public be consulted about:

- policy guidelines or codes of practice;
- a variation of a licence to release a GMO into the open environment;
- declarations that a GMO dealing is a low risk dealing or an exempt dealing; or
- the inclusion of a GMO on the Register.



## Can the Regulator's decisions be reviewed?

Licence applicants and licence holders may apply to the Federal Administrative Appeals Tribunal for a review of the merits of decisions under the GT Act. However, no such review rights are available to other people. This means that neighboring landowners, organic producers and community groups are excluded from seeking review of the merits of the Regulator's decisions, even though they may be affected by those decisions.

Any "person aggrieved" may apply for an injunction to restrain a person from engaging in conduct that would be an offence under the GT Act. The Courts have found that in order to be considered a "person aggrieved", a person must suffer not just as any member of the public, but as a person who suffers a grievance beyond that suffered by an ordinary member of the public. This means it will, in all likelihood, be only those people whose *commercial* interest will suffer due to a proposal who will be able to bring such proceedings.

If the Regulator has made an error of law in making the decision, it may be possible to have that decision reviewed in the Federal Court. You should seek legal advice if you believe the Regulator has made an error of law.



## What information is available about GMO activities?

The Regulator must maintain a publicly accessible Record about GMO dealings. The Record is available at: <http://www.ogtr.gov.au/gmorec/index.htm> This Record must contain details about licences, notifiable low risk dealings, matters on the GMO Register and GMO products. However, information can be excluded from the Record if it is confidential commercial information.



## State Laws

### The Gene Technology Bill 2005 (WA)

The Western Australian Gene Technology Bill mirrors the Federal legislation. The Western Australian legislation is needed because the Federal government's legislative power is limited to the heads of power in the Commonwealth Constitution. In practice, this covers most dealings with GMOs, but there are some gaps. By contrast, the State government's legislative powers although limited to State territory are not limited as to subject matter.

### Genetically Modified Crops



## Summary: key opportunities for public involvement

The GT Act allows any person to:

1. Make submissions to the Regulator about any licence application before the Regulator prepares a risk assessment or risk management plan for that licence application, if the proposed licence may pose significant risks to the health and safety of people or the environment;

Under the *Genetically Modified Crops Free Areas Act 2003* (WA), the Minister for Agriculture may order that genetically modified crops must not be cultivated within a designated area in Western Australia (**a GMO free order**).

A genetically modified crop (**GMC**) means a crop that consists of or includes plants that are genetically modified organisms (**GMO**). The GMCFA Act adopts the same definition of GMO's as found in the GT Act. Cultivate includes breeding, propagating, growing, raising or culturing plants, or parts of plants, for that crop.

In March 2004, the Minister exercised this prerogative, designating the whole state of WA to be GMO free from that date onwards.

Pursuant to any order made by the Minister, the CEO of the Department of Agriculture has the power to order the destruction of GM crops that contravene any of the Minister's orders, and authorised officers may, in order to enforce

this, enter land and take possession of crops and destroy them.

Some exemption orders have been published under the Act. These include exemptions for GM canola trials and for a few GM cotton plants to be grown in pots for display purposes at the Gene Technology conference. These and other exemptions may be found in the Gazette Notices on the State Law Publisher 's website ([www.slp.wa.gov.au](http://www.slp.wa.gov.au))

### Do State environmental laws apply to GMOs?

There is an important legal issue as to whether laws such as the State environmental assessment and State environmental harm laws apply to GMOs. There are conflicting legal opinions about it. You should seek legal advice if you have a particular legal issue about which you are concerned.

2. Make submissions on any risk assessment and risk management plan prepared by the Regulator about a licence application; and
3. Make submissions at any public hearing which the Regulator holds into a licence application.

In addition, a person or organisation can, in some circumstances, take legal action against a person who deals with a GMO without, or outside the scope of, an authorisation under the GT Act.

### Where do I go to get more information?

Office of the Gene Technology Regulator.  
Commonwealth Department of Health and Ageing.  
MDP54 PO Box 100 Woden ACT 2606  
Tel 1800 181 030 | Fax 02 6271 4202  
<http://www.ogtr.gov.au/index.htm>

## The Environmental Defender's Office WA (Inc)

The Environmental Defender's Office WA (EDO) is a community legal centre specialising in public interest environmental law.

The objects of the EDO include:

- ◆ to provide community groups and individuals with legal advice and representation to help protect the environment;
- ◆ to promote law reform that improves environmental protection; and
- ◆ to provide community education about environmental law.

The EDO is a non-profit, non-government organisation. The EDO receives its principal funding from the Federal Attorney-General's Department. However, these funds are limited and donations from the public provide a vital source of funds for many of our activities. Donations over \$2 are fully tax deductible. The EDO also welcomes people with a commitment to the environment to join as members.

If you require legal advice on an environmental issue or wish to find out more about the EDO, please contact us at the following address:

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