

*For Who's Benefit? -
Evaluating Genetically Modified Organisms in Western Australia
from a Different Perspective*
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**The Regulatory Framework –
*Gene Technology Act 2000 (Cth) and the Gene Technology Bill 2001 (WA)***

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1 Introduction

This paper outlines the regulatory regime which applies to genetically modified organisms ("GMOs"). While the paper specifically refers to the Commonwealth *Gene Technology Act 2000* ("Commonwealth Act"), it is germane to WA as the *Gene Technology Bill 2001 (WA)* ("the State GMO Bill") currently mirrors (apart from minor differences) the Commonwealth Act.

In summary, the Commonwealth Act:

1. Defines GMOs as any organisms which are modified by gene technology or inherit particular traits from an organism which has been modified by gene technology.
2. Establishes the independent office of the Gene Technology Regulator ("the Regulator") to administer and make decisions under the legislation¹.
3. Establishes the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee (from which the Regulator may request advice).
4. Prohibits people from dealing with GMOs (including researching, manufacturing, producing, releasing or importing GMOs) without relevant approvals (such as a licence).
5. Establishes a scheme to assess the risks to human health and the environment associated with dealings with GMOs.
6. Creates a centralised, publicly available database of all GMOs and GMO products approved in Australia.

The paper also provides brief observations about the nature and coverage of the Commonwealth Act, highlights potential problems associated with that coverage, and explores whether GMO free zones may be implemented in WA.

2 A nationally consistent scheme to regulate GMOs

The Commonwealth Act (and the associated *Gene Technology Regulations 2001*) (Cth) came into force on 21 June 2001.

¹ Note: the Regulator is a single person.

In making the Commonwealth Act, the Commonwealth Parliament could not regulate all dealings with GMOs. This is because the Parliament can only make laws about particular matters which are listed in the Commonwealth Constitution, and neither GMOs specifically (nor the environment generally) are listed in the Constitution as matters about which the Commonwealth may make laws. The Commonwealth does, however, have a specific power to make laws about corporations (and their activities) and about other entities which are engaged in interstate or overseas trade and commerce². This means that the Commonwealth government has the power to regulate corporations dealings with GMOs. Indeed, the Commonwealth Act relies upon this power to regulate corporations dealings with GMOs³. The Commonwealth does not, however, have the constitutional power to regulate individuals' dealings with a GMO unless they are involved in interstate or overseas trade and commerce. Only States have such power.

The comprehensive regulation of GMOs relies upon the gaps in the application of the Commonwealth Act being overcome by State laws. Indeed, the Commonwealth Act states that "it is the intention of the Parliament that this Act form a component of a nationally consistent scheme for the regulation of certain dealings with GMOs by the Commonwealth and the States"⁴. To this end, the Commonwealth Act specifically provides that the Minister may declare a State law to be a "corresponding State law"⁵ if the provisions of that law correspond to the provisions of the Commonwealth Act. The Commonwealth Act then states that a corresponding State law may confer functions, powers or duties on the agencies and bodies set up under the Commonwealth Act⁶. If State laws do this, the bodies (such as the Regulator) set up under the Commonwealth Act will be the only GMO regulating bodies in Australia but the power of those bodies to make decisions will be found in various corresponding State laws and the Commonwealth Act.

To date, the Minister has only declared corresponding State laws in Victoria and South Australia⁷. In Western Australia, the *Gene Technology Bill 2001* ("the State GMO Bill") has recently passed through the Legislative Assembly and has now been referred to the Legislative Council Standing Committee on Environment and Public Affairs. The State GMO Bill currently mirrors the Commonwealth Act⁸ and therefore could, if passed, be expected to be declared a corresponding State law.

The Commonwealth Act nor the State GMO Bill regulate matters which are concerned with products containing GMOs (as opposed to GMOs themselves), as such matters are covered by other agencies. Specifically, the Commonwealth Act does not deal with:

² Commonwealth Constitution section 51 (xx)

³ *Gene Technology Act 2000* section 13. Note that the Commonwealth Act also applies to other matters which are authorised by Commonwealth head powers under the Commonwealth Constitution, such as matters involving interstate and overseas trade and commerce.

⁴ *Gene Technology Act* section 5

⁵ *Gene Technology Act 2000* section 12

⁶ *Gene Technology Act 2000* section 17

⁷ *Gene Technology Act 2001* (Vic), *Gene Technology Act 2001* (SA)

⁸ Note, however, there are minor differences, such as ss 8, 12A, 192E, 195 and 196 of the State Bill.

