



# Genetically Modified Organisms

## ***An Introduction to 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, and this has caused community concern.*

*This fact sheet outlines the Western Australian and Commonwealth regulatory regime which controls the use of genetically modified organisms in Western Australia.*

## **How are GMOs regulated in Western Australia?**

The principal legislative instruments applying to GMOs are the Commonwealth *Gene Technology Act 2000* (Cth) ("*Cth GT Act*") and the Western Australian *Gene Technology Act 2006* (WA) ("*WA GT Act*"). These two Acts are substantially similar.

The enactment of the *WA GT Act* brings Western Australia formally into a national scheme applying to all dealings with GMOs. Comprehensive, uniform state legislation on GMOs was enacted because the scope of the *Cth GT Act* was restricted by the limits that are placed on the Commonwealth's power to legislate on certain subjects by the Constitution. The interaction of the State and Commonwealth legislation is determined by the intergovernmental *Gene Technology Agreement*.

The *Cth GT Act* and the *WA GT Act* only regulate matters that relate to GMOs themselves, rather than products that contain GMOs, as such matters are addressed by other agencies. Specifically, the *Cth GT Act* and the *WA GT Act* do not deal with food safety and labeling, medicines and drugs, or registration of chemicals.

In addition to the *WA GT Act*, Western Australia has also enacted the *Genetically Modified Crops Free Areas Act 2003* (WA), which relates specifically to the power of the Government to prevent the cultivation of genetically modified ("GM") crops in Western Australia.

## **What is a GMO?**

A GMO is defined in the *Cth GT Act*, the *WA GT Act* and the *Genetically Modified Crops Free Areas Act 2003* (WA) as an organism that has been modified by gene technology, has inherited a particular genetically modified trait from such an organism, or has been declared by the regulations to be a GMO.

The *Cth GT Act* and the *WA GT Act* defines an "organism" as any biological entity that is viable, capable of reproduction or capable of transferring genetic material.

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## Authorities responsible for regulating GMOs

The *Gene Technology Agreement* established a Gene Technology Ministerial Council to make policy decisions about the *Cth GT Act*, and the operation of the national GMO scheme (of which enactment of the *WA GT Act* is a part). This body is made up of Ministerial representatives from each of the parties to the Gene Technology Agreement, i.e. from each of the States and Territories and the Commonwealth.

The *Cth GT Act* established the independent Office of the Gene Technology Regulator ("the Regulator"). The Regulator is responsible for authorising dealings with GMOs and collecting and providing information about GMOs.

The *Cth GT Act* and subsequent amendments has also established a Gene Technology Technical Advisory Committee, and a Gene Technology Ethics and Community Consultative Committee. Both of these committees provide advice to the Regulator and the Gene Technology Ministerial Council.

## Controls on dealings with GMOs under the *Cth GT Act* and the *WA GT Act*

The *Cth GT Act* and the *WA GT Act* prohibit all "dealings" with GMOs unless the dealing is authorized by a licence, is an exempt dealing, a notifiable low risk dealing, a dealing included on the GMO Register, an emergency dealing, or an inadvertent dealing.

"Dealings" with a GMO are defined to include:

- (a) conducting experiments with a GMO;
- (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, any dealing.

## Licences to deal with GMOs

A person can apply to the Regulator for a licence to authorise specified dealings with specified GMOs. There are different processes depending on whether or not the application involves the intentional release of a GMO into the environment.

Before issuing a licence to authorise a dealing, the Regulator must prepare a risk assessment and a risk management plan in relation to the proposed dealing with the GMO.

In preparing the risk assessment and risk management plan, the Regulator must take into account the risks posed to the health and safety of people and to the environment. In the case of risk assessments and risk management plans for the intentional release of GMOs, the Regulator must consult and take the

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advice of the Commonwealth Minister for Environment, the States, the Gene Technology Technical Advisory Committee, and any other prescribed agency.

Once the Regulator has prepared a risk assessment and risk management plan, the Regulator must advertise this fact in the Gazette, a State newspaper and on its website. The public must be given at least 30 days to make submissions, or 50 days if the Regulator thinks that the proposed dealing may pose significant risk to the health and safety of people or to the environment.

Before issuing a licence for the intentional release of GMOs, the Regulator must also take into account things like any previous revocation or suspension of a licence (whether in Australia or overseas), and whether the person or body corporate has the capacity to meet the conditions of the licence. The Regulator must also consider the 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.

## Licence Conditions

A GMO licence is subject various conditions, including in regards to notification, monitoring and auditing, and informing the Regulator of any contraventions or of any information about additional risks of which the licence holder becomes aware. The Regulator also has broad powers to impose other conditions as the Regulator thinks appropriate. It is an offence for a licence holder to breach a condition of their licence.

## Cancellation of a licence

Licences are valid for the period specified in each individual licence or until it is cancelled or surrendered.

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.

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## Review of licence decisions

Licence applicants and licence holders may apply to the Federal Administrative Appeals Tribunal for a review of the merits of decisions under the *Cth GT Act* and the *WA GT Act*. This means that neighbouring landowners, organic producers and community groups are excluded from seeking review on 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 the Supreme Court of Western Australia in the case of the *WA GT Act*, or the Federal Court of Australia in the case of the *Cth GT Act*, to restrain a person from engaging in conduct that would be an offence under the *WA GT Act* or the *Cth GT Act*. A "person aggrieved" must be affected by the action to a greater degree than an ordinary member of the public.

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

## Exempt dealings

The *Gene Technology Regulations 2001* (Cth) and *Gene Technology Regulations 2007* (WA) set out various "exempt" dealings which involve a very low degree of risk such as contained laboratory research on well understood organisms and processes for creating and studying GMOs. 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.

