AUSTRALIAN REGULATION OF GENE TECHNOLOGY: IMPACTS ON BIODIVERSITY

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I INTRODUCTION

Gene technology has the potential to improve, as well as impair, all facets of life including biodiversity. To avoid the latter and facilitate the former, gene technology must be effectively and efficiently regulated. The Commonwealth of Australia has attempted to do this by enacting the *Gene Technology Act* 2000 (Cth),[1] which came into force on 21 June 2001. Before providing a critique of this Act, this paper will discuss the possible impacts of gene technology on biodiversity. A discussion of the *Gene Technology Act*'s regulatory regime, object, incorporation of the precautionary principle, relationship with the States, regulatory bodies, licensing system and review provisions will then be provided.[2] This discussion will outline and identify the shortcomings of the aforementioned facets of the *Gene Technology Act*. Suggestions as to how the *Gene Technology Act* can better protect and conserve biodiversity, and thereby be improved, will also be proposed.

II IMPACTS OF GENE TECHNOLOGY ON BIODIVERSITY

Gene technology[3] has been identified as a modern aspect of the 'old science'[4] of biotechnology.[5] Like traditional hybridisation, gene technology can alter the characteristics of an organism through modifying its DNA.[6] However, unlike

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1 *Gene Technology Act* 2000 (Cth).

2 It is recognised that this paper does not cover all facets of the *Gene Technology Act*, such as powers of inspection (Part 11), that are important for the protection and conservation of biodiversity.

3 Gene technology is also known as recombinant-DNA technology.

4 L J Daniel, 'The Case for GM Food: Biotechnology and Food do Mix' (2000) 73 *New Doctor* 2.

5 'Biotechnology can be defined as the manipulation of biological organisms or parts thereof, at the cellular, sub-cellar or genetic level with the intention of producing unique changes for specific applications'. See: Daniel, above n 4, 2.

6 Daniel, above n 4, 2.

traditional hybridisation, the 'sophisticated molecular techniques'[7] of gene technology allow for the transfer of genes between different species.[8] Organisms produced by gene technology are commonly known[9] as 'genetically modified organisms'.[10]

By altering organisms, and thereby the environment, gene technology impacts on biodiversity. Whether these impacts are negative or positive is highly contentious.[11] Opponents of GMOs argue biodiversity will be threatened via crossbreeding[12] that will 'result in significant incursions on genome and gene pool integrity of natural species, populations and ecosystems'.[13] Moreover genetically modified ('GM') weeds, which may also promote the growth of other pests, purportedly imperil biodiversity.[14] Similarly, GM animals may escape, become feral and thereby become pests. Additionally, releasing GMOs into the environment will introduce them into the food chain and may consequently alter the characteristics of the consumer.[15] In fact, GMOs and their by-products[16] are toxic to some species.[17] Opponents of GMOs also point to evidence that GM crops do not necessarily reduce pesticide/herbicide use.[18]

However, supporters of GMOs point to conflicting evidence suggesting that GM crops do reduce pesticide/herbicide use.[19] Moreover, gene technology has been

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7 Ibid.

8 For example, transferring genes from an animal to a plant: J L Huppatz and P A Fitzgerald, 'Genetically Modified Foods - Safety and Regulatory Issues' (2000) 172 *Medical Journal of Australia* <http://www.mja.com.au/public/issues/172_04_210200/huppleed/huppatz.html> (15 October 2003).

9 Office of the Gene Technology Regulator, *What is Biotechnology? What is Gene Technology?* (2003) <http://www.ogtr.gov.au/pdf/public/factwhatis.pdf> (15 October 2003).

10 Hereinafter GMOs.

11 This author contends that this is not a dichotomous issue. That is, the impacts of gene technology are neither wholly negative nor positive. Rather, the impacts of gene technology on biodiversity will be highly contingent on numerous variables. For example, the local conditions of its application and the level of regulation imposed on its application.

12 G Chin, 'The Role of Public Participation in the Genetically Modified Organisms Debate' (2000) 17(6) *Environmental and Planning Law Journal* 519.

13 R Polya, 'Genetically Modified Governance Issues' (Research Paper No 17, Canberra, Department of Parliamentary Library, 2001) 31.

14 For example in South Carolina GM cotton has become a weed that offers a refuge for pests, such as the cotton boll weevil. See: Polya, above n 13, 32.

15 For example, a Western Australian 'application to inoculate guts of cattle sheep and goats with genetically modified bacteria to make them resistant to the active ingredients of 1080' was rejected by the Genetic Manipulation Advisory Committee (GMAC). GMAC based its decision on the grounds that feral animals, such as rabbits, could become resistant to 1080 poisoning. See: Polya, above n 13, 32.

16 M Young and S Haynes, 'Genetically Modified Organisms : Environmental Regulation in Australia' (2000) 52(5) *Australian Company Secretary* 295, 296.

17 For example, Dr Stanley Robert contends that roots of Bt corn produces Bt toxins that binds to soil particles and is toxic to insect larvae. See: Polya, above n 13, 34.

18 For example, Dr Stanley Robert observes that in the US GM soybeans use two to five times more herbicides than non-GM soybeans. See: Polya, above n 13, 33.

