

GENE TECHNOLOGY REGULATION AND THE ENVIRONMENT PROTECTION AND BIODIVERSITY CONSERVATION ACT 1999 (Cth)

KARINNE LUDLOW*

Diverse risks arise from the release of genetically modified organisms into the environment, including possible environmental and socio-economic impacts. Not all risks are addressed by the national GMO regulatory regime created by the Gene Technology Act 2000 (Cth). Some risks, namely socio-economic impacts, are instead addressed by recently introduced State moratorium legislation. Yet others, in particular some environmental concerns, are assessed under the Environment Protection and Biodiversity Conservation Act 1999 (Cth) but only if the operation of that Act is triggered. This article considers the interaction of the regulation of agricultural GMO releases by the Gene Technology Act 2000 (Cth), State moratorium legislation and the Environment Protection and Biodiversity Conservation Act 1999 (Cth).

I INTRODUCTION

In October 1990 a special Premiers' Conference endorsed a national approach to, amongst other things, the control of genetically modified organisms ('GMOs').¹ Following a report by the House of Representatives Standing Committee on Industry, Science and Technology on GMOs,² the Australian Government announced in October 1992 that it would establish a statutory body to regulate GMOs in Australia.³ Negotiations between the Commonwealth and States⁴ to establish the body began in 1993. Finally, on 21 June 2001 a new national regulatory regime for GMOs was introduced with the commencement of the *Gene Technology Act 2000* (Cth) ('GT Act').⁵ The GT Act is the primary Australian legislation regulating GMOs. The GT Act is administered by a newly

* Lecturer, Faculty of Law, Monash University, Australia.

¹ Gerard Maxwell Bates, *Environmental Law in Australia* (5th ed, 2002) 76-7.

² House of Representatives Standing Committee on Industry, Science and Technology, Parliament of Australia, *Genetic Manipulation: The Threat or the Glory?* (1992).

³ Genetic Manipulation Advisory Committee, *Annual Report 1993-4* (1994) 12. As to whether a regulatory system is sufficient to protect the public, see, 'Designer Genes That Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products' (1987) 100 *Harvard Law Review* 1086.

⁴ In this article, 'States' includes all Australian States and Territories unless otherwise stated.

⁵ Each State must then adopt the *Gene Technology Act 2000* (Cth) into its own law for the national scheme to apply. All jurisdictions except Western Australia and the Northern Territory have introduced the necessary complementary legislation. See *Gene Technology Act 2003* (ACT); *Gene Technology (New South Wales) Act 2003* (NSW); *Gene Technology Act 2001* (Qld); *Gene Technology Act 2001* (SA); *Gene Technology Act 2001* (Tas); *Gene Technology Act 2001* (Vic). See also *Gene Technology Bill 2001* (WA). The Commonwealth and State Governments also entered into the Gene Technology Agreement which sets out the understandings between the participating governments regarding the national scheme.

created regulator, the Gene Technology Regulator ('the Regulator'), in the Office of the Gene Technology Regulator, part of the Australian Department of Health and Ageing.

Less than a year before the commencement of the GT Act, the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ('EPBC Act') came into operation.⁶ The EPBC Act is the Australian Government's principal environmental legislation and reflects Australia's obligations under the United Nations Convention on Biological Diversity.⁷ It is administered by the Australian Department of the Environment and Heritage.

Pursuant to the GT Act, the Commonwealth Environment Minister must be consulted on environmental risks during the risk assessment process where a GMO is to be released into the environment. However, as will be discussed below, not all risks arising from GMO releases are addressed by the GT Act.⁸ In particular, socio-economic impacts are not considered in the risk assessment process under the GT Act. In light of that and faced with the prospect of the commercial release of GM canola,⁹ all States but Queensland¹⁰ and the Northern Territory¹¹ have recently acted to prohibit releases of certain GMOs even if licensed under the GT Act. Further, not all environmental impacts relevant under the approval provisions of the EPBC Act are assessed under the GT Act, even following consultation with the Commonwealth Environment Minister. If the approval provisions of the EPBC Act are triggered by a GMO release, a different risk assessment will be made by the Department of the Environment and Heritage to that undertaken where the Environment Minister is consulted under the GT Act.

This article considers the interaction of the regulation of the release of agricultural GMOs into the environment by the GT Act, the State moratorium legislation and the EPBC Act. The review of the national gene technology

⁶ On 16 July 2000.

⁷ *Convention on Biological Diversity*, opened for signature on 5 June 1992, [1993] ATS 32 (entered into force 29 December 1993).

⁸ This has led to calls for the expansion of the risk assessment process under the *Gene Technology Act 2000* (Cth). For example, South Australia has called for other considerations to be included in the current risk assessment process under the *Gene Technology Act 2000* (Cth), including the risk of contamination and its consequences: see Select Committee on Genetically Modified Organisms, South Australia House of Assembly, *Final Report* (tabled 17 July 2003), Recommendation 16. A review of that risk assessment process has also recently commenced: Office of the Gene Technology Regulator, *Invitation to Comment on the Office of the Gene Technology Regulator's Risk Analysis Framework* (circa March 2004).

⁹ See, eg, in the case of Victoria, Victoria, *Parliamentary Debates*, Legislative Assembly, 9 April 2003, 963 (Savage, Member for Mildura).

¹⁰ Queensland has developed a Code of Ethical Practice for Biotechnology in Queensland, effective 1 September 2001, but has not banned the release of GMOs in that State: Department of Innovation and Information Economy, *Code of Ethical Practice for Biotechnology in Queensland* (1 September 2001).

¹¹ The Northern Territory Government's pre-election position on GMOs was to oppose any commercial development but support ongoing experimentation and testing: Northern Territory, *Parliamentary Debates*, 15 August 2002, Ninth Assembly, First Session Parliamentary Record No 6 (McAdam, Minister for Business, Industry and Resource Development). No formal moratorium has been introduced.

regulatory scheme due by September 2005¹² makes an examination of such interaction timely. It begins in Part II with a brief introduction to the environmental and socio-economic consequences that may follow agricultural GMO releases. In Part III the international regulation of GMOs and the relevance of that regulation to releases in Australia is considered. Part IV describes the relevant provisions of the GT Act. The recent State responses to the limited risk assessment under the GT Act are then discussed in Part V. In Part VI the application of the EPBC Act to GMO releases is examined. Conclusions are brought together in Part VII. It is submitted that the limited risks assessed during the licensing process under the GT Act has had and will have significant consequences for those wanting to release agricultural GMOs. First, it was a factor in the introduction of the piecemeal State moratorium legislation. Secondly, it means opponents to GMO releases can use legislative schemes, other than the one introduced to establish a nationally consistent regulatory regime for GMOs, to prevent releases approved under the GT Act.

II CONSEQUENCES OF GMO RELEASES

A Possible Environmental Consequences

GMOs are essentially organisms modified by gene technology and their progeny that inherit such modifications.¹³ Gene technology, or genetic modification ('GM') as it is more commonly known,¹⁴ is broadly any technique for the modification of genetic material other than, amongst other things, sexual reproduction and standard plant breeding techniques.¹⁵

GM has been applied to, and is said to have enormous further potential for, commercial applications in a wide variety of industries.¹⁶ In agriculture, plants and animals are being modified to make them herbicide-tolerant, pest-resistant,¹⁷ improve their nutritional value,¹⁸ change their usual growth pattern¹⁹ or reduce

¹² Gene Technology Agreement cl 37. The commencement date of the Agreement was 11 September 2001.

¹³ *Gene Technology Act 2000* (Cth) s 10(1) (definitions of 'GMO' and 'genetically modified organism'). See also definition of 'organism'.

¹⁴ GM is also used here to refer to 'genetically modified', as the case may require.

¹⁵ *Gene Technology Act 2000* (Cth) s 10(1) (definition of 'gene technology'). For further explanation of the techniques involved in genetic modification, see Australian Government Analytical Laboratories, *Review of Technologies for Detecting Genetically Modified Materials in Commodities and Food*, prepared for the Department of Agriculture, Fisheries and Forestry – Australia (undated, circa 2002); Bernard R Glick and Jack J Pasternak, *Molecular Biotechnology. Principles and Applications of Recombinant DNA* (3rd ed, 2003).

¹⁶ Such industries include health care, therapeutic goods production (such as insulin and human growth factor), mining and agriculture. For a description of the benefits of genetic modification to agriculture see House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution. Primary Producer Access to Gene Technology* (2000) 7-16. See pages 16-26 with respect to the risks and disadvantages.

¹⁷ Including resistance to viral, bacterial, fungal and nematode attack.

¹⁸ Eg, by reducing lactose content in milk or reducing fat content in meat.

¹⁹ Eg, by delaying the ripening of fruits or changing their flower colour or, in the case of animals, causing the animals to grow more rapidly.

their environmental impact.²⁰ Although assessing the potential benefits and risks of agricultural GMOs is difficult, two recent Commonwealth agency reports have concluded that it may be detrimental to Australia's agricultural trade if GM crop production does not proceed.²¹

However, to take advantage of agricultural GMOs, farmers must release them into the environment. Release brings with it risk of harm.²² GMO releases have the potential to cause harm to the environment, such releases even having been described as 'living pollution'²³ and prompting fear of 'ecological catastrophe'.²⁴ Potential for harm arises because GMOs and their parts or products, such as pollen or progeny, could escape from their release site.²⁵ The organism, parts or products cannot be recalled once released.

Any 'escapee' population, GM or not, may harm the quality of the physical environment. For example, canola is inherently weedy.²⁶ It spreads and grows in places where it is not intended to be. However, some GMOs such as GM canola may have an increased potential for weediness.²⁷ GMOs may even become 'super-weeds' in the case of plants²⁸ or pests in the case of animals. A GMO may

²⁰ There are other commercial applications of genetic modification to agriculture. See, eg, Department of Human Services, Environmental Health Branch, Genetically Modified Food Unit, *Preserving the Identity of non-GM Crops in South Australia*, Discussion Paper (September 2001) <<http://www.dh.sa.gov.au/pehs/id-non-gm-crops.htm>> at 31 December 2004; Department of Agriculture, Fisheries and Forestry – Australia, *Biotechnology Strategy for Agriculture, Food and Fibre* (August 2003) <<http://www.affa.gov.au/agbiotech>> at 31 December 2004, Appendix 1, 5-7.