## Notifiable Low Risk Dealings

Schedule 3 of the *Gene Technology Regulations 2001* (Cth) and *Gene Technology Regulations 2007* (WA) sets out dealings that are and are not "notifiable low risk" dealings. 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.

## 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.

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## Emergency Dealings

Under the *Cth GT Act*, the Commonwealth Minister for Environment may make an emergency dealing determination authorising dealings with GMOs for a limited period of time in an emergency. The Minister must be satisfied that there is an actual or imminent threat to people or the environment, that the emergency dealing determination would adequately address the threat and that the risks posed are able to be managed so as to protect people and the environment.

## Inadvertent Dealings

Where a person finds themselves inadvertently dealing with a GMO, if they are able to satisfy the Regulator that they have come into possession inadvertently, the Regulator may treat them as having made an inadvertent dealings application and grant the person a licence to deal with GMOs. The *WA GT Act* does not contain this provision.

## Record of GMO dealings

Under the *WA GT Act* and the *Cth GT Act*, the Regulator must maintain a record of GMO dealings. Under the *Cth GT Act*, the Regulator must permit any person to inspect the record.

The record must contain details about licences, including licence holders, authorised dealings and any licence conditions, and also information about notifiable low risk dealings. Under the *Cth GT Act*, the register must also contain information relating to emergency dealings. Confidential commercial information must be excluded from the record.

## Offences under the *WA GT Act* and the *Cth GT Act*

It is an offence under the *GT Act* to deal with a GMO without one of the methods of authorisation discussed above. An offence will be an "aggravated offence" if the person intended to or was reckless as to whether their unauthorised dealing would cause significant damage to the health and safety of people or to the environment.

The *WA GT Act* and the *Cth GT Act* also establish a strict liability offence for dealing with a GMO when that person knows that it is a GMO. For strict liability offences, no element of intention needs to be established. This could mean that farmers affected by the unintended presence of GMOs in their crops may face liability for unauthorised dealing.

Farmers could also become liable for infringement of the intellectual property rights of the seed manufacturer, and may also be in breach of fair trading legislation if they do not comply with labeling requirements about GM content.

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## Controls on GMOs in State and Commonwealth environment Acts

There are no specific GMO or invasive species controls within the Commonwealth *Environment Protection and Biodiversity Conservation Act 1999* (Cth), however this act may be triggered if GMO activities are likely to have a significant impact on a matter of national environmental significance (see [Fact Sheet 6: Commonwealth Environmental Impact Assessment](#)).

The *Environmental Protection Act 1986* (WA) was amended in 2002 to include provisions on “environmental harm” which may improve its applicability to the environmental risks associated with GMO contamination. Causing environmental harm is an offence under the *Environmental Protection Act 1986* (WA). Environmental harm includes damaging native vegetation and the alteration of the environment to its detriment. This definition may be wide enough to include any damage that may be caused by the spread of GM crops into the native environment.

## Controls under the *Genetically Modified Crops Free Areas Act 2003* (WA)

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 or throughout the whole State. Pursuant to a GM crop free areas order, the Department of Agriculture has the power to order the destruction of GM crops that contravene any of the Minister's orders.

The *Genetically Modified Crops Free Areas Act 2003* (WA) also allows the Minister for Agriculture to issue exemption orders to allow trial cultivation of GM crops within designated GM crop free areas in Western Australia. Exemption orders have been granted for GM cotton and GM canola crops. Cultivation of Regulator approved GM canola was granted an exemption in January 2010. This resulted in over 70 000 hectares of Roundup Ready® canola being planted that year.

## Liability at Common Law

Australia has decided to rely on the existing common law to deal with liability issues that arise through the use of GMOs. This is consistent with the approaches taken by the United Kingdom, Canada and the United States. The US and Canada have been cultivating GMOs long enough for some case law to develop.

The economic impacts of GMO contamination may be actionable at Common Law in either private nuisance or negligence proceedings, however there have not yet been any cases brought in Australia to test the law in this area.

For more information on the Common Law in Australia, see [Fact Sheet 2: Common law: nuisance, negligence and trespass](#).

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## Opportunities for public involvement

- if you are concerned about an advertised risk assessment or risk management plan, for a new application for a GMO licence, you can make submissions to the Regulator;
- to know what licences have been approved in your area and their conditions, you can look up the GMO Record at: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1>
- if you would like more information about the use of Roundup Ready® Canola crops in Western Australia, you can contact the Department of Agriculture and Food; and
- if you are concerned about the legal implications of contamination of crops or the environment with GMOs, please seek legal advice.

## Contacts and further information

Office of the Gene Technology Regulator, Tel: 1800 181 030, [www.ogtr.gov.au](http://www.ogtr.gov.au)

Department of Health and Ageing (Commonwealth), Tel: 1800 020 103, [www.health.gov.au](http://www.health.gov.au)

Department of Agriculture and Food (WA), Tel: (08) 9368 3333, [www.agric.wa.gov.au](http://www.agric.wa.gov.au)

For copies of legislation, contact the State Law Publisher (Western Australian legislation),

Tel: (08) 9426 0000, [www.slp.wa.gov.au](http://www.slp.wa.gov.au), or Comlaw (Commonwealth legislation), [www.comlaw.gov.au](http://www.comlaw.gov.au)

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## 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 and State Attorney-General's Departments.

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:

Environmental Defender's Office WA (Inc)

Suite 4, 544 Hay Street, Perth WA 6000

Tel: (08) 9221 3030

Fax: (08) 9221 3070

Freecall: 1800 175 542 (for WA callers outside the Perth metropolitan region)

Email: [edowa@edowa.org.au](mailto:edowa@edowa.org.au)

## Thank you to our donors

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