19 For example, the study by Marlin Rice shows that insecticide use was reduced by 13% in 1996 to 26% in 1998 through the use of Bt corn. See: Polya, above n 13, 33.

exalted as a tool to protect biodiversity for it can be used to preserve threatened and rare species.[20] Furthermore, gene technology has the potential to produce sustainable resources, such as bioplastics.[21] GMOs could also help address some of the root causes of biodiversity loss, such as world population growth[22] and poverty.[23]

However, notwithstanding these potential benefits, the impacts of GMOs upon biodiversity, especially in inter-generational terms,[24] are largely unknown.[25] Moreover, since once released into the environment GMOs are beyond recall,[26] it is imperative that developments in gene technology are effectively regulated.

III THE *GENE TECHNOLOGY ACT*'S REGULATORY REGIME

Gene technology in Australia is regulated by a 'patchwork of laws and regulatory agencies'.[27] The *Gene Technology Act*, which attempts to effectively and efficiently regulate gene technology, is 'expressly limited to GMOs which are not already covered by a regulatory regime'.[28] Under the *Gene Technology Act* dealings with GMOs, save authorised dealings,[29] are prohibited. Commercial releases of GMOs

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20 Daniel, above n 4, 4.

21 Ibid 7.

22 For example, gene technology can increase the yield of a farmer's crop thereby rendering it unnecessary for him/her to convert non-agriculture land to agricultural land. See: Ibid; A S Truswell, 'Genetically Modified Plant Foods - Hopes and Fears' (2002) 2 *Macquarie Law Journal* 177, 178.

23 For example, GM rice with increased vitamin A and iron levels can be made available to countries of the South where nutrient deficiencies are widespread. See: J L Huppatz and P A Fitzgerald, above n 8. See also: World Commission on Environment and Development, *Our Common Future* (1990) 75.

24 C Lawson, 'Risk Assessment in the Regulation of Gene Technology under the *Gene Technology Act* 2000 (Cth) and the Gene Technology Regulations 2001 (Cth)' 19(3) *Environmental and Planning Law Journal* 195, 196.

25 The significance of this issue is heightened by the limitations in science to identify, let alone manage, the potential hazards of GMOs. See: Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes. Report on the Gene Technology Bill 2000*, series/cate (2000) 43. Furthermore, Professor A Stewart Truswell notes that releasing GMOs into the environment means that 'we are placing things in the environment where there is no evolutionary history on how to accommodate them'. See also: A S Truswell, above n 22, 180.

26 B Phelps, 'Genetic Engineering into the Law and the Environment?' 29(1) *Habitat Australia* (2001) 26.

27 B Bennett and G Williams, 'Gene Technology Regulation: an Overview of the Act and the Penalties for non-compliance' (2001) 12(5) *Australian Product Liability Reporter* 69, 70.

28 B Bennett and G Williams, 'Gene Technology Regulation: the Australian Approach' (2001) 1(2) *Biotechnology: Law and Policy Reporter* 29.

29 Authorised dealings with GMOs include dealings that are included on the GMO register; licensed dealings; notifiable low risk dealings; exempt dealings; licensed dealings; or 'a dealing with an organism, or class of organism declared to be outside the definition of a GMO'. See: The State of Queensland Department of Primary Industries, 'An Overview of the *Gene Technology Act* 2000' (2003) <http://www.dpi.qld.gov.au/biotechnology/7646.html> (15 October 2003); *Gene Technology Act*, above n 1, s 10; *Gene Technology Regulations* 2000 (Cth) Pt 3 Div 1.

that are to 'be used as, or in, a food, medicine, or agricultural, veterinary or industrial chemical'[30] are subject to a two-tier regulatory regime.[31] The initial stage is governed by the *Gene Technology Act* and requires approval by the Gene Technology Regulator.[32] The second stage requires the appropriate regulating agency[33] to authorise the GMO's commercial release.

The *Gene Technology Act*'s gap filler approach[34] has appended another layer of bureaucracy to the regulation of gene technology.[35] This has purportedly resulted in a complex[36] and confusing[37] regime that allows for regulatory gaps,[38] regulatory duplication[39] and loop-holes[40] which encourages non-compliance.[41]

In light of this, it is unlikely that the *Gene Technology Act* is effectively and efficiently regulating gene technology. Thus, to improve the *Gene Technology Act*,

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30 M Hain, C Cocklin and D Gibbs, 'Regulating Biosciences: the *Gene Technology Act* 2000' (2002) 19(3) *Environmental and Planning Law Journal* 163, 165.

31 Thus, a GM flower that will be not be used as, or in, a food, medicine, or agricultural, veterinary or industrial chemical can be released for commercial purposes upon the approval of the Gene Technology Regulator for commercial release. See: M Hain, C Cocklin, and D Gibbs, above n 30, 165.

32 The Gene Technology Regulator is an independent statutory officer established by the *Gene Technology Act*. His/her functions (*Gene Technology Act*, above n 1, s 27) include, *inter alia*, preparing a risk assessment and risk management plan for a proposed dealing (*Gene Technology Act*, above n 1, s 50); and providing to the public advise and information pertinent to the regulation of GMOs (*Gene Technology Act*, above n 1, s 27(f)). The Gene Technology Regulator is hereinafter referred to as the GTR.