²¹ S Stone et al, Australian Productivity Commission, *Modelling Possible Impacts of GM Crops on Australian Trade*, Staff Research Paper (2002) <<http://www.pc.gov.au/research/staffres/gmcrops/gmcrops.pdf>> at 31 December 2004; M Foster, Grains Research and Development Corporation, *GM Canola: What are its Economics under Australian Conditions?* (2003) <<http://www.abareonlineshop.com/product.asp?prodid=12526>> at 31 December 2004.

²² For a discussion of the harms that could be caused by GMOs see Tim Sampson, 'Environmental Risk Assessment of GMOs under Directive 2001/18: An Effective Safety-Net or a "Collective Illusion"' (2003) 25 *European Intellectual Property Review* 79.

²³ Ms Hubbard quoted in M Marino, 'Shoppers Prompt Crackdown on GM Food', *Sunday Age* (Melbourne), 26 January 2003, News 8.

²⁴ Joanne M Merry, 'The Bioengineering Revolution: Genesis of a Compromise Solution' (1988) 20 *Pacific Law Journal* 163, 163.

²⁵ Plants and animals escaping into the wild have been identified as community concerns about GMOs: Explanatory Memorandum, Gene Technology Bill 2000 (Cth), 6.

²⁶ See Part IV below for discussion of issues raised during the assessment of the licence application for GM canola.

²⁷ GM herbicide-resistant canola plants are becoming a major weed problem in some parts of Canada: The Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* (January 2001) 122. Although the Society notes that the overall likelihood of GM crops themselves becoming serious invasive problems may be remote. See also G N Mandel, 'Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals' (19 June 2003) <<http://ssrn.com/abstract=418221>> at 31 December 2004.

²⁸ Eg, the transfer of genes for herbicide tolerance from GM crops to related species may result in herbicide resistant weeds: Senate Committee on Community Affairs, Senate, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report on the Gene Technology Bill 2000* (November 2000) 18. See also L L Wolfenbarger and P R Phifer, 'The Ecological Risks and Benefits of Genetically Engineered Plants' (2000) 290 *Science* 2088. But see United Kingdom Department of Trade and Industry, The GM Science Review Panel, *GM Science Review (First Report): An open review of the science relevant to GM crops and food based on interests and concerns of the public* (2003) <www.gmsciencedebate.org.uk/report> at 31 December 2004 which concluded that the current generation of GM crops were unlikely to invade the United Kingdom countryside and become problematic plants. Nor were they likely to be toxic to wildlife.

also harm other organisms because of the GMO's effect on the physical environment, because the GMO is toxic to certain organisms²⁹ or because of genetic contamination of wild relatives.³⁰ Genetic contamination may cause a critical decrease in the genetic purity of unique wild relatives, the wild relative even then breeding itself out of existence as a genetically distinct subspecies.³¹ Such consequences will have adverse effects on biodiversity.³² Biodiversity could also be harmed indirectly by GMOs because GMOs could replace landraces and their inherent diversity.³³ This type of monoculture may then make a country more susceptible to widespread crop failures and other crop disturbances.³⁴ It is also claimed that GMOs could lead to increased environmental damage due to greater use of chemicals, such as herbicides, given that some GMOs will be resistant to such chemicals.³⁵

These are not problems unique to GMOs. Some of the harms arise from the pursuit of agriculture generally rather than because GMOs are involved. The escape of non-GMOs could also cause many of these harms. In 1983 the authority overseeing the voluntary regulatory system for GMOs that existed at the time, the Recombinant DNA Monitoring Committee ('RDMC'), noted that the problem of being unable to destroy an organism released into the environment was not a new dilemma.³⁶ The RDMC also noted that the same risks must be weighed each time any new species of plant, animal, insect or microorganism is imported into Australia or when new strains of commercially important crops or

²⁹ Eg, insect resistant crops may adversely affect non-target insects. Senate Committee on Community Affairs, above n 28, 18.

³⁰ Gene transfer frequencies are dependent upon such factors as sexual compatibility between the donor and recipient species, flowering synchrony, sharing a common insect pollinator and closeness of distance: Lillian Auberson, 'Risk Semantics and GM organisms' <http://binas.unido.org/binas/show.php?id=10&type=html&table=book_sources&dir=binasnews#sem> at 31 December 2004, citing J A Scheffler and P J Dale, 'Opportunities for gene transfer from transgenic oilseed rape (*Brassica napus*) to related species' (1994) 3 *Transgenic Res* 263. See also J Glover, Bureau of Rural Sciences, *Gene flow study: Implications for GM crop release in Australia* (2002) <http://www.affa.gov.au/corporate_docs/publications/pdf/innovation/Gene_flow_report.pdf> at 16 January 2005.

³¹ Thomas P Redick and Christina G Bernstein, 'Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date With Damocles' (2000) 30 *Environmental Law Reporter* 10328, 10338.

³² Biodiversity as used in the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) has been said by Branson J to mean the 'variability among living organisms from all sources including inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.' *Booth v Bosworth* (2001) 114 FCR 39, 43. See also *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 528 (definition 'biodiversity').

³³ United Nations Food and Agriculture Organisation, Committee on Agriculture, Fifteenth Session, 25-29 January 1999, *Biotechnology* <<http://www.fao.org/unfao/bodies/coag/coag15?x0074e.htm>> at 1 February 2005, para 41. Environmental risks from the use of monocultures compromising biodiversity was identified as a risk associated with the release of GM products by the Lay Panel of Australia's First Consensus Conference on Gene Technology in the Food Chain in March 1999. Jan McDonald, 'Mechanisms for Public Participation in Environmental Policy Development – Lessons from Australia's First Consensus Conference' (1999) 16 *Environmental and Planning Law Journal* 258, 261.

³⁴ Mandel, above n 27, 23.

³⁵ This risk was suggested to a government committee during an inquiry into the Gene Technology Bill 2000 (Cth): see Senate Committee on Community Affairs, above n 28, 18.

³⁶ Australian Department of Industry, Technology and Commerce, *Recombinant DNA Monitoring Committee. Report for the Period 1 July 1983 to 30 June 1984* (1985) 5.

animals are bred in Australia whether they are GM or not. In fact, it observed, some types of exotic organisms could pose more of a risk than GM ones if they are very invasive. Nevertheless, the risk of environmental harm arising from GMO releases means both the GT Act and EPBC Act are relevant. How that legislation is relevant is discussed in Parts IV and VI below.

B Socio-Economic Impacts

GMO releases may have social and economic impacts for the community and for individuals.³⁷ Social impacts for the purposes of this article are the effects of GMO releases on others' way of life. A commonly raised possible social impact is that contamination or threatened contamination by GMOs will make non-GM agriculture impossible. GMO releases may also cause third parties distress because of their personal attitude to GMOs.³⁸ For example, distress may arise because of a third party's opposition to GMOs or because of their concern that they, their family, their property (both land and the organisms raised on it) or their business will be harmed by the GMO release.³⁹ All such concerns can arise whether or not GMOs have spread to another's land.

Economic impacts may also arise, particularly because of contamination or threatened contamination by the GMO of others' organisms or land. The 'contaminated' person may be a non-GMO farmer, growing conventional or organic organisms.⁴⁰ Agricultural markets can be divided into three categories.⁴¹ First, non-discriminating markets. These markets do not require that GM and non-GM material be kept separate. Secondly, non-GM markets. These markets are those where regulatory authorities or commercial customers specify a threshold for the presence of GM material in non-GM material. Finally, identity

³⁷ Other socio-economic consequences besides those discussed in this Part are also possible, although more distantly removed from releases by the releasers than the ones described in the text. For example, purchasers of agricultural produce who are unaware that the produce has been contaminated by a GMO may claim to have been harmed. These more distant consequences are not considered in this article.

³⁸ See, eg, with respect to concerns about GM crops, UK, Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (1999) <<http://www.nuffieldbioethics.org/fileLibrary/pdf/gmccrop.pdf>> at 23 January 2005. Regarding GM animals see Rebecca Dresser, 'Ethical and Legal Issues in Patenting New Animal Life' (1988) 28 *Jurimetrics Journal* 399; UK, Agriculture and Environment Biotechnology Commission, *Animals and Biotechnology. A Report by the AEBBC* (2002) <http://www.aebc.gov.uk/aebc/pdf/animals_and_biotechnology_report.pdf> at 23 January 2005. See also Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002) <[http://cbac-cccba.ca/epic/internet/incbac-cccba.nsf/vwapj/IPPHL_biotech_Interim_e.pdf/\\$FILE/IPPHL_biotech_Interim_e.pdf](http://cbac-cccba.ca/epic/internet/incbac-cccba.nsf/vwapj/IPPHL_biotech_Interim_e.pdf/$FILE/IPPHL_biotech_Interim_e.pdf)> at 23 January 2005.

³⁹ For further discussion see, eg, Victorian Law Reform Commission, *Genetic Manipulation*, Report No 26 (1989), ch 1; House of Representatives Standing Committee on Industry, Science and Technology, above n 2, ch 4; F W A Brom et al, 'Public Policy and Transgenic Animals: Case-by-Case Assessment is a Moral Learning Process' in P Wheale et al (eds), *The Social Management of Genetic Engineering* (1998), ch 15; The Royal Society of Canada, above n 27; Tasmania, Parliamentary Joint Select Committee, *Report on Gene Technology* (2001), ch 6.

⁴⁰ In 2000 there were 2 000 producers certified organic in Australia: Ian Gilfillan, South Australian Member of Parliament, *GM Moratorium Plan Gathers Support* (Press Release, 20 June 2000).

⁴¹ The following categories and examples are from Australia, Gene Technology Grains Committee, *A strategic framework for maintaining coexistence of supply chains* (draft-for-discussion) (31 July 2002), 6.

preserved markets. These markets require the preservation of unique characteristics of a product desired by a customer or consumer. This may be a GM product, a non-GM product or a product based on a production system, such as 'organic' canola.⁴² Actual or threatened GM contamination may cause the invaded party to lose access to a particular market.⁴³ Contamination may also mean the third party no longer satisfies contractual warranties provided by them regarding the GM status of their organisms.⁴⁴ Even on the assumption that all GMOs grown in Australia have regulatory approval, not all will be of the same status with respect to overseas markets.⁴⁵ Some may not have been approved by overseas markets. Contamination of organisms that have been approved or are non-GM by non-approved GMOs may mean the loss of overseas markets for the approved or non-GM organisms or delay in shipment whilst overseas regulators assess the significance of the contamination.⁴⁶ Loss of such access could in turn cause the loss of some premium available in the relevant market.⁴⁷

Threatened contamination could also cause third parties to take precautions to prevent spread onto their properties.⁴⁸ Actual contamination may cause third parties to have to change normal agricultural practices.⁴⁹ It has been claimed GM

⁴² Australian anti-GM activist groups, Australian GeneEthics Network and Greenpeace Australia-Pacific, have reportedly been unable to find organic canola farmers in Australia. G O'Neill, 'Melbourne University report positive on GM Canola varieties' *Australian Biotechnology News* <<http://www.biotechnews.com.au/index.php?id=1387312272&taxid=5>> at 26 March 2003.