- ∉ Food safety and labelling (which is dealt with by the Australia New Zealand Food Authority);
- ∉ Medicines and drugs (which are dealt with by the therapeutic goods administration); and
- ∉ Registration of chemicals (which is dealt with by the National Registration Authority).

3 What is a GMO?

A GMO is defined in the Commonwealth Act as:

- (a) an organism that has been modified by gene technology; or
- (b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or
- (c) anything declared by the regulations to be a genetically modified organism;

but does not include:

- (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
- (e) an organism declared by the regulations not to be a genetically modified organism⁹.

Subparagraph (e) enables a particular GMO to be specifically excluded from the operation of the Commonwealth Act by the making of mere regulations. That is, it enables a particular GMO to be excluded from the operation of the Commonwealth Act without any formal public notification or consultation.

In reading the definition of GMO, also note that an “organism” is defined as “any biological entity that is:

- (a) viable;
- (b) capable of reproduction; or
- (c) capable of transferring genetic material.”¹⁰

It is not clear whether this definition includes biological entities with “terminator” genes. It is arguable that terminator genes result in a biological entity not being viable, capable of reproduction, or capable of transferring genetic material. If such an argument is accepted, organisms with terminator genes are not included in the definition of “organism” and therefore are not covered by the Commonwealth Act.

4 Objects of the Commonwealth Act

The object of the Commonwealth Act is to protect the health and safety of people and to protect the environment, by identifying risks posed by or as a result of gene technology,

⁹ *Gene Technology Act 2000* section 10

¹⁰ *Gene Technology Act 2000* section 10

and by managing those risks through regulating certain dealings with GMOs¹¹. The promotion of ecologically sustainable development is not one of the specific objects of the Commonwealth Act even though many of the key issues which the Gene Technology Regulator (“the Regulator”) must take into account in issuing authorisations under the Commonwealth Act are in truth aspects of ecologically sustainable development.

Decisions made under the Commonwealth Act must involve some consideration of the objects clauses. Such consideration must be adequate, and not a mere cursory review. However, the Commonwealth Act does not specifically require that the objects clause be taken into account by any person making any decision under the Act. Therefore as long as some consideration is given to an objects clause, no particular weight needs to be given to that objects clause, or indeed any weight at all¹². This means that the efficacy of the objects clause in the Commonwealth Act is marginal. If it is to be of real force in directing the decisions made under the Commonwealth Act, the Regulator (and indeed all decision makers under the Commonwealth Act) should be required to give paramouncy to the objects of the Commonwealth Act when making any decisions.

5 “Dealings” with GMOs

The Commonwealth Act prohibits all “dealings” with GMOs unless authorisation has been granted for that dealing¹³. “Dealings” with a GMO are defined under Commonwealth Act to include:

- (a) conducting experiments with the GMO;
 - (b) making, developing, producing or manufacturing the GMO;
 - (c) breeding the GMO;
 - (d) propagating the GMO;
 - (e) using the GMO in the course of manufacturing a thing that is not the GMO;
 - (f) growing, raising or culturing the GMO;
 - (g) importing the GMO;
- and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (g).¹⁴

There are four authorisations available for dealings:

1. exempt dealings¹⁵ - the Regulations can prescribe dealings which do not involve an intentional release of a GMO into the environment as “exempt”, in which case those dealings do not require a licence.
2. GMOs listed on the Register¹⁶ – if the Regulator is satisfied that any risks posed by a dealing are minimal and that it is not necessary for persons undertaking the

¹¹ *Gene Technology Act 2000* section 3

¹² *Randwick Municipal Council v Manousaki* (1988) 66 LGRA 330

¹³ *Gene Technology Act 2000* Part 4 Division 2

¹⁴ *Gene Technology Act 2000* section 10

¹⁵ *Gene Technology Regulations 2001* (Cth) Regulation 6

¹⁶ *Gene Technology Act 2000* Part 6 Division 3

- dealing to have a GMO 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.
3. notifiable low risk dealings¹⁷ – those prescribed by the Regulations as dealings which would not involve the intentional release of a GMO into the environment and involve minimal risk to the health and safety of people and to the environment.
 4. licensed dealings¹⁸ - any other dealings, regardless of whether or not they involve the intentional release of a GMO into the environment.