33 The appropriate regulatory agencies for GMOs that will 'be used as, or in, a food, medicine, or agricultural, veterinary or industrial chemical' are respectively the Australian New Zealand Foods Standards Authority, Therapeutic Goods Administration, National Registration Authority for Agricultural and Veterinary Chemicals, National Industrial Chemicals Notification and Assessment Scheme. These regulatory agencies regulate the end-uses of the GMO and have authority over issues such as labelling. See: Hain, Cocklin and Gibbs, above n 30, 165.

34 That is, the *Gene Technology Act* has neither the ultimate authority to determine the release of all GMOs nor all issues pertinent to GMOs, such as labelling. As discussed earlier, the *Gene Technology Act*'s scope is 'expressly limited to GMOs which are not already covered by a regulatory regime'. See Bennett and Williams, above n 28, 29.

35 D K Anton, 'Submission to the Senate Community Affairs References Committee in the matter of the Inquiry into the Gene Technology Bill 2000' (21 October 2000) < http://www.aph.gov.au/senate/committee/clac_ctte/gene/submissions/sub34.doc> (16 October 2003).

36 Bennett and Williams, above n 27, 70.

37 R Chalmers and N Waterhouse, '*Gene Technology Act 2000* - Regulating Frankenstein' (2001) *The Law Society of South Australia Continuing Legal Education Seminar on Biotechnology and Intellectual Property Issues* 15.

38 For example, Polya notes that under the *Gene Technology Act* 'the status of a procedure involving the insertion of a human nucleus into an enucleated human egg cell' is unclear. See: Polya, above n 13, 38.

39 Australian Chamber of Commerce and Industry, 'Regulating Gene Technology' (2000) 62 *ACCI Review* 7.

40 Phelps, above n 26.

41 P Neilson, 'The Impact of the Gene Technology Act on the Biotechnology Industry' (2001) 11(2) *Australasian Biotechnology* 23, 24.

it is suggested that the GTR operate as the 'one-stop shop' for regulating gene technology. That is, the *Gene Technology Act* should establish a nationally comprehensive and integrated regime regulating all aspects of gene technology.[42] Under such a regime all dealings involving GMOs or GM products are subjected to a 'streamlined assessment process requiring approval from only one regulator'.[43] This regime is likely to effectively and efficiently regulate gene technology, especially since evidence holds that a 'one-stop shop' ensures greater transparency and certainty.[44]

IV THE OBJECT THE *GENE TECHNOLOGY ACT*

The object of the *Gene Technology 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, and by managing those risks through regulating certain dealings with GMOs.[45]

Although biodiversity protection may be implied from this object, biodiversity would better protected if the protection, conservation and maintenance of 'biological diversity against threats posed by GMOs' were an explicit object[46] of the *Gene Technology Act.*[47]

Biodiversity would also be better protected and conserved by explicitly including ecological sustainable development (ESD)[48] into the *Gene Technology Act*'s object.[49] The exigency for this is evinced by claims that the GTR omits to consider

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42 Anton, above n 35.

43 Australian Parliament Senate Community Affairs References Committee, *A Cautionary Tale-Fish Don't Lay Tomatoes. Report on the Gene Technology Bill 2000* (2000) 85.

44 Ibid.

45 *Gene Technology Act*, above n 1, s 3.

46 N Beuret, 'Submission to the Interim Office of the Gene Technology Regulator Comments from Friends of the Earth (Fitzroy) Genetix Campaign On the Draft Commonwealth Gene Technology Bill 2000' *Comments from the Friends of the Earth (Fitzroy) Genetix Campaign on the Draft Commonwealth Gene Technology Bill 2000*' (27 October 2000) <http://www.gov.au/senate/committee/clac_ctte/gene/submissions/sub51.doc > (16 October 2003).

47 However for this object to confer adequate protection on biodiversity, the *Gene Technology Act* must define the term 'biological diversity' in a manner that encompasses all levels of biodiversity. It is suggested that the *Gene Technology Act* adopt the CBD's definition of biological diversity, which is 'the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems'. See: *Convention for Biological Diversity*, United Nations Environment Programme, 5 June 1992, available at <http://www.biodiv.org/doc/legal/cbd-en.pdf.> (entered into force 29 December 1993) Article 12 para 1.

48 This measure was rejected by the Commonwealth Senate on the grounds that ESD is neither separate nor distinct from the environment. See Network of Concerned Farmer, *Network of Concerned Farmers Submission* (May 2003) <http://www.non-gm-farmers.com/news_print.asp?ID=3> (16 October 2003).

49 W Blake and M Blake, 'Submission 124' (27 October 2000) <http://www.aph.gov.au/senate/committee/clac_ctte/gene/submissions/sub124.doc> (16 October 2003).