⁴³ See Richard A Repp, 'Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift' (2000) 36 *Idaho Law Review* 585, 594-5 with respect to the repercussions this may have for organic farmers.

⁴⁴ Australia, Department of Agriculture, Fisheries and Forestry, Science and Economic Policy Branch, *Liability Issues Associated with GM Crops in Australia* (2003) 6. See also M Marino, 'Farmers testy over GM', *The Age* (Melbourne), 1 October 2004, 7 News.

⁴⁵ For a summary of GM legislation and labelling issues concerning the export of Australian produce to 15 overseas countries see Western Australia, Department of Agriculture, *International Market Trends for Genetically Modified Crops* (2002), 62-3, Table 21.

⁴⁶ Redick and Bernstein, above n 31, 10343. See also Repp, above n 43, 591 where Repp describes events leading to rejection of a shipment of organic tortilla chips by European authorities after DNA testing showed traces of GM corn. The manufacturer claimed that pollen from GM corn in nearby fields was the probable cause. See also with respect to this case A Bryan Endres, "GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union" (2000) 22 *Loyola of Los Angeles International and Comparative Law Review* 453, 456, 482.

⁴⁷ The Victorian Government has found that markets are generally not willing to pay a premium for non-GM products. Premiums for non-GM products are, at best, only niche sales in the context of global production and world markets. Nevertheless, non-GM products may be anticipated to have advantages in market access and premiums may emerge in niche markets: Victoria, *Genetic Engineering-free Zones – Report of the Victorian Government Consultation* (2001) 10. See also Western Australia, Department of Agriculture, above n 45; Foster, above n 21, who concluded that there was no clear trend emerging for significant premiums for differentiated (GM and non-GM) products; Max Foster, Peter Berry and John Hogan, *Market Access Issues for GM Products: Implications for Australia*, ABARE eReport 03.13 to the Department of Agriculture, Fisheries and Forestry – Australia (2003); Peter J Lloyd, *Report of the Independent Reviewer to the Government of Victoria. Review of Market Impacts of Genetically Modified Canola and Industry Preparedness* (circa 2004) for a discussion of premiums paid on non-GM crops by overseas markets.

⁴⁸ Such precautions include the establishment of buffer zones or other barriers around a property or changes in crop selection or farming practices or the separation of GMOs and non-GMOs throughout the supply chain.

⁴⁹ Maria Lee and Robert Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 530. For example, the new gene may transfer to a weed and the weed may then become difficult to control requiring the neighbour to change weed management techniques.

contamination may even cause crops to fail.⁵⁰ Costs may also be incurred trying to eradicate the invading organism.⁵¹

Furthermore, an advantage held because particular legislative or regulatory requirements did or did not previously apply to the third party's organisms may be lost following GMO releases. A Tasmanian Government report concluded that 'food regulations, trade practices legislation and standards for certification of organic produce all provide in some form legal responsibility to ensure claims of GM-free can be substantiated'.⁵² For example, GM contamination may mean the invaded party can no longer claim GM-free status under such regulations. They may then be obliged to take steps, such as labelling, they otherwise would not have. Cultivating, saving and planting GM contaminated organisms or seed may also be regulated under the GT Act and State moratorium legislation discussed below. Invaded parties will then have to comply with the GT Act and relevant State legislation where they otherwise did not have to. GM contamination may even result in the destruction of the contaminated crop and restrictions being imposed on the future use of the land under State legislation.⁵³

GMO releases may have other economic implications for agriculture generally. For example, there is concern that their use may generate insect resistance or render particular herbicides or pesticides useless because resistance to such chemicals may spread to other organisms.⁵⁴

As discussed in Part IV below, socio-economic impacts of GMO releases into the environment are not considered in the risk assessment process under the GT Act. It seems that such impacts were excluded from the assessment process to avoid compromising the assessment of environment and health risks under the GT Act.⁵⁵ However, the relevant regulator under the GT Act may consult on such matters with either or both of two new advisory committees established under the

⁵⁰ See Repp, above n 43, 595.

⁵¹ Remediation of the contaminated property can be extremely difficult and expensive: see, eg, *Monsanto Canada Inc v Schmeiser* 2001 FCT 256 [59] where it was acknowledged that although all new non-GM seed was planted on Schmeiser's property, GM canola was still found on the property. See also Australian Capital Territory, Legislative Assembly, Standing Committee on Health, *Inquiry into the Gene Technology Bill 2002. Report No 2* (2002) [2.30] referring to case in Tasmania where GM-canola appeared on land five years after a trial was held on the site.

⁵² Tasmania, Parliamentary Joint Select Committee, above n 39, 107.

⁵³ *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) ss 11(2), 12; *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 14(2), (3); *Genetically Modified Crops Management Act 2004* (SA) ss 18(1), (2); *Genetically Modified Organisms Control Act 2004* (Tas) ss 26, 27; *Control of Genetically Modified Crops Act 2004* (Vic) s 15(1); *Genetically Modified Crops Free Areas Act 2003* (WA) ss 8(1), (2). With respect to restrictions on future use of land, see *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) s 11(3), *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 14(4).

⁵⁴ Rebecca Bratspies, 'Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco' (2003) 27 *William & Mary Environmental Law & Policy Review* 593, 600. For example, BT GM crops may lead to the loss of effectiveness of BT, a natural bacterial pesticide used by organic farmers to control caterpillars.

⁵⁵ Office of the Gene Technology Regulator, 'Rigorous Assessment Confirms GM InVigor Canola Safe as Non-GM Canola' (Press Release, 25 July 2003).

legislation.⁵⁶ That consultation may be with the Gene Technology Ethics Committee on ethical issues and/or the Gene Technology Community Consultative Committee on matters of general concern.⁵⁷ Whilst the licensing decisions of the Regulator could be restricted on the basis of the socio-economic impacts of GMO releases, the steps necessary for this to occur have not been taken.⁵⁸ Accordingly, other than complying with the Policy Principle described in Part V below, socio-economic objections to GMO releases are considered by the Regulator during the assessment process under the GT Act only in so far as they are relevant to the scientific assessment of the human health and safety or environmental hazards referred to in Part IV below.

III GMOs AND INTERNATIONAL ENVIRONMENTAL REGULATION

Australia is not a signatory to any international convention directly regulating GMOs. It is a signatory to the Convention on Biological Diversity referred to above. That Convention aims, inter alia, to conserve and encourage the sustainable use of biological diversity. The EPBC Act adopts the Convention's provisions into Australian law.⁵⁹ However, the Convention imposes no binding obligations on signatories specifically with respect to GMOs.

On 29 January 2000 an international Biosafety Protocol to the Convention was finalised in Cartagena, Columbia.⁶⁰ The Protocol is known as the Cartagena Protocol on Biosafety.⁶¹ The Protocol's objective is to promote conservation and sustainable use of biological diversity by addressing the potential risks posed by transboundary trade in living GMOs ('LMOs').⁶² In particular measures relating to the safe international transfer, handling and use of LMOs are established. These measures must be undertaken in a manner that prevents or reduces the risks to biological diversity taking into account risks to human health.⁶³

⁵⁶ A third new advisory body not relevant here, the Gene Technology Technical Advisory Committee, was also created under the Act. It provides expert scientific and technical advice to the Regulator at her request (*Gene Technology Act 2000* (Cth) s 101). See also *Gene Technology Act 2000* (Cth) s 100 and *Gene Technology Regulations 2001* (Cth) pt 4 with respect to this Committee.

⁵⁷ See *Gene Technology Act 2000* (Cth) pt 8 divs 4, 3 respectively with respect to these Committees.

⁵⁸ This would require the making of a policy principle (or mandatory guideline) by the Gene Technology Ministerial Council. This has not been done. Policy principles are discussed further in Part V below.

⁵⁹ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ch 5 provides for Australia's obligations with respect to protecting Australia's biodiversity.

⁶⁰ With respect to the Protocol generally see Philippe Sands, *Principles of International Environmental Law* (2nd ed, 2003), 652-8.

⁶¹ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, opened for signature 29 January 2000.

⁶² Cartagena Protocol on Biodiversity to the Convention on Biological Diversity, art 1. The Protocol focuses on LMOs rather than all GMOs because LMOs were seen as posing more risk given that they may have the ability to survive and persist in an environment compared with nonviable tissues or commodities. Editorial, (1998) 4 BINAS News 1 <http://binas.unido.org/binas/binasnews/bn2_3_98.pdf> at 26 January 2005.

⁶³ Cartagena Protocol on Biodiversity to the Convention on Biological Diversity, art 2(1) and (2).

Australia, although a signatory to the Convention, has not signed the Protocol. Nevertheless the Protocol will affect those Australians exporting LMOs to countries party to the Protocol.⁶⁴ As noted by the Australian Productivity Commission, it is likely the Protocol's provisions governing import decision making and its handling, transport, packaging and identification requirements would then need to be complied with.⁶⁵ For example, when exporting Australian products, such as meat or aquaculture products, the receiving country may demand to know if LMOs (such as GM feed-meal) were used in their production.⁶⁶ Therefore much of the information required under the Protocol will need to be provided by Australian producers to users on import into foreign countries. However, the Protocol does not affect domestic regulation of GMOs. Further, it is unlikely that the Protocol affects Australian importers of LMOs because existing domestic regulation rather than the Protocol would apply.⁶⁷ This article is concerned only with regulation of GMOs in Australia.

IV GENE TECHNOLOGY ACT 2000 (Cth)

The object of the GT 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'.⁶⁸ It does this by prohibiting all 'dealings' with GMOs in Australia unless authorised under the GT Act.⁶⁹ 'Dealings' for these purposes include most commercial uses of GMOs, including release into the environment.⁷⁰ As with the Protocol discussed above, the GT Act focuses on living and viable GMOs rather than the products of such organisms because it was decided that the environmental risks associated with most non-living, non-viable GM products were already adequately controlled by other regulators.⁷¹

Although there are four categories of authorised dealings under the GT Act, GMO releases into the environment are possible in only two of those categories. These are dealings listed in the GMO Register and licensed dealings. No GMO has yet been approved for inclusion in the GMO Register.⁷² The last category, licensed dealings, is therefore the focus of this article.