The authorisation available is dependent upon whether the dealing will involve an “intentional release of a GMO into the environment”. Unfortunately, however, the scope of “open environment” is not clear¹⁹. For example, is an organism released into the “open environment” if it is used in a greenhouse with an earthen floor, or discharges to a water system connected to the stormwater system? Is an organism released into the “open environment” if it is used in a walled but unroofed courtyard? It is therefore unclear what authorisation will be required in some cases.

6 How are dangers of an intentional release of GMO into the environment assessed?

6.1 Assessment under the Commonwealth Act

Before issuing the licence, the Regulator must prepare 1) a risk assessment and 2) a risk management plan in relation to the dealings proposed to be authorised by the licence²⁰.

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 assessment (whether in Australia or overseas), and any submissions or advice received about the proposal²¹. Further, the Regulator must consider the long and short term potential of the GMO to:

- (i) be harmful to other organisms;
- (ii) adversely affect any ecosystems;
- (iii) transfer genetic material to another organism;
- (iv) spread, or persist, in the environment;
- (v) have, in comparison to related organisms, selective advantage in the environment; and
- (vi) be toxic, allergenic or pathogenic to other organisms²².

¹⁷ *Gene Technology Act 2000* Part 6 Division 2

¹⁸ *Gene Technology Act 2000* Part 5

¹⁹ *Gene Technology Act 2000* section 11

²⁰ *Gene Technology Act 2000* section 50

²¹ *Gene Technology Act 2000* section 51, *Gene Technology Regulations 2001* regulation 10

²² *Gene Technology Regulations 2001* regulation 10

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 proposal²³.

The Regulator may not issue a licence unless the Regulator is 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 environment²⁴.

6.2 Assessment under the Environmental Protection Act 1986 (WA)

The *Environmental Protection Act 1986 (WA)* (“EP Act”) establishes a process for the environmental impact assessment of all proposals in Western Australia which are likely to have a significant effect upon the environment²⁵. The EP Act therefore has the capacity to apply to the assessment of proposals to deal with GMOs.

As noted above in section 2, the Commonwealth does not have the power to regulate individuals unless they are involved in interstate or overseas trade and commerce, and therefore such individuals will be regulated by the State GMO Bill. Clause 15 of that Bill provides that its provisions are in addition to, and not in substitution of, the requirement of any other laws of Western Australia. In addition, section 5 of the EP Act provides that whenever a provision of the EP Act is inconsistent with a provision contained in another State law (such as the State GMO Bill), the provision of the EP Act will prevail. The result of these provisions is that the risk assessment/environmental impact assessment provisions of both the State GMO Bill and the EP Act will apply to proposals by individuals to deal with GMOs.

However, a corporation and indeed all entities which are involved in interstate or overseas trade and commerce could seek to argue it is regulated, at least in part, by the Commonwealth Act. If such an argument is accepted, issues of constitutional law become relevant. It is a principle of constitutional law that a State law such as the EP Act is invalid if it is inconsistent with a Commonwealth law. A State law can be inconsistent with a Commonwealth law for several reasons, including if the Commonwealth intends to completely, exhaustively or exclusively govern the particular conduct or matter to which its attention is directed²⁶. Unfortunately it is not clear on the face of the Commonwealth Act whether the Commonwealth intends to completely, exhaustively or exclusively govern any particular aspect of GMOs. While section 16 of the Commonwealth Act provides that it is not intended to exclude the operation of any State laws provided that the State law is capable of operating concurrently with the Commonwealth Act, there is no guidance as to which State laws do in fact operate concurrently. However, guidance can be obtained in the Explanatory Memorandum to the Commonwealth Act, which states that:

²³ *Gene Technology Act 2000* section 51

²⁴ *Gene Technology Act 2000* section 56

²⁵ *Environmental Protection Act 1986 (WA)* Part IV

²⁶ *Ex parte McLean* (1930) 43 CLR 472 per Dixon J at 483

“the intention of these provisions is to ensure that existing and future legislation (such as general environmental... legislation) continues to operate concurrently with the Bill provided it is capable of doing so. However, where State legislation is enacted that is inconsistent with the national scheme of regulation for GMOs, or effectively establishes a dual licensing system, there is capacity for such laws to be prescribed as not operating concurrently...”.