ESD when determining whether to release GMOs into the environment.[50] For example, the GTR failed to consider the broader ecological effects, save weediness and crossbreeding, before approving the release of transgenic cotton.[51]

The object of the *Gene Technology Act* also fails to adequately protect and conserve biodiversity because the *Gene Technology Act* narrowly defines 'environment',[52] 'deal with'[53] and 'GMOs'.[54] For example, by excluding social, economic and cultural issues from the term 'environment', the GTR need not append buffer zone conditions on licences to deal with GMOs.[55] This is because the present GTR deems contamination of non-GM crops, and thereby buffer zones, an economic issue[56] that falls outside the *Gene Technology Act*'s ambit.[57] Hence, by failing to ensure that growers of GM-crops establish adequate buffer zones, the risk of crossbreeding is heightened. To better protect biodiversity, it is suggested that the GTR be required to comprehensively address the issue of contamination. This can be achieved through adopting a more expansive definition of the environment so that social, economic and cultural issues are duly considered by the GTR when she/he determines whether to release a GMO.[58] For example, by adopting the *Environmental Protection and Biodiversity Conservation Act 1999* (Cth)[59]

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50 M Kerr, 'The Gene Technology Bill and Ecological Sustainable Development - Worlds Apart' (12 October 2000) <http://www.acfonline.org.au/asp/pages/print.asp?IdDoc=339> (15 October 20003).

51 See: Lawson, above n 24, 207.

52 Section 10 of the *Gene Technology Act* states that 'environment includes (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and the characteristics of locations, places and areas'.

53 Section 10 of the *Gene Technology Act* states that 'deal with' means to make, develop, produce, manufacture, breed, propagate, grow, raise, culture, import or conduct experiments with a GMO. 'Deal with' also means the possession, use, supply, transport or disposal for the purposes of, or in the course of the aforementioned dealings.

54 Section 10 of the *Gene Technology Act* states that a GMO means '(a) an organism that has been modified by gene technology; or (b) an organism that has inherited particular traits from an organism … being traits that occurred in the initial organism because of gene technology; or (c) anything declared by the regulations to be a GMO, or that belongs to a class of things declared by regulations to be GMOs; but does not include (d) a human being, if the human begin is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or (e) an organism declared by regulations not to be a GMO, or that belongs to a class of organisms declared by the regulations not to be GMOs'.

55 C McGrath, 'A System Under the Strain: the Regulation of Gene Technology' (2003) 2 *National Environmental law Review* 32, 35.

56 This author disagrees with the GTR that crossbreeding is exclusively an economic issue. As discussed earlier, crossbreeding can adversely impact on biodiversity for it can, *inter alia*, violate the genome integrity of non-GMOs.

57 The GTR has stated that the 'Evaluation of trade, marketing and cost-benefit issues have been intentionally excluded from the GTS assessment process'. See: McGrath, above n 55, 34; K Del Villar and A Martin, 'Gene Technology Bill 2000' in *Bills Digest No 11 2000-2001* (2000) <http://www.aph.gov.au/library/pubs/bd/2000-01/01BD011.htm#Main> (16 October 2003).

58 McGrath, above n 55, 37.

59 Hereafter the '*EPBC Act*'.

definition of the environment,[60] the GTR would be required to address crossbreeding notwithstanding its classification as an economic issue.[61]

Moreover, biodiversity would be better protected and conserved if the *Gene Technology Act* augmented its definition of 'deal with' to include, *inter alia*,[62] all exports[63] of GMOs. Biodiversity would also be better protected if the term 'GMOs' was broadened[64] to encompass 'any biological entity capable of replication or transfer of genetic information … in which the genetic material has been altered in a way that does not occur naturally.'[65]

Section 3 of the *Gene Technology Act* also inadequately protects and conserves biodiversity because it merely adopts a risk management approach to regulating gene technology. To address this, it is suggested that s 3 be amended to state that the *Gene Technology Act*'s object be achieved by identifying the risks posed as a result of gene technology, and by preventing, reducing[66] and eliminating those risks.[67]

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60 *EPBC Act*, above n 59, s 528; Section 528 of the *EPBC Act* holds that the 'environment includes (a) ecosystems and their constituent parts, including people and communities; (b) natural and physical resources; (c) the qualities and characteristics of locations, places and areas; and d) the social, economic, cultural aspects of a thing mentioned in paragraph (a) (b) or (c)'. Thus, the *EPBC Act* provides for a broader definition of the environment. Notably, it, unlike the *Gene Technology Act*, includes social, economic and cultural matters in its definition of the environment.

61 Alternatively, the GTR may be amended to require the GTR to attach conditions pertinent to reducing the risk of crossbreeding, including buffer zone specifications, to licences for dealings with GMOs.

62 Examples of other things that should be included in the *Gene Technology Act* definition of 'deal with' include all deliberate releases of GMOs or products derived from GMOs into to the environment and the marketing of GMOs and products derived from GMOs. See Anton, above n 35.

63 Although Australia has not signed the Cartagena Protocol on Biosafety, Phelps suggests that Australia should nonetheless comply with its import/export provisions via amendments to the *Gene Technology Act*. See: B Phelps, 'Submission to the Senate Inquiry into the Gene Technology Bill 2000' (27 October 2000) < http://www.aph.gov.au/senate/committee/clac_ ctte/ gene/submissions/sub85.doc> (16 October 2003).