⁶⁴ Commonwealth, Productivity Commission, *Productivity Commission Submission to the Department of Foreign Affairs and Trade on the Cartagena Protocol on Biosafety* (2000) 9.

⁶⁵ *Ibid.*

⁶⁶ *Ibid.*

⁶⁷ *Ibid.* Imported products, whether GM or not, are regulated in Australia under the *Quarantine Act 1908* (Cth) and the *Imported Food Control Act 1992* (Cth) administered by the Australian Quarantine and Inspection Service.

⁶⁸ *Gene Technology Act 2000* (Cth) s 3.

⁶⁹ *Gene Technology Act 2000* (Cth) ss 32(1), 33(1).

⁷⁰ *Gene Technology Act 2000* (Cth) s 10(1) (definition of 'deal with').

⁷¹ Commonwealth-State Consultative Group on Gene Technology and the Interim Office of the Gene Technology Regulator, *Proposed National Regulatory System for Genetically Modified Organisms. How Should It Work?* Discussion Paper (1999) 14. GM products can nevertheless be regulated under the *Gene Technology Act 2000* (Cth). See, eg, *Gene Technology Act 2000* (Cth) s 10(1)(c) (definition 'genetically modified organisms').

⁷² The GMO Register is maintained by the Regulator (*Gene Technology Act 2000* (Cth) s 76(2)) and is open to public inspection (*Gene Technology Act 2000* (Cth) s 81).

The Regulator grants licences under the GT Act. There are two types of licences – those not involving intentional release of a GMO into the environment ('DNIR licences') which are not considered here and those that do involve such release ('DIR licences'). An 'intentional release of a GMO into the environment' is defined in the GT Act as meaning a dealing where:

the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment.⁷³

Licence applications must specify whether any of the dealings proposed to be authorised involve the intentional release of a GMO into the environment.⁷⁴ This determines the next steps taken by the Regulator. There are separate assessment processes for each of the two types of licence application.⁷⁵ A more rigorous process is required for DIR licence applications.

Where a DIR licence is being sought the Regulator must prepare a risk assessment and a risk management plan.⁷⁶ The risk assessment identifies any hazards posed by the GMO and 'the level of risk posed by such hazards based on an assessment of the likelihood and consequence of the hazard occurring'.⁷⁷ The risk management plan details how any risks posed by the GMO may be managed to ensure that unacceptable risks are not realised and describes any proposed licence conditions.⁷⁸ Both when preparing the risk assessment and risk management plan and again when the documents have been prepared the Regulator must consult with, amongst others, the Commonwealth Environment Minister.⁷⁹ Advice given during such consultations must be taken into account by the Regulator when preparing the documents.⁸⁰ The Biotechnology Section of the Department of the Environment and Heritage is responsible for advising the Environment Minister with respect to that Minister's comments on the assessment process under the GT Act. There is no formal arrangement in place between the Biotechnology Section and the Approvals and Wildlife Division of the Department which is responsible for assessments under the EPBC Act. Nevertheless there is an informal arrangement pursuant to which the Biotechnology Section consults with the Approvals and Wildlife Division if it is

⁷³ *Gene Technology Act 2000* (Cth) s 11.

⁷⁴ *Gene Technology Act 2000* (Cth) s 40(3).

⁷⁵ *Gene Technology Act 2000* (Cth) pt 5.

⁷⁶ *Gene Technology Act 2000* (Cth) s 50(1). See also s 51.

⁷⁷ Office of the Gene Technology Regulator, *Handbook on the Regulation of Gene Technology in Australia* (2001) 79. See also Office of the Gene Technology Regulator, *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator* (2002) which provides general guidance to applicants, evaluators and other stakeholders when identifying and assessing the risks posed by dealings with GMOs and assists in determining the measures necessary to manage any such risks.

⁷⁸ Office of the Gene Technology Regulator, *Handbook*, above n 77, 79.

⁷⁹ *Gene Technology Act 2000* (Cth) ss 50(3), 52(3).

⁸⁰ *Gene Technology Act 2000* (Cth) s 51. The Regulator must also take into account those matters prescribed by the Regulations: *Gene Technology Act 2000* (Cth) ss 51(1)(g), 51(2)(g). See also *Gene Technology Regulations 2001* (Cth) reg 10. The Regulator may also take any other action she considers appropriate for the purpose of deciding the application: *Gene Technology Act 2000* (Cth) s 53.

possible that the EPBC Act itself could be triggered by a proposed GMO release.⁸¹ The Minister then has the power to trigger the assessment and approval procedure under the EPBC Act without any action by the person wanting to release the GMO.⁸²

The Regulator is prohibited from issuing a licence unless satisfied that any risks posed by the proposed dealings can be managed in a way that protects human health and safety and the environment.⁸³ Environmental risks assessed by the Regulator with respect to agricultural GMOs include hazards to the flora and fauna, habitat and biodiversity of the receiving environment posed by the GMO.⁸⁴ 'Environment' is defined in the Act as including 'the qualities and characteristics of locations, places and areas'.⁸⁵

Because of the definition of environment and the object of the legislation, the Regulator considers that she is limited in the consequences that she can consider during risk assessment and attempt to control.⁸⁶ First, the consequences of those hazards that are addressed by the Regulator are only those that adversely affect the health and safety of people and the environment.⁸⁷ Accordingly, some of the environmental consequences identified in Part II above are considered. For example, potential hazards to the environment because of contamination by a GMO and gene transfer from the GMO to other organisms are assessed.⁸⁸ However, trade and marketing ramifications of GMO releases, such as impacts on domestic and export markets and impacts on organic status, are not evaluated.⁸⁹ Nor does the Regulator consider the possible costs or benefits of GMOs to the agricultural industry.⁹⁰ Secondly, the relevant hazards must arise because of gene technology rather than because of, for example, agriculture generally.

⁸¹ Interview with Judy Johnson, Director, Biotechnology Section, Department of the Environment and Heritage (Canberra, 29 September 2004). The circumstances in which the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) would be triggered are discussed in Part VI below.

⁸² *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 70. See Part VI of this article with respect to the effect of referrals.

⁸³ *Gene Technology Act 2000* (Cth) s 56. Applicants can seek a review of a decision to refuse a licence or impose particular licence conditions: *Gene Technology Act 2000* (Cth) pt 12 div 2.

⁸⁴ Office of the Gene Technology Regulator, *Risk Analysis Framework*, above n 77, 20.

⁸⁵ *Gene Technology Act 2000* (Cth) s 10(1).

⁸⁶ There is some support for the Regulator's view that she cannot consider the economic ramifications of the commercial production of GM crops on neighbouring farmers: see Nicole Rogers, 'Seeds, Weeds and Greed: An Analysis of the *Gene Technology Act 2000* (Cth), Its Effect on Property Rights, and the Legal and Policy Dimensions of a Constitutional Challenge' (2002) 2 *Macquarie Law Journal* 1, 2. But see Mark Tranter, 'A question of confidence: an appraisal of the operation of the *Gene Technology Act 2000*' (2003) 20 *Environmental and Planning Law Journal* 245, 253; Mark Tranter, 'A system under strain: The Regulation of Gene Technology' (2003) 2 *National Environmental Law Review* 32, 35; Karinne Ludlow, 'Cultivating Chaos: State Responses to Releases of Genetically Modified Organisms' (2004) 9 *Deakin Law Review* 1.

⁸⁷ Office of the Gene Technology Regulator, *Risk Assessment and Risk Management Plan for Commercial Release of Bayer GM Canola into the Environment: Application No. DIR 021/2002* (1 April 2003), Appendix 1, definitions 'Hazard' and 'Hazard identification'.

⁸⁸ Office of the Gene Technology Regulator, *Full Risk Assessment and Risk Management Plan for Application for licence for dealings involving an intentional release into the environment, DIR 021/2002* (25 July 2003).

⁸⁹ Office of the Gene Technology Regulator, above n 87, Appendix 10 [702], [704].

⁹⁰ Office of the Gene Technology Regulator, above n 87.

The Regulator must decide, after completing the risk assessment process, whether to grant the licence and, if so, on what conditions.⁹¹ Relevantly here, the 'precautionary principle', a well established principle of environmental law,⁹² is included in the GT Act as one method by which the Act's object is to be achieved.⁹³ The relevant section provides:

that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.⁹⁴

There is considerable uncertainty as to the meaning of many of the terms used in this section.⁹⁵ For example, 'the government did not articulate the meaning or intention of "cost effectiveness"' in this scheme.⁹⁶

Licences cannot be granted to an applicant who is not a 'suitable person'.⁹⁷ Suitability depends, in part, on whether the applicant has any 'relevant convictions' and their past history with other licences or permits issued under any Australian (Federal or State) or foreign law where the law concerns the health and safety of people or the environment.⁹⁸ A relevant conviction is a conviction for an offence under a law relating to the health and safety of people or the environment. It must also have occurred within the prior 10 years and have been punishable by a fine of \$5 000 or more or imprisonment of one year or more.⁹⁹

The GT Act makes no provision for compensation to any person injured by an authorised release. Conversely though, it provides no immunity to any person releasing a GMO with the Regulator's authority. Members of the public, including the GMO releaser's neighbours and opponents to GMOs, cannot apply to the Administrative Appeals Tribunal for a merits review of the Regulator's decisions.¹⁰⁰ Where members of the public seek review on a question of law with respect to a Regulator's decision, they must establish that they are a 'person aggrieved' for the purposes of the *Administrative Decisions (Judicial Review) Act*

⁹¹ *Gene Technology Act 2000* (Cth) s 55.

⁹² See *Rio Declaration on Environment and Development*, United Nations Conference on Environment and Development, UN Doc A/CONF.151/5 (1992), reprinted in 31 ILM 874, 879 (1992), Principle 15. See also *Convention on Biological Diversity*, opened for signature on 5 June 1992, [1993] ATS 32 (entered into force 29 December 1993), Preamble; Cartagena Protocol on Biosafety to the Convention on Biological Diversity art 11.8.

⁹³ *Gene Technology Act 2000* (Cth) s 4(aa). The inclusion of this principle was recommended by the Senate Committee on Community Affairs, above n 28, xiv.

⁹⁴ *Gene Technology Act 2000* (Cth) s 4(aa).

⁹⁵ Charles Lawson, 'Risk Assessment in the Regulation of Gene Technology under the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001 (Cth)' (2002) 19 *Environmental and Planning Law Journal* 195, 209.