The Explanatory Memorandum therefore indicates that environmental impact assessment of GMOs is one area in which it is clear that the State processes will be inconsistent with the Commonwealth processes. The Commonwealth Act establishes a process specifically for the assessment of GMO proposals which are likely to have a significant effect upon the environment. Indeed, it establishes a comprehensive regime for the identification and assessment of the risks of a licensed GMO activity, and provides that a licence cannot be granted unless the Regulator is satisfied that the risks will not eventuate. It is therefore arguable that the Commonwealth Act intends to completely, exhaustively or exclusively govern the assessment of GMO proposals, and to allow the State environmental impact assessment process to operate as well would effectively establish a dual assessment and decision-making system. If such an argument is successful, the EP Act will be invalid to the extent that it seeks to assess the impact of proposals that are concerned with GMOs, and the State environmental impact assessment process will not apply to corporations’ and entities involved in interstate or overseas trade and commerce proposed dealings with GMOs.

7 Licence conditions and monitoring

The Regulator may impose any conditions on a licence which the Regulator thinks fit²⁷. Licences are valid for the period specified in each individual licence – there is no maximum period for a licence.²⁸ This may be problematic if new scientific evidence emerges after the licence is issued which reveals that the GMO poses a danger to human health or the environment and therefore that a licence for dealing with that GMO should not have been issued. However, this problem may be alleviated by the fact that the Regulator may suspend or cancel the licence if the Regulator 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 risks²⁹.

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 dealing³⁰. Whether or not this results in appropriate monitoring of GMO dealings or not will depend upon how frequently and comprehensively the Regulator or an authorised person actually carry out

²⁷ *Gene Technology Act 2000* section 62

²⁸ *Gene Technology Act 2000* section 60

²⁹ *Gene Technology Act 2000* section 68

³⁰ *Gene Technology Act 2000* section 64

such inspections. 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 licence³¹. It is an offence to breach such a licence condition.

8 Offences

It is an offence under the Commonwealth Act to deal with a GMO without an appropriate authorisation³². It is also an offence for a person who has a licence permitting the release a GMO into the environment to breach a condition of their licence³³. An offence will be an “aggravated offence” if the unauthorised release causes significant damage to the environment and the person either intended to or was reckless as to whether that conduct would cause such damage³⁴. The maximum penalties under the Commonwealth Act are \$220,000 for an aggravated offence, \$55,000 for an offence involving some knowledge about or recklessness as to whether the dealing was authorised, and \$22,000 for an offence where there is no evidence of any intention or recklessness.

All offences prescribed by the Bill rely upon some degree of *actual* knowledge on the part of the offender as to the fact that organisms are in fact GMOs. For example, it is an offence under the Bill for a person to deal with a GMO in an unauthorised way only if that person knows that the organisms they are dealing with are in fact GMOs. It will, however, be difficult in some cases to prove that a person had actual knowledge of this fact, and therefore difficult to successfully prosecute in those cases.

9 Public participation and review of decisions

The public does not need to be consulted about most matters under the Commonwealth Act. Specifically, the Commonwealth Act does not require that the public be consulted about:

- ∄ policy guidelines or codes of practice;
- ∄ 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.

Further, the Regulator is not required to consult the public about any licence it proposes to grant unless the dealings which will be authorised by the licence may pose significant risks to the health and safety of people or the environment³⁵. Given the high level of public interest and concern about GMOs, it is arguable that all proposed decisions under the Commonwealth Act should be publicly notified. The public should also have the right to make submissions on all such decisions, and the Regulator should be required to take all such submissions into account.

³¹ *Gene Technology Act 2000* section 65

³² *Gene Technology Act* section 32

³³ *Gene Technology Act* section 34

³⁴ *Gene Technology Act* section 38

³⁵ *Gene Technology Act 2000* section 49

Licence applicants and licence holders may apply to the Administrative Appeals Tribunal for a review of decisions under the Commonwealth Act³⁶. However, no review rights are available to other people. This means that neighboring landowners, organic producers and community groups are excluded from seeking review of 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 Commonwealth Act³⁷. 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 what an ordinary member of the public suffers³⁸. The requirement that a person be “aggrieved” before they can bring an action for an injunction will therefore seriously limit the capacity of members of the community to bring an action. 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.

As noted above, in making most decisions under the Commonwealth Act, the Regulator is not required to consult any person, including peak environmental groups or people in a local area who may be affected by, or concerned about, GMOs. Neither is the Regulator required to consult the specific advisory bodies set up under the Commonwealth Act. For example, in making a decision about whether to issue a licence, the Regulator *may* consult any person considered “appropriate”³⁹. However, it are not *required* to consult any particular person. Specifically, it is not required to consult any of the statutory bodies established under the Bill such as the Technical Advisory Committee, the Community Consultative Committee or the Ethics Committee.