64 Western Australia's Environmental Defenders Office (EDO (WA)) furthermore suggests that biodiversity would be better protected and conserved if the *Gene Technology Act* did not allow for regulations to declare organisms to not be GMOs. Alternatively, the EDO (WA) argues that the *Gene Technology Act* should ensure that there is extensive community input as to whether an organism should be declared not a GMO. See: S Boulter, and C Poustie, 'Submission to the Interim Office of the Gene Technology Regulator on the Consultation Draft of the Gene Technology Bill 2000' (27 October 2000)< www.edo.org.au/policy/genebill.rtf >(16 October 2003).

65 Anton, above n 35.

66 World Wide Fund for Nature Australia, *Submission to the Senate Community Affairs Reference Committee Inquiry into the Gene Technology Bill 2000*, (3 August 2000) <http://www.aph.gov.au/senate/committee/clac_ctte/gene/submissions/sublist.htm> (16 October 2003).

67 Anton, above n 35.

The *Gene Technology Act* offers a limited degree of protection to biodiversity through adopting the weaker cost-effective formulation of the precautionary principle.[68] Thus, to better protect and conserve biodiversity, it is suggested that s 4(aa) be amended so that a lack of full scientific certainty shall[69] not be used as a reason for postponing measures[70] to prevent environmental degradation. Moreover, in light of claims that the GTR is not applying the precautionary principle,[71] the *Gene Technology Act* would better protect and conserve biodiversity if it explicitly emphasised the 'primary place of the precautionary principle in decision-making' pertinent to regulating gene technology.[72]

V THE STATES AND THE *GENE TECHNOLOGY ACT*

The absence of an opt-out clause for States undermines the protection of biodiversity with the result that States are bestowed very limited avenues for adopting a more precautionary approach to regulating gene technology.[73] These avenues include the right to advise the GTR in relation to Risk Assessment and Risk Management Plans (RARMPs) and via the 2003 policy principle.[74] Thus, it is suggested that the *Gene Technology Act* explicitly empower States, Territories and local governments to impose standards or laws[75] that confer greater protection of the environment.[76]

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68 The cost-effective formulation of the precautionary principle means that if measures to prevent environmental degradation are not cost-effective then they need not be taken. See: K Bristow, 'Explicit Recognition of the Precautionary Principle in the *Gene Technology Act* 2000' (2001) 11(3) *Australasian Biotechnology* 33.

69 It is suggested that the *Gene Technology Act* follow the 1992 Rio Declaration by replacing the word 'should' with the word 'shall'. See: C Tinker, 'Is the United Nations Convention the Most Appropriate Means to Pursue the Goal of Biological Diversity? Responsibilities for Biological Diversity Convention Under the International Law' (1995) 28 *Vanderbilt Journal of Transnational Law* 777, 794. This will confer greater protection upon biodiversity as the word 'shall' implies that the GTR has no discretion as to whether to take measures to prevent environmental degradation.

70 It is suggested that the GTR implement measures to prevent environmental degradation even if such measures are not considered to be cost-effective. In fact, if such measures are not cost-effective then the GTR should consider not approving the dealing with the GMO.

71 Lawson, above n 24, 211.

72 This suggested amendment is important in light of the immense political and commercial pressure for commercialising GMOs. See: Lawson, above n 24, 203. In fact, Hain, Cocklin and Gibbs contend that the actual primary purpose of the *Gene Technology Act* is to facilitate the commercialisation of gene technologies rather than to protect the health and safety of people and the environment. See: Hain, Cocklin and Gibbs, above n 30, 165.

73 Hain, Cocklin and Gibbs, above n 30, 174.

74 Section 4 of the *Gene Technology (Recognition of Designated Areas) Principle 2003* (Cth) states that its purpose is to recognise areas 'designated under a State law for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for the marketing purpose'.

75 This might include laws that prohibit the release of GMOs within all or parts of their jurisdiction.

76 Phelps, above n 63; C Graham-Taylor, *Friends of the Earth (Perth) Submission to the Senate Community Affairs Reference Committee Inquiry into the Gene Technology Bill 2000* (27 October 2000) <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ submissions/sublist. htm> (16 October 2003).

VI BODIES ESTABLISHED BY THE *GENE TECHNOLOGY ACT*

The *Gene Technology Act* establishes an independent GTR[77] to administer it. This requires that the GTR undertake a broad range of functions, including determining whether to release a GMO into the environment.[78] To advise the GTR, the *Gene Technology Act* has established[79] the Gene Technology Technical Advisory Committee,[80] the Gene Technology Community Consultative Committee[81] and the Gene Technology Ethics Committee.[82]

However, there are numerous problems with the aforementioned bodies that hinder biodiversity protection and conservation. Firstly, it is argued that the *Gene Technology Act* vests excessive power in one person, that is, the GTR. This is dangerous because a person is more likely to yield[83] to intense political and commercial pressure to approve the release of GMOs.[84] To reduce this likelihood it is firstly suggested that the GTR be an independent corporation[85] composed of three members.[86] A second measure to ensure that the GTR does not operate in a biased fashion is to allow all three committees, rather than just the GTTAC,[87] to advise the GTR in regard to specific licence applications. Moreover, these committees should be able to advise the GTR in the absence of the GTR's request for advice. The GTR must then take such advice into account when making a decision under the Act. To ensure this, the GTR should be prevented from issuing a licence unless there is a two-third-majority support for that decision from all the committees.[88]

Moreover, the *Gene Technology Act* should disqualify 'any person that has had any connection or interest (financial or otherwise) with'[89] a regulated entity for any period during the previous five years from serving as a member of any body

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77 *Gene Technology Act*, above n 1, s 26.