⁹⁶ *Ibid* 209.

⁹⁷ *Gene Technology Act 2000* (Cth) s 57(2), see also s 58.

⁹⁸ *Gene Technology Act 2000* (Cth) s 58. Other matters include the applicant's capacity to meet the conditions of the licence. This presumably includes matters such as the applicant's financial capacity.

⁹⁹ *Gene Technology Act 2000* (Cth) s 58(3).

¹⁰⁰ See *Gene Technology Act 2000* (Cth) s 183.

1977 (Cth) ('ADJR Act').¹⁰¹ In most cases, members of the public will not have standing to challenge a decision under the GT Act. However, residents and landowners, such as organic farmers, whose land adjoins or is near the property on which a GMO is to be released, may have sufficient special interest in the relevant decision of the Regulator to seek review under the ADJR Act.¹⁰² In some cases, environmental groups may also have standing.¹⁰³ There is uncertainty though as the question of standing is determined by judicial tests rather than legislative definition.¹⁰⁴ Members of the public may also seek an injunction from the Federal Court to restrain offences or threatened offences under the GT Act.¹⁰⁵ However, again, they must be an aggrieved person in order to have standing. There is no explanation of this term in the legislation. It is suggested that it would be interpreted in the same way as for the purposes of the ADJR Act.

V STATE MORATORIUM LEGISLATION

The agreement by all States to participate in the national gene technology regulatory scheme described in the GT Act means that risks assessed by the Regulator cannot be grounds for the States refusing to allow the release of GMOs in their jurisdiction. Accordingly, States cannot refuse GMO releases on the basis of risks to human health and safety and the environment. However, there has been continued concern about GMO releases given the limited risks assessed by the Regulator under the GT Act. For example, the proposed commercial release of GM canola generated considerable controversy.¹⁰⁶ Concerns exist about, inter alia, the impact of GMO releases and GM contamination on local trade and export markets and the liability of those inadvertently contaminated by GMOs. Some States want the capacity to refuse to allow GMO releases within their jurisdiction on the basis of such considerations.¹⁰⁷

¹⁰¹ *Administrative Decisions (Judicial Review) Act 1977* (Cth) ss 3(4), 5(1). See also *Australian Institute of Marine and Power Engineers v Secretary, Department of Transport* (1986) 13 FCR 124, 131-3; *Big Country Developments Pty Ltd v Australian Community Pharmacy Authority* (1995) 60 FCR 85, 92; *Right to Life Association (NSW) Inc v Secretary, Department of Human Services and Health* (1995) 56 FCR 50, 64-5, 84; *Transurban City Link Ltd v Allan* (1999) 95 FCR 553, 565.

¹⁰² Senate Committee on Community Affairs, above n 28, [5.72] citing Interim Office of the Gene Technology Regulator, submission No 77, 130. See *Day v Pinglen Pty Ltd* (1981) 148 CLR 289, 299-300; *Spitzer v Nichols Properties Ltd* (Unreported, Supreme Court of Tasmania, Zeeman J, 27 September 1990); *Sims v Planning Appeal Tribunal* (1992) 57 SASR 325, 341.

¹⁰³ The Interim Office of the Gene Technology Regulator considered that organisations that have, as part of their constitution or terms of reference, a reference to gene technology are likely to have standing according to Senate Committee on Community Affairs, above n 28, [5.72] citing Interim Office of the Gene Technology Regulator, submission No 77, 130. See also *Tasmanian Conservation Trust Inc v Minister for Resources* (1995) 55 FCR 516; *North Coast Environment Council Inc v Minister for Resources* (1994) 55 FCR 492. See further Tranter, 'A question of confidence. An appraisal of the operation of the Gene Technology Act 2000', above n 86, 255.

¹⁰⁴ Tranter, 'A question of confidence. An appraisal of the operation of the Gene Technology Act 2000', above n 86, 255.

¹⁰⁵ *Gene Technology Act 2000* (Cth) s 147(1). The Regulator may also seek injunctions in such cases.

¹⁰⁶ See, eg, A Wahlquist, 'It's safe to license GM, say farmers' *The Weekend Australian* (Sydney), 26-27 July 2003, 7; S Cauchi, 'GM: food for thought' *The Age* (Melbourne), 25 October 2003, 6 Insight; R Baker, 'Bracks "ignoring" Labor's GM policy' *The Age* (Melbourne), 18 March 2004, 8 News.

¹⁰⁷ Commonwealth-State Consultative Group on Gene Technology and the Interim Office of the Gene Technology Regulator, above n 71, 29.

It was agreed by all governments during the creation of the national gene technology regulatory scheme that the States should have the option of declaring part or all of their jurisdiction GM-free in limited circumstances not dealt with by the GT Act.¹⁰⁸ All States but Queensland and the Northern Territory have acted on that option. The relevant State legislation has important consequences for those wanting to release GMOS. The direct consequences of the State legislation are discussed in this Part. The indirect consequences arising because of the interaction between the State legislation, the GT Act and the EPBC Act are considered in the final Part of this article.¹⁰⁹

The State legislation prohibiting GMO releases ('the State moratorium legislation') was mostly enacted after the making of the *Gene Technology (Recognition of Designated Areas) Principle 2003* on 31 July 2003.¹¹⁰ That Principle was made by the Gene Technology Ministerial Council pursuant to the GT Act.¹¹¹

The Principle was issued for the purposes of 'recognising areas (if any) 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 marketing purposes.'¹¹²

It says '[a]n area is recognised as an area that is designated for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes, if the area is so designated under a State law'.¹¹³ The Principle does not change the risks assessed by the Regulator. Nor does it give the States any legislative power they previously did not have. Further, because of the limitation of the Principle to areas designated under State law, it has no direct relevance to the EPBC Act. Nevertheless, the Principle was thought necessary to ensure that any State moratorium legislation could not be successfully challenged on constitutional grounds.

Policy Principles are mandatory guidelines for the Regulator.¹¹⁴ The Regulator cannot issue a licence under the GT Act if to do so would be inconsistent with a Policy Principle.¹¹⁵ Licensing a release under the GT Act is not inconsistent with a State law protecting the identity of crops for marketing purposes because licenses do not exempt licensees from complying with State moratorium legislation.

¹⁰⁸ Gene Technology Agreement cl 6(d)(i).

¹⁰⁹ For further regarding the State legislation see Ludlow, above n 86.

¹¹⁰ The Principle took effect from 5 September 2003. See *Gene Technology (Recognition of Designated Areas) Principle 2003* s 2. The Policy Principle was gazetted in *Commonwealth Government Special Gazette No S340* on 5 September 2003 and tabled in both Houses of Parliament on 9 September 2003. For background on this issue see Senate Committee on Community Affairs, above n 28, [6.33]-[6.88].

¹¹¹ *Gene Technology Act 2000* (Cth) s 21(1).

¹¹² *Gene Technology (Recognition of Designated Areas) Principle 2003* s 4.

¹¹³ *Gene Technology (Recognition of Designated Areas) Principle 2003* s 5.

¹¹⁴ *Gene Technology Act 2000* (Cth) ss 21, 22.

¹¹⁵ *Gene Technology Act 2000* (Cth) s 57(1) and *Gene Technology Regulations 2001* (Cth) sch 3, s 2.1.

The Policy Principle refers only to GM or non-GM *crops*. The section of the GT Act empowering the Gene Technology Ministerial Council to make such principles limits its power in that way.¹¹⁶ The Regulatory Impact Statement on the Principle states that 'crop can be interpreted broadly and in this Regulatory Impact Statement it has been considered in this broad sense to cover all farmed GMOs, both terrestrial and aquatic.'¹¹⁷ Accordingly, both GM plants and animals are covered by the Principle's introduction.

The legislation of each State other than Queensland and the Northern Territory makes it an offence to release GMOs contrary to a moratorium order.¹¹⁸ Pursuant to the South Australian, Western Australian and Tasmanian State moratorium legislation all of the State has been or will be declared GM-free.¹¹⁹ In the Australian Capital Territory, New South Wales and Victoria, cultivation of certain GMOs is prohibited.¹²⁰ Exemptions or permits are then provided for in all States.¹²¹

The legislation creates new offences and compensation obligations that GMO releasers must be aware of. In South Australia and Western Australia GMO releasers can be ordered to compensate anyone inadvertently contaminated by a GMO or repay the government any compensation the government pays to such persons, where their crops are destroyed or ordered to be destroyed.¹²² Further, the penalties for offences under the State legislation are serious, being a

¹¹⁶ *Gene Technology Act 2000* (Cth) s 21(1)(aa).

¹¹⁷ Gene Technology Standing Committee, Regulatory Impact Statement on *Gene Technology (Recognition of Designated Areas) Principle 2003* s 1.1 <<http://www.tga.gov.au/gene/policy/grdapp03.htm>> at 31 January 2005.

¹¹⁸ *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) s 9; *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 7; *Genetically Modified Crops Management Act 2004* (SA) s 5(12); *Genetically Modified Organisms Control Act 2004* (Tas) s 7; *Control of Genetically Modified Crops Act 2004* (Vic) s 17(1); *Genetically Modified Crops Free Areas Act 2003* (WA) s 5.

¹¹⁹ *Genetically Modified Crops Management Act 2004* (SA) s 5(1); *Genetically Modified Crops Management (Designation of Areas) Regulations 2004* (SA) reg 3; *South Australian Government Gazette No 34*, 22 April 2004, 1092; *Genetically Modified Crops Free Areas Act 2003* (WA) s 4(1), Western Australia Department of Premier and Cabinet, 'Western Australia to be "GM-free"' (Press Release, 22 March 2004); *Genetically Modified Organisms Control Act 2004* (Tas) s 5(1). In some States, orders may also be made that specify that certain GMOs cannot be grown in a particular area in the State or designate an area as one in which GMOs may be grown: see *Genetically Modified Crops Management Act 2004* (SA) s 5(1); *Control of Genetically Modified Crops Act 2004* (Vic) s 4(1); *Genetically Modified Crops Free Areas Act 2003* (WA) s 4. Tasmania's new legislation does not allow for this: see *Genetically Modified Organisms Control Act 2004* (Tas) s 5(1). In the Australian Capital Territory and New South Wales the prohibition must be of a stated/specified GMO (or class of GMO in New South Wales) in all of the State: see *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) s 7(1); *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 6. In Victoria, an order may also be made designating all or part of the State to be genetic modification-free.