10 Access to information

The Regulator must maintain a Record about GMO dealings⁴⁰. 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 has been declared to be confidential commercial information⁴¹. Given the nature of the GMO industry, there will be many applications to have information treated confidentially. This could seriously undermine the efficacy of the Commonwealth Act’s requirement to make information publicly available.

11 GMO free zones

³⁶ *Gene Technology Act 2000* section 183

³⁷ *Gene Technology Act 2000* section 147

³⁸ *Tooheys Ltd v Minister for Business and Consumer Affairs* (1981) 36 ALR 64

³⁹ *Gene Technology Act 2000* section 47

⁴⁰ *Gene Technology Act 2000* section 138

⁴¹ *Gene Technology Act 2000* section 184. It is an offence for any person to release such information, and the information is also exempt matter for the purposes of the operation of the *Freedom of Information Act 1982* (Cth) section 38, schedule 3

The Commonwealth Act anticipates that areas may, under State law, be designated for the purpose of preserving the identity of non-GMO crops (or GMO crops) for marketing purposes⁴². Specifically, it provides that the Ministerial Council (a body containing Ministerial representatives from the Commonwealth, States and Territories) may issue a policy principle in relation to “recognising areas, if any, designated under State law for the purpose of preserving the identity of one or both of the following:

- (i) GM crops;
 - (ii) non-GM crops;
- for marketing purposes.”

If the Ministerial Council recognises a State’s designation of a particular area, the Regulator cannot issue to approve a dealing with a GMO in that area.

The State GMO Bill proposes to make amendments to the *Agriculture and Related Resource Protection Act 1976* (WA) to allow regulations to be made for the purpose of “designating areas of the State for the purposes of the Commonwealth Act.” Therefore if the State GMO Bill is passed in its current form, it will be possible for the State to designate areas in order to protect the identity of non-GMO crops. However, that designation will only be given legal effect if it is approved by a Ministerial Council made up of representatives of the Commonwealth, States and Territories. It would therefore be possible for the State government to designate a GMO Free Zone, but also possible for Ministerial representatives from other jurisdictions to prevent that zone from having any practical effect.

Further, if the State GMO Bill is passed in its current form, the State will not be able to provide for the designation of GMO-Free Zones for any purpose other than other marketing purposes. It will also not be able to designate a GMO Free Zone for any organisms other than GMO crops. There may, however, be many reasons other than “marketing purposes” for which the State wishes to designate GMO Free Zones. For example, the State may wish to designate a GMO Free Zone to protect a particularly important established crop, or to protect biodiversity in a particularly sensitive area. There may also be many reasons why the State may wish to designate a GMO Free Zone in respect of GMOs other than crops.

It is possible for the State GMO Bill to be amended to provide that the State have a specific power to declare a GMO Free Zone for any purpose and in respect of any GMO. The Commonwealth Act does not place any restraint upon the State GMO Bill which would preclude the insertion of such a provision, and as a State law prohibiting GMOs in a particular area could be obeyed at the same time as any provision of the Commonwealth Act there would be no direct inconsistency between the Commonwealth Act and the State law. Further, as the Commonwealth Act indicates that that Act is not intended to “cover the field”⁴³ and no indirect inconsistency arises, the State has the power to make GMO Free Zones in addition to those currently specified in the Commonwealth Act and the State GMO Bill.

⁴² *Gene Technology Act 2000* section 21 (1) (aa)

⁴³ *Gene Technology Act 2000* (Cth) section 16

While the State GMO Bill does not currently contain provisions which would enable the designation of broadly defined GMO free zones, note that local governments have a broad power to make town planning schemes⁴⁴ and it is arguable that such schemes may include GMO-Free Zones. Further, local governments have a broad power to make local laws in order to fulfill their function under the *Local Government Act 1995* (WA) of providing for the good governance of persons in their district. These powers are broad enough to permit the making of laws that seek to regulate or prohibit the use of GMOs. However, it must be remembered that such laws must be authorised by either the Minister for Planning or the Governor (effectively Cabinet), so it is unlikely that a local government would be able to pass laws making GMO Free Zones if they were inconsistent with the State government's policy.

⁴⁴ *Town Planning and Development Act 1928* (WA)