78 *Gene Technology Act*, above n 1, s 55(a).

79 These bodies also provides advice to the Ministerial Council: *Gene Technology Act*, above n 1, s 107, s 112 and s 101.

80 *Gene Technology Act*, above n 1, s 100(1). The Gene Technology Technical Advisory Committee shall hereinafter be referred to as the GTTAC.

81 *Gene Technology Act*, above n 1, s 106. The Gene Technology Community Consultative Committee shall hereinafter be referred to as the GTCC.

82 *Gene Technology Act*, above n 1, s 111(1). The Gene Technology Ethics Committee shall hereinafter be referred to as the GTEC.

83 L Matthews, 'The *Gene Technology Act* 2000: Competing Values and the Regulation of Risk' (2001) 12(1) *Polemic* 54, 57.

84 Hain, Cocklin and Gibbs observe that the Commonwealth and State governments display great enthusiasm for the bioscience sector. They note the substantial competition among the States (particularly New South Wales, Queensland and Victoria) to establish themselves as the nation's bioscience hub. See: Hain, Cocklin and Gibbs, above n 30, 165.

85 Anton, above n 35.

86 Since preparing RARMPs involves much scientific data, it is suggested that at least one of the three members possess scientific qualifications.

87 *Gene Technology Act*, above n 1, s 101(b).

88 Phelps, above n 63.

89 Anton, above n 35.

established under the *Gene Technology Act*.[90] This debarment must also extend to inspectors appointed under the *Gene Technology Act* and to people who are delegated some of the GTR's power. The latter entails the deletion of Part 7 of the *Gene Technology Act* as it undermines the GTR's independence by allowing regulated entities to carry out some of the GTR's functions.[91] It is argued that a period of two years[92] cannot 'remove the shared knowledge, political and ethical values'[93] that favour advancing gene technology over protecting biodiversity that is likely to be inculcated into people employed by regulated entities. Moreover, in appointing any person to a position established under the *Gene Technology Act*, any public objections against that appointment must be considered.

VII THE *GENE TECHNOLOGY ACT*'S LICENSING SYSTEM

A *The Scope of the Licensing System*

The *Gene Technology Act* establishes a licensing system whereby it is an offence to deal with a GMO unless the dealing is an authorised dealing,[94] for example it has been authorised by a licence. Notwithstanding the flaws of the *Gene Technology Act*'s licensing system, it is the most comprehensive measure under the *Gene Technology Act* to protect and conserve biodiversity.[95] However, the *Gene Technology Act*'s licensing system does not extend to dealings that are notifiable low risk dealings, exempt dealings or dealings included on the GMO register. Thus, by limiting the scope of the *Gene Technology Act*'s licensing system, biodiversity protection and conservation is hindered. To address this shortcoming, it is suggested that any person who intends to engage in any type of dealing involving gene technology be required to obtain a licence.[96]

B *The Licensing Process*

A second measure to better protect and conserve biodiversity is to streamline the licensing processes for all dealings. This means that the *Gene Technology Act* must not distinguish between dealings involving an intentional release of a GMO into the environment from dealings that do not involve an intentional release. It is contended that biodiversity will be better protected if the latter dealings are subjected to the more rigorous licence processes of the former dealings. This, it is argued, will better prepare the person dealing with the GMO to cope with an inadvertent release of the GMO.

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90 This includes people the Minister wishes to appoint to as members of the subcommittees established to assist the GTTAC, the GTCC or the GTEC.

91 Australia Conservation Foundation *ACF Summary Analysis of Gene Technology Bill 2000* (2000) <http:///www.acfonline.org.au/asp/pages/print.asp?IdDoc=340 (16 October 2003).

92 *Gene Technology Act*, above n 1, s 118 (5).

93 Australian Parliament Senate Community Affairs References Committee, above n 43, 202.

94 *Gene Technology Act*, above n 1, s 33.

95 Australia Conservation Foundation, above n 91.

96 Anton, above n 35.

A streamlined licensing process will furthermore augment public participation since the *Gene Technology Act* does not currently allow public input into RARMPs for dealings not involving the intentional release of a GMO.[97] Public participation would be further augmented if s 49 of the *Gene Technology Act*, which limits public participation to dealings that the GTR believes will pose a significant risk to the health and safety of people and the environment, were deleted.