¹²⁰ *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) s 7(1); *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 6; *New South Wales Government Gazette*, No 119, 25 July 2003, 7513; *New South Wales Government Gazette*, No 198, Moratorium Order Number 2, 24 December 2003, 11686; *Control of Genetically Modified Crops Act 2004* (Vic) ss 4(1), 28 and sch.

¹²¹ *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) s 8; *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 8; *Genetically Modified Crops Management Act 2004* (SA) s 6; *Genetically Modified Organisms Control Act 2004* (Tas) pt 3 div 1; *Control of Genetically Modified Crops Act 2004* (Vic) s 6; *Genetically Modified Crops Free Areas Act 2003* (WA) s 6.

¹²² *Genetically Modified Crops Management Act 2004* (SA) ss 18(4), 24(1)(c); *Genetically Modified Crops Free Areas Act 2003* (WA) ss 10(2), (3).

substantial fine in South Australia, Tasmania, Victoria and Western Australia and a fine, imprisonment or both in the Australian Capital Territory and New South Wales.¹²³

Further, there are considerable differences and uncertainties between and in the legislation that are significant to those wanting to release GMOs. For example, the GMOs regulated by the State moratorium legislation differs between jurisdictions. For example, the moratorium applies or can apply to all GMOs under the Tasmanian legislation,¹²⁴ GM plants in Victoria and Western Australia,¹²⁵ both GM *food* plants and animal feed plants in South Australia¹²⁶ and only GM food plants in the Australian Capital Territory and New South Wales.¹²⁷ In New South Wales¹²⁸ and Victoria,¹²⁹ GM canola is the only GMO to actually have had a moratorium order made with respect to it. In the other States, except the Australian Capital Territory which had not acted at the time of writing, the release of all GMOs falling within the definition of GMO in the particular legislation has been banned.¹³⁰

Most importantly, although all the legislation purports to be for the purpose of market protection, there is no definition or explanation of that term in the legislation nor of the risks that will be considered when decisions under it are made. The Regulatory Impact Statement on the Policy Principle states that 'marketing purposes' has been taken broadly to mean impacts on the marketability of a specific product or its entrance into the marketplace although it may be interpreted in different ways by the States.¹³¹ Only the South Australian legislation explicitly requires consideration of the likely impact of GMO cultivation on markets in making a moratorium order.¹³² The Tasmanian legislation explicitly requires consideration of the impact of GMOs on non-GM agriculture when making decisions regarding permits that allow GMO releases despite the legislative prohibition.¹³³ However, even then it is limited to the likely

¹²³ See *Gene Technology (GM Crop Moratorium) Act 2004 (ACT)* s 9; *Gene Technology (GM Crop Moratorium) Act 2003 (NSW)* s 7; *Genetically Modified Crops Management Act 2004 (SA)* s 5(12); *Genetically Modified Organisms Control Act 2004 (Tas)* s 7; *Control of Genetically Modified Crops Act 2004 (Vic)* s 17(2); *Genetically Modified Crops Free Areas Act 2003 (WA)* s 5(1).

¹²⁴ *Genetically Modified Organisms Control Act 2004 (Tas)* s 3 (definition 'genetically modified organism' and 'GMO').

¹²⁵ *Control of Genetically Modified Crops Act 2004 (Vic)* s 4; *Genetically Modified Crops Free Areas Act 2003 (WA)* s 4(1).

¹²⁶ *Genetically Modified Crops Management Act 2004 (SA)* s 5.

¹²⁷ *Gene Technology (GM Crop Moratorium) Act 2004 (ACT)* s 7(1); *Gene Technology (GM Crop Moratorium) Act 2003 (NSW)* s 6.

¹²⁸ *New South Wales Government Gazette*, No 119, 25 July 2003, 7513. See also Exemption Order Number 1 and 2, 7516 and 7517.

¹²⁹ *Control of Genetically Modified Crops Act 2004 (Vic)* s 28 and sch.

¹³⁰ The moratorium in Western Australia does not apply to Regulator licensed field trials (*Genetically Modified Crops Free Areas Act 2003 (WA)* s 5(2)) or cultivation not involving intentional release into the environment (*Genetically Modified Crops Free Areas Act 2003 (WA)* s 5(3)). In Victoria, there is an automatic exemption for the cultivation of GMOs in accordance with a DNIR licence from the Regulator (*Control of Genetically Modified Crops Act 2004 (Vic)* s 6(3)).

¹³¹ Gene Technology Standing Committee, Parliament of Australia, Regulatory Impact Statement on *Gene Technology (Recognition of Designated Areas) Principle 2003* s 2.

¹³² *Genetically Modified Crops Management Act 2004 (SA)* s 5(5)(c).

¹³³ *Genetically Modified Organisms Control Act 2004 (Tas)* s 9(2)(b).

impact on market access for non-GMOs. In all other respects, it is unclear what consequences are relevant to decisions under the State moratorium legislation and what steps will be taken to assess those consequences.¹³⁴ The South Australian legislation is alone in requiring consultation before a moratorium order is made.¹³⁵ In the Australian Capital Territory, New South Wales and South Australia consultation is required before making an exemption.¹³⁶

Therefore it is not certain whether the State Minister(s) when making decisions with respect to GMO releases will consider all of the socio-economic risks not considered by the Regulator. Certainly some economic repercussions of GMO releases will be considered. However, how they will be determined and assessed is not clear. Social objections, such as concern that farmers' freedom to farm as they choose may be lost upon the release of a GMO, may or may not be considered. It is suggested that this will depend upon how broadly 'market' is interpreted and how that objection is linked to economic and trade issues. The relevance of ethical issues and how they would be determined and assessed is similarly uncertain. It is suggested that once again their relevance will depend upon matters such as whether 'market' is interpreted as including the views of the public, being possible consumers and therefore relevant to marketing.

Except in New South Wales, none of the State moratorium legislation provides for the issuing of injunctions where there is a breach or threatened breach of the legislation.¹³⁷ Further, the review of decisions to make a moratorium order or grant an exemption/permit made under the legislation is expressly prohibited in the Australian Capital Territory and New South Wales¹³⁸ and not provided for in the other States.¹³⁹ Nevertheless, opponents to GM could seek to use the State

¹³⁴ Some prerequisites for the granting of exemptions or permits are specified in two States. See *Genetically Modified Crops Management Act 2004* (SA) s 6(2); *Genetically Modified Organisms Control Act 2004* (Tas) s 9.

¹³⁵ There must be consultation with the public (see *Genetically Modified Crops Management Act 2004* (SA) s 5(3)) and an Advisory Committee (see *Genetically Modified Crops Management Act 2004* (SA) s 5(8)). See pt 3 div 1 of the Act with respect to that Committee. See also the Victorian legislation which provides that advice from anyone may be sought in Victoria: *Control of Genetically Modified Crops Act 2004* (Vic) s 10.

¹³⁶ In the Australian Capital Territory and New South Wales there must be consultation with an Advisory Council created under the legislation: *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) s 8(2) and *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 8(2). With respect to the Advisory Councils see *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) ss 8(2), 11 and *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 13. In South Australia consultation with an Advisory Committee is required: *Genetically Modified Crops Management Act 2004* (SA) s 6(3).

¹³⁷ The New South Wales legislation provides for the Minister to seek an injunction in such circumstances: *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 32.

¹³⁸ *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) ss 10, 39; *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) ss 11, 18.

¹³⁹ Other than under the *Genetically Modified Organisms Control Act 2004* (Tas) s 30(a) where a person aggrieved by a decision, inter alia, to refuse to grant a permit can have the decision reviewed.

moratorium legislation to prevent Regulator licensed releases by putting pressure on the Minister regarding decisions made under the State legislation.¹⁴⁰

VI ENVIRONMENT PROTECTION AND BIODIVERSITY CONSERVATION ACT 1999 (Cth)

It will be demonstrated in this Part that the EPBC Act applies to those releasing GMOs. Accordingly, the Commonwealth Environment Minister can be involved regarding GMO releases not only when consulted by the Regulator pursuant to the GT Act but also when the EPBC Act is triggered in its own right.

Previously proposed amendments to the EPBC Act are described in section A. The current interaction between the Regulator and Commonwealth Environment Minister is summarised in section B. Section C describes, by reference to the relevant terms used in the EPBC Act, why GMO releases will attract the operation of the EPBC Act. The general process followed under the EPBC Act is then outlined in sections D and E. The penalty and review provisions of the EPBC Act are outlined in section F. The implications of the application of the EPBC Act for those wanting to release GMOs is considered in the final section of this Part, section G.

A Proposed Amendment of the EPBC Act

The Commonwealth Government in June 1999 gave a commitment that it would, with the passage of the GT Act, amend the EPBC Act to provide for environmental risk assessment of proposed dealings with GMOs. Specifically the EPBC Act was to be amended so that before any licence decision by the Regulator, certain proposed GMO dealings were to undergo the assessment, but not the approval, process in the EPBC Act.¹⁴¹

Following the release of the Gene Technology Bill 2000 (Cth) for public comment, the proposed amendments to the EPBC Act were also released. The public was assured that the proposed amendments would 'not establish a dual approval regime, but will establish a transparent mechanism for ensuring the [Regulator] is properly advised on any environmental risks'.¹⁴²

¹⁴⁰ The Australian Law Reform Commission has suggested that 'regulators operating in a field of regulation that attracts a high level of public interest may be subject to a greater degree of political and public pressure in their enforcement decisions'. Australian Law Reform Commission, *Securing Compliance: Civil and Administrative Penalties in Australian Federal Regulation*, Discussion Paper No 65 (2003) [5.5].

¹⁴¹ Department of the Environment and Heritage, *Environmental Assessment of Genetically Modified Organisms. Draft amendments to the Environment Protection and Biodiversity Conservation Act 1999* (2000) <<http://www.deh.gov.au/epbc/publications/archive/gmoamendments.html>> at 30 December 2004 released with Commonwealth Senator Robert Hill, 'Environmental Assessment of Genetically Modified Organisms' (Press Release, 21 January 2000) <<http://www.deh.gov.au/minister/env/2000/mr21jan00.html>> at 30 December 2004.