Therefore, it is suggested that upon receiving all licence applications the GTR publish a notice of the application that, *inter alia*, invites public written submissions as to whether the application should be approved. In addition to publishing the notice in the media currently specified under the *Gene Technology Act*, it is recommended that the notice be sent directly to people who neighbour the location in which the proposed dealings are to be carried out. Moreover, the *Gene Technology Act* should also require that the notice be posted on the public notice boards of the local council and libraries of the region in which the applicant intends to deal with the GMO. Additionally, the notice should be publicised in numerous non-English newspapers.[98]

The GTR must then prepare a RARMP in relation to the proposed dealing. Much criticism has been directed at the *Gene Technology Act*'s provisions pertaining to RARMPs. These provisions have been criticised for being ambiguous and lacking in rigour and comprehensiveness.[99] Since these shortcomings compromise the protection and conservation of biodiversity, it is imperative that they are addressed. This is especially true since evidence suggests that the GTR fails to adequately consider ESD and the precautionary principle when preparing RARMPs. For example, in preparing the RARMP for GE-canola, the GTR failed to assess the impacts of herbicide use on the grounds that 'the use of insecticides and herbicides ... do not fall within the scope of the evaluations conducted under the Act'.[100]

Thus to better protect and conserve biodiversity, the matters that the GTR must take into account when preparing a RARMP must be substantially augmented. In regard to a risk assessment plan the GTR should consider, *inter alia*, risks to biodiversity and all socio-economic impacts.[101] In preparing a risk management plan the GTR should give regard to, *inter alia*, all possible means of not merely managing, but also preventing, reducing and eliminating any risks the dealing poses to the health and safety of humans, the environment and biodiversity.[102] Moreover, the GTR

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97 *Gene Technology Act*, above n 1, s 47.

98 This should include, in particular, indigenous publications. Furthermore, as in the Environmental Planning and Assessment Regulations 2000 (NSW) cl. 234, the notice should be published across 2 or 3 columns of the display section of a daily State-wide and local newspaper on two separate occasions for 30 days.

99 Hain, Cocklin and Gibbs, above n 30, 177.

100 Greenpeace Australia Pacific, *Response to the Risk Assessment and Risk Management Plan for DIR021/2002* (26 May 2003) <www.greenpeace.org.au/canola/pdfs/bayer_submission.pdf > (16 October 2003) 34.

101 Anton, above n 35.

102 Ibid.

should consider the advice of any person/body[103] notwithstanding the GTR's failure to request for that advice.

Furthermore, in preparing a RARMP it is suggested that the GTR be prohibited from exclusively relying on data provided by either the applicant or industry. However, when such data is used, it is recommended that it be peer reviewed and independently confirmed.[104] These measures will confer greater protection on biodiversity as they will ensure that the RARMP is not based on data that favours the release of the GMO.

Furthermore, the EPBC Act's environmental impact assessment provisions should be inserted into the *Gene Technology Act* in light of the *Gene Technology Act*'s broad scope.[105] A failure to do so is arguably a failure to honour Australia's commitment to the Convention for Biological Diversity, specifically to Article 14[106] and Article 8(g)[107] of the CBD. Moreover, the *Gene Technology Act* should explicitly mandate the completion of a social impact assessment, cumulative impact assessment and strategic environmental impact statement.

Upon completing a RARMP, the public must be given an opportunity to make a written submission in relation to the RARMP in accordance to the notice requirements mentioned earlier in this paper. Since RARMPs are likely to be lengthy and contain technical and complex material, it is suggested that the public be given 60,[108] rather than 30 days to make a submission. Moreover, public

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103 This includes the GTCC, the GTTAC, the GTEC, any State authority, any Commonwealth authority and the general public.

104 Greenpeace Australia Pacific, above n 100, 11.

105 Currently there exist draft amendments to *EPBC Act* that, *inter alia*, state that a proposed dealing with a GMO which may pose a significant risk of harm to the environment is required to undergo the EPBC Act's assessment process. See Environment Australia, *Environmental Assessment of Genetically Modified Organisms* (3 September 2003) http://www.ea.gov.au/epbc/publications/archive/gmoamendments.html> (16 October 2003)

106 Convention for Biodiversity (hereafter 'CBD'), above n 47, Article 14(a) and Article 14(b); Article 14 of the CBD deals with impact assessment and minimising adverse impacts. The first two subsections of the Article 14 reads 1. Each Contracting Party, as far as possible and as appropriate, shall (a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures; (b) Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account;

107 CBD, above n 47, Article 8(g); Article 8 of the CBD deals with in-situ conservation. Article 8(g) specifically deals with GMOs and reads: 'Each Contracting Party shall, as far as possible and as appropriate: (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health'.

108 Phelps, above n 63.

hearings,[109] intervenor funding and workshops should be provided to assist people discuss and understand RARMPs and prepare submissions.[110]

C *Licence Conditions*

Biodiversity would be better protected and conserved if the measures set out in the risk management plan become the conditions of the licence. Other conditions that this paper suggests be attached to the GMO licence include that the applicant:

(a) renew the licence every three years;

(b) continually monitor and evaluate any risk associated with the GMO;

(c) submit an annual report to the GTR with respects to such monitoring;

(d) post adequate financial assurances with the GTR, for example performance bonds, that can be used to address any harm caused by the dealing.[111]

Moreover, the GTR should not be able to vary licence conditions unless such variations have been subjected to the public participation and approval processes required for issuing GMO licences.