¹⁴² *Ibid.*

Specifically, it was proposed that whenever the Regulator received DIR licence applications under the GT Act or licence applications which, although not involving deliberate release to the environment posed significant risk of harm to the environment, the application would be referred to the Commonwealth Environment Minister.¹⁴³ The Minister would then determine whether the risk assessment process carried out by the Regulator was adequate to ensure a full assessment of environmental risks and, if not, what further environmental assessment under the EPBC Act was necessary.¹⁴⁴ It was envisaged that the Minister could accredit the Regulator's risk assessment process in relation to a particular process or direct some other assessment be done.¹⁴⁵ Any advice of the Minister, following an environmental assessment, was then to be taken into account by the Regulator when making the licensing decision.¹⁴⁶

B Current Interaction between the Gene Technology Regulator and the Commonwealth Environment Minister

Although the GT Act was enacted, the EPBC Act was not amended as 'promised'.¹⁴⁷ Instead the GT Act requires the Commonwealth Environment Minister, amongst others, be consulted during the DIR licensing process. As discussed in Part IV, consultation with the Commonwealth Environment Minister must occur both when a risk assessment and a risk management plan are being prepared and after the draft risk assessment and risk management plan have been completed. Importantly there is no requirement in either the GT Act or the EPBC Act that the Commonwealth Environment Minister undertake an environmental assessment during that consultation. Nor is it required that the Minister be consulted on licence applications in respect of dealings not involving intentional release into the environment, whether or not they pose significant risk to the environment.¹⁴⁸ As discussed in Part IV above, a specific section in the Department of the Environment and Heritage is responsible for advising the Minister with respect to the Regulator's risk assessment process. However, in that instance the section considers environmental impacts caused by the fact that gene technology has been used to create the organism rather than all environmental impacts relevant under the EPBC Act.¹⁴⁹

Conversely, there is no provision in the EPBC Act exempting those with DIR licences and/or complying with State moratorium legislation from compliance with the assessment and approval process under the EPBC Act. Section 15 of the GT Act provides that its provisions are additional to, and not in substitution for,

¹⁴³ Ibid cl 43B.

¹⁴⁴ Ibid cls 43D and 43E.

¹⁴⁵ For criticisms of the proposed arrangement see submission by the Australian Biotechnology Association on Draft EPBC Act Amendments (12 March 2000) <<http://www.aba.asn.au/pages/epbcact.html>> at 27 August 2001.

¹⁴⁶ Department of the Environment and Heritage, above n 141, cl 43F(5). The Regulator was then to report to the Minister on how the environmental advice had been dealt with: cl 43G.

¹⁴⁷ The reason(s) for this are unclear.

¹⁴⁸ The Regulator has discretion to consult in such cases: *Gene Technology Act 2000* (Cth) s 47(4).

¹⁴⁹ Interview with Judy Johnson, above n 81.

the requirements of any other Commonwealth law.¹⁵⁰ The EPBC Act has no provision dealing with its relationship to other Commonwealth Acts generally.¹⁵¹ Therefore if a GMO release triggers the EPBC Act and is an offence under the EPBC Act, that release remains an offence even if licensed under the GT Act (following consultation with the Environment Minister). Similarly, the EPBC Act provides that it is not intended to exclude or limit the concurrent operation of a State law.¹⁵²

It is an offence under the EPBC Act to undertake certain actions, called 'controlled actions' which are described in section C below, unless that action has been approved by the Commonwealth Environment Minister.¹⁵³ The EPBC Act provides that actions can be exempted from the approval process by the Minister where the action has already been approved by the Commonwealth or a Commonwealth agency.¹⁵⁴ However, no such declaration has been made with respect to Regulator decisions.¹⁵⁵ Further, although assessment processes under Commonwealth or State law can be accredited on a case-by-case basis,¹⁵⁶ assessment under the GT Act has not been accredited.¹⁵⁷ It should be noted though that as yet no Regulator licensed release has been referred to the Environment Minister for approval under the EPBC Act.

C Application of the EPBC Act to GMOs

Whilst 'action' for the purposes of the EPBC Act includes, inter alia, activities and projects,¹⁵⁸ seeking and granting a DIR licence under the GT Act are not actions for these purposes.¹⁵⁹ The actual releasing of the GMO would, however, be an action. However, the EPBC Act applies only to 'controlled actions'. 'Controlled actions' are:¹⁶⁰

1. Actions that have, or are likely to have a significant impact on a matter of national environmental significance and do not fall within an exception provided in the Act.

¹⁵⁰ As to the possibility of a constitutional challenge to the *Gene Technology Act 2000* (Cth) see Rogers, above n 86.

¹⁵¹ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 9 deals with its relationship with certain expressly described Acts which do not include the *Gene Technology Act 2000* (Cth).

¹⁵² *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 10, except in so far as the contrary appears.

¹⁵³ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) pt 3.

¹⁵⁴ See *Environment Protection and Biodiversity Conservation Act 1999* (Cth) pt 4 div 2, sub-div A-D.

¹⁵⁵ Interview with Judy Johnson, above n 81.

¹⁵⁶ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 87(4).

¹⁵⁷ Interview with Judy Johnson, above n 81.

¹⁵⁸ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 528 (definition 'action') and ss 523, 524.

¹⁵⁹ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ss 524, 524A. See Ian G Thomas, *Environmental Impact Assessment in Australia: Theory and Practice* (3rd ed, 2001) 126 with respect to governmental authorisations generally.

¹⁶⁰ Thomas, above n 159, 126.

2. Actions that will have or are likely to have a significant impact on the environment associated with a Commonwealth area,¹⁶¹ that is, the action will take place:

- on Commonwealth land; or
- on land outside Commonwealth land where the significant impact would be on Commonwealth land; or
- on land anywhere where the action is taken by the Commonwealth (including a Commonwealth agency¹⁶²).¹⁶³

When a GMO release will be a controlled action pursuant to the EPBC Act is now considered.

1 *Matters of National Environmental Significance*

The EPBC Act applies if the GMO release has, will have or is likely to have a significant impact on a matter of national environmental significance and is not subject to one of the exceptions provided for in the Act.¹⁶⁴ The Act lists six matters of national environmental significance. These are World Heritage properties,¹⁶⁵ Ramsar wetlands of international importance,¹⁶⁶ listed threatened species and ecological communities,¹⁶⁷ listed migratory species,¹⁶⁸ nuclear activities¹⁶⁹ and Commonwealth marine areas.¹⁷⁰ During the consultation process on the EPBC Bill the inclusion of GMO regulation was suggested by an environmental group but the suggestion was not taken up.¹⁷¹ They could also now be prescribed as an additional matter of national environmental significance.¹⁷² However, this has not occurred.

Although GMO users are unlikely to want to release and raise GMOs inside areas such as World Heritage properties, Ramsar wetlands or Commonwealth marine areas, the EPBC Act is triggered if a GMO release is likely to have a significant impact on a matter of national environmental significance although the action itself is not within the area.¹⁷³ GMO releases may therefore have a significant impact on a nearby matter of national environmental significance. For example, the escape of a GMO into the matter of national environmental significance may

¹⁶¹ See *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 525 with respect to a 'Commonwealth area'.

¹⁶² See *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 528 (definition 'Commonwealth agency').

¹⁶³ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) pt 3 div 2.

¹⁶⁴ Thomas, above n 159, 126.

¹⁶⁵ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 12.

¹⁶⁶ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 16.

¹⁶⁷ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 18.

¹⁶⁸ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 20.

¹⁶⁹ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 22.

¹⁷⁰ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 23.

¹⁷¹ Environment Defender's Office, 'Submission on the Consultation Paper' (1998) 4, referred to in L Hughes, 'Environmental Impact Assessment in the Environment Protection and Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 441, 445.

¹⁷² *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 25.

¹⁷³ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ss 12(1), 16(1), 23(2). See also *Booth v Bosworth* (2001) 114 FCR 39.

trigger the EPBC Act if its presence in a World Heritage property has, will have or is likely to have a significant impact on the world heritage values of that property.¹⁷⁴ This is possible given that natural heritage,¹⁷⁵ which includes certain habitats of threatened species of animals and plants, is a world heritage value.¹⁷⁶ Similarly, although the releaser may not intend to affect a migratory or listed threatened species, the GMO release may nevertheless have a significant impact on that species. For example, the destruction of the habitat of a particular species may cause such a trigger.¹⁷⁷

2 Commonwealth Actions

Alternatively the land involved may be Commonwealth land or land outside Commonwealth land but the activity may still have a significant effect on the environment of Commonwealth land or the releaser may be a Commonwealth agency, such as CSIRO. If the activity on that land or by the agency is likely to have a significant impact on the environment of land associated with a Commonwealth area, the Act applies.

The Act defines 'environment' as including:

- (a) ecosystems and their constituent parts, including people and communities; and
- (b) natural and physical resources; and
- (c) the qualities and characteristics of locations, places and areas; and
- (d) the social, economic and cultural aspects of a thing mentioned in paragraph (a), (b) or (c).¹⁷⁸

This definition of environment is broader than that in the GT Act. The GT Act's definition of environment is as above except it makes no reference to people and communities as does the EPBC Act definition in paragraph (a).¹⁷⁹ Nor does it include an equivalent to paragraph (d) of the EPBC Act definition. Some economic and social repercussions of GMO releases are therefore part of the 'environment' under the EPBC Act but, under the Regulator's current approach, will not be under the GT Act. For example, that an area includes non-GM farmers who may be affected by a GMO release in that area could be a social or economic aspect of the 'qualities and characteristics of locations, places and areas' referred to in paragraph (c) of the EPBC Act definition. Broader political and commercial repercussions, such as effects on Australia's economy of the abandonment of GM

¹⁷⁴ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 12(1).

¹⁷⁵ Defined in *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 12(4) as having the meaning given in the World Heritage Convention. See *Convention for the Protection of the World Cultural and Natural Heritage*, opened for signature 23 November 1972, [1975] ATS 47, art 2 (entered into force 17 December 1975).

¹⁷⁶ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 12(3).

¹⁷⁷ However, in all of these cases the Minister is permitted only to assess those parts of the project which specifically affect the matters of national environmental significance. The remainder of the proposal must be assessed by the States: Hughes, above n 171, 452; *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 133.

¹⁷⁸ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 528.