Currently under the *Gene Technology Act* a failure to abide by licence conditions constitutes a strict liability offence.[112] Although this provision is commendable, it would better protect biodiversity if the penalties for this offence were increased ten fold.[113] Moreover, it is recommended that s 6(2) be deleted as it undermines the protection of biodiversity by conferring immunity to the Crown against any offences it commits under the *Gene Technology Act*.[114]

D *Determining whether to issue a GMO licence*

To best protect and conserve biodiversity it is suggested that a licence must not be issued unless there is clear, convincing and sufficient evidence that the licence will not pose a significant risk to the health and safety of either people, the environment or biodiversity.[115] In determining this, the GTR must have regard to the precautionary principle, ESD, the RARMP and the advice from any person/body.

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109 Section 53 of the *Gene Technology Act* gives the GTR the discretion to determine whether to hold a public hearing.

110 I Thomas, *Environmental Impact Assessment in Australia: Theory and* Practice (2001) 27.

111 Anton, above n 35.

112 *Gene Technology Act*, above n 1, s 35.

113 Phelps, above n 63.

114 This recommendation is particularly important in light of the unlikelihood that the GTR will be found liable at common law for any loss of biodiversity resulting from the release of a GMO. See: L McIntosh, 'Liabilty for loss of Biodiversity caused by the Release of GMOs' (2002) 4 *National Environmental Law Review* 40, 49.

115 Anton, above n 35.

Moreover, it is suggested that the *Gene Technology Act* permit the Environment Minister to veto[116] the GTR's decision to issue a licence. Furthermore, as currently required, the GTR must not issue a licence if it is either inconsistent with a policy principle[117] or the applicant is not a suitable person to hold the licence. Moreover, it is recommended that the GTR make publicly available a report that justifies its decisions and why it rejected or adopted specific public submissions or advice.[118]

E *Review Rights under the Gene Technology Act*

A significant shortcoming of the *Gene Technology Act*, which hinders the protection and conservation of biodiversity, is its failure to provide for third party[119] review rights.[120] Thus, to improve the *Gene Technology Act* it is suggested that the *Gene Technology Act* offer open standing provisions in relation to internal, merits and judicial review of any decision made by the GTR under the *Gene Technology Act*.[121]

To ensure that this measure is not tokenistic, the *Gene Technology Act* must adequately facilitate public access to information. Although the *Gene Technology Act* permits public access to information save confidential commercial information, procedural fairness would be better facilitated if the *Gene Technology Act* explicitly presumed that all information collected under it is accessible to the public. Information can then only be declared confidential commercial information if the applicant is able to rebut this presumption by proving beyond reasonable doubt that, *inter alia*, the declaration will not create a significant risk to human safety, the environment or biodiversity.[122] Moreover, to facilitate effective public participation the *Gene Technology Act* should establish and vigorously apply 'a flexible but stringent set of entitlement criteria'[123] for intervenor funding.

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116 National Genetic Awareness Alliance, *Inquiry into Gene Technology* (27 October 2000) <http://www.aph.gov.au/senate/committee/clac_ctte/gene/submissions/sublist.htm> (16 October 2003).

117 The *Gene Technology Act* should be amended to allow the general public to participate in formulating policy principles.

118 Clinch-Jones, *Submission on Gene Technology Bill 2000*, (27 October 2000) <http://www.aph.gov.au/senate/committee/clac_ctte/gene/submissions/sublist.htm> (16 October 2003).

119 The *Gene Technology Act* also fails to provide for third party rights for compensation for breaches of the *Gene Technology Act*. See: O Griffiths, 'Human Cloning Offences; the Gene Technology Act 2000 (Cth)' (2001) 9(1) *Journal of Law and Medicine* 14, 16.

120 Section 179 of the *Gene Technology Act* limits review rights to either applicants for, or holders of a licence, certification and accreditation.

121 Phelps, above n 26.

122 Anton, above n 35.

123 M Jeffery, 'Intervenor Funding: Improving the Quality of Environmental Decision-making, Revised Article, February 2001, based on earlier article titled 'The Role of Intervenor Funding in Project Approval' *International Business Lawyer* (1986) 371 as extracted in D Craig, N Robinson and K L Koh (eds), *Capacity Building for Environmental Law in the Asian and Pacific Region: Approaches and Resources* (2002) Vol 1, 678.

VIII CONCLUSION

In light of the above critique, it is concluded that the *Gene Technology Act* neither effectively nor efficiently regulates gene technology in Australia. Thus, it is questionable whether Australia is respectively facilitating and preventing the potential benefits and threats that gene technology may impose upon all facets of life, including biodiversity. To better protect and conserve biodiversity, and thereby improve the *Gene Technology Act*, the Commonwealth Parliament might consider adopting some of the suggestions canvassed in this paper. This is particularly important since the current shortcomings of the *Gene Technology Act* may be construed as Australia's failure to honour its commitments under the CBD.