¹⁷⁹ *Gene Technology Act 2000 (Cth)* s 10.

research in this country, would not, however, fall within either Act's definition of environment. There must be a proximal nexus between the social, economic and cultural aspect being considered and 'a thing' in the remainder of the definition.¹⁸⁰

3 Assessment of Significant Impact

Neither the EPBC Act nor the Regulations deal with when actions have a significant impact.¹⁸¹ There are, however, Administrative Guidelines issued by the Department of the Environment and Heritage.¹⁸² These provide that in assessing whether an action will have a significant impact, the nature and magnitude of the action's impact will be considered.¹⁸³ Amongst the relevant considerations is the indirect impact of the action, its frequency and duration, the total impact attributable to the action over the entire geographical area affected and over time, the sensitivity of the receiving environment and the degree of confidence with which the impacts of the action are known and understood.¹⁸⁴

In *Booth v Bosworth* Branson J accepted that 'significant impact' is an 'impact that is important, notable or of consequence having regard to its context or intensity'.¹⁸⁵ Her Honour also indicated, without deciding, that she thought that to be 'likely' an impact had only to be prone or liable rather than more likely than not.¹⁸⁶

The onus on proponents, such as GMO releasers, to decide whether an action will have a significant impact has been described by one commentator as onerous.¹⁸⁷ As Kennedy has noted it will, at least in some cases, be difficult to assess impacts that are indirect and perhaps geographically remote, but potentially significant. It is unclear how far GMO releasers will be required to look for impacts beyond the immediate vicinity of the project area.¹⁸⁸ In the Administrative Guidelines though, in respect of most matters of national environmental significance¹⁸⁹ it is noted that an action has a significant impact if it results in an invasive species becoming established in the matter of national environmental significance or habitat of the particular protected species. The Guidelines say this is because such establishment may cause harm by direct competition with native species, modification of habitat or predation. There is no definition of 'invasive species'. However, a Bill under consideration by the Senate will, if passed, amend the

¹⁸⁰ See, eg, *Coastal Waters Alliance of Western Australia v EPA* (1996) 90 LGERA 136 which discusses such requirements with respect to Western Australia legislation.

¹⁸¹ The *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 520 authorises the making of such regulations which prescribe the matters to be taken into account in determining whether an impact that an action has, will have or is likely to have is significant but this has not occurred.

¹⁸² *EPBC Administrative Guidelines on Significance* (July 2000) Department of the Environment and Heritage <<http://www.deh.gov.au/epbc/assessmentsapprovals/guidelines/administrative/index.html>> at 31 December 2004.

¹⁸³ Thomas, above n 159, 127.

¹⁸⁴ *Ibid.*

¹⁸⁵ (2001) 114 FCR 39, 65.

¹⁸⁶ *Ibid.* 64.

¹⁸⁷ B Kennedy, 'The operation of the new EPBC Act' (2000) 74 *Law Institute Journal* 61, 63.

¹⁸⁸ *Ibid.*

¹⁸⁹ The exceptions are World Heritage properties, nuclear actions and marine environments.

EPBC Act to include a definition of invasive species.¹⁹⁰ That definition expressly includes GMOs.¹⁹¹

D Referrals and Environmental Assessment

If a person wanting to release a GMO believes that their proposed release is a controlled action or are unsure of this, they should seek a determination from the Environment Minister by referring a proposal to take the action to the Minister.¹⁹² It is not an offence to fail to refer, but commencing the action without a referral can lead to the penalties described in section F below. Commonwealth agencies such as the Regulator may also refer proposals to the Minister for determination.¹⁹³ However, given that the obligation is imposed on the proponent to have approval, releasers should not rely on referral by the Regulator. Of interest for GMO users is that environmental groups and other third parties cannot refer proposals to the Minister. However, some proposals referred to the Minister must be notified to the public via the internet¹⁹⁴ and the Minister is required to consider public comments on them.¹⁹⁵ Further, reports by the public to the Department of the Environment and Heritage of activities potentially in breach of the EPBC Act are investigated.¹⁹⁶

In deciding whether the action is a controlled action, the Minister must consider all adverse impacts, if any, that the action has, will have or is likely to have on the matters protected under the Act.¹⁹⁷ Unfortunately for those wanting to release GMOs, the Minister must not consider any beneficial impacts.¹⁹⁸ Adverse impacts include all likely impacts including those caused by third parties in response to the proponent's action.¹⁹⁹ For example, that the introduction of

¹⁹⁰ Environment Protection and Biodiversity Conservation Amendment (Invasive Species) Bill 2002 (Cth) introduced into the Senate on 19 November 2002 by Senator Bartlett. See also Commonwealth, *Parliamentary Debates*, Senate, 19 November 2002, 6738-43 (Senator Andrew Bartlett). The Bill has been referred to the Senate Environment, Communications, Information Technology and the Arts References Committee (on 26 June 2003) which reported on 8 December 2004.

¹⁹¹ Environment Protection and Biodiversity Conservation Amendment (Invasive Species) Bill 2002 (Cth) (as read for the first time) s 266AB(1).

¹⁹² *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 68. The Regulations prescribe the form and content of the referral: *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 72 and *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth) pt 4, sch 2.

¹⁹³ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 71. The Environment Minister may also trigger the Act in the absence of a referral: *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 70. See also s 69 regarding State agencies.

¹⁹⁴ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 74(3).

¹⁹⁵ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 75(1A).

¹⁹⁶ Environment Australia, *Environment Australia Annual Report 2001-02* (2002). Indeed, the Australia Government Department of the Environment and Heritage relies heavily on third parties to identify non-compliance with the *Environment Protection and Biodiversity Conservation Act 1999* (Cth): Auditor-General, *Referrals, Assessments and Approvals under the Environment Protection and Biodiversity Conservation Act 1999*, Audit Report No 38 2002-2003, Performance Audit, [6.11].

¹⁹⁷ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 75(2)(a).

¹⁹⁸ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 75(2)(b).

¹⁹⁹ *Queensland Conservation Council Inc v Minister for the Environment and Heritage* [2003] FCA 1463 (Unreported, Kiefel J, 19 December 2003) ('*Nathan Dam Case*'). See also C McGrath, 'Qld Minister's dam decision overturned – Queensland Conservation Council Inc v Minister for the Environment & Heritage [2003] FCA 1463' (2003) 4 *National Environmental Law Review* 24.

herbicide tolerant GM canola may lead to an increase in the use of certain herbicides by farmers would seem to be relevant; that its introduction may lead to a reduction in the use of more harmful herbicides seems irrelevant.

If the Minister determines that the proposal is not a controlled action, then actions in accordance with that decision do not contravene the Act. If it is a controlled action, then the Minister's approval for the action is required. Prior to making a decision on approval there must be an assessment of the relevant impacts of the action. Assessment for the purposes of EPBC Act referrals and approvals is done by the Approval and Wildlife Division of the Department of the Environment and Heritage. Normal assessment processes would be followed by the Division regardless of whether the release has been licensed under the GT Act.²⁰⁰

The Minister decides, subject to certain prerequisites and standards being met, which of the assessment approaches in the EPBC Act should be used.²⁰¹ The assessment provides information for the Minister's decision whether or not to approve the taking of the action and what conditions if any to impose. This choice of assessment process may cause delay and greater expense for GMO users because they may do things not required by the relevant assessment process but which were done so as to be prepared for the possibility of another assessment process being relevant. In all cases, an assessment report on the controlled action must be forwarded to the Environment Minister at its conclusion.²⁰²

One method of assessment is by State assessment.²⁰³ State environmental impact assessment ('EIA') processes may be accredited under the EPBC Act by bilateral agreement.²⁰⁴ However, as Hughes has pointed out, 'despite Senate amendments to encourage uniformity, the Act is unlikely to facilitate the development of completely uniform EIA procedures and processes across all states'.²⁰⁵ The EPBC Act provides for a minimum standard before a State EIA process can be accredited.²⁰⁶ It does not, though, prohibit more stringent EIA requirements.²⁰⁷

²⁰⁰ Interview with Wayne Fletcher, Approvals and Wildlife Division, Department of the Environment and Heritage (Canberra, 29 September 2004).

²⁰¹ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 87(1). See Thomas, above n 159, 131-6 with respect to the assessment process.

²⁰² *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 130(1)(a). See Department of the Environment and Heritage website which provides information on Commonwealth procedures and links to State activities <<http://www.deh.gov.au>>.

²⁰³ Alternatively assessment may be done on preliminary documentation, Public Environment Report (PER), Environmental Impact Statement (EIS) or assessment by Public Enquiry: *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 87(1). For a description of such processes see Bates, above n 1, 289-90.

²⁰⁴ Standards for drawing up bilateral agreements are set out in the *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth) pt 3. There are bilateral agreements in place with Western Australia, Northern Territory and Tasmania: *Department of the Environment and Heritage, Department of the Environment and Heritage Annual Report 2002-2003*. State approval processes can also be accredited.

²⁰⁵ Hughes, above n 171, 447.

²⁰⁶ See *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ss 29, 45-65A regarding national benchmarks for State legislation to meet to receive accreditation. Essentially, management plans can only be accredited if the plan and relevant State or Commonwealth law meet criteria specified in the Regulations, have been tabled in both Houses of Parliament and not been disallowed.

²⁰⁷ Hughes, above n 171, 448.

Nor can the Commonwealth force States to seek accreditation. GMO users will therefore need to consider whether any particular State is a better jurisdiction, in terms of its EIA, in which to release its GMOs if it is possible that State assessment will be used.

E Approval

Two types of considerations are described as mandatory considerations in the Minister's decisions regarding approval of controlled actions.²⁰⁸ The first are environmental and ecological matters.²⁰⁹ The relevant environmental impacts under the EPBC Act are broader than those under the GT Act because they are not limited to environmental impacts arising from gene technology. Accordingly a GMO may be licensed by the Regulator after consultation with, amongst others, the Environment Minister because it seems to fulfill the GT Act's requirements but could still have adverse environmental impacts for the purposes of the EPBC Act.

In complete contrast to the GT Act, 'economic and social matters' are included as the second type of mandatory considerations.²¹⁰ As Fisher points out, it is unclear whether economic and social matters have the same priority as environmental and ecological matters in making a decision.²¹¹ In considering those matters, the Minister is required to take into account the principles of ecologically sustainable development²¹² and any assessment report.²¹³ Relevant principles of ecologically sustainable development include long and short-term economic, environmental, social and equitable considerations.²¹⁴ As in the GT Act the precautionary principle must also be taken into account.²¹⁵ However, unlike the GT Act²¹⁶ there is no mention of cost-effective measures. Arguably the principle therefore has wider application in the EPBC Act than the GT Act.²¹⁷ A further principle relevant to this study which is also to be taken into account is that of inter-generational

²⁰⁸ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 136(1). See *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* ss 136-140A with respect to other relevant matters. See also S Campbell, 'Governance, Responsibility and the Market: Neoliberalism and Aspects of the Environment Protection And Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 290, 299.

²⁰⁹ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 136(1)(a).

²¹⁰ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 136(1)(b).

²¹¹ Douglas Edgar Fisher, *Australian Environmental Law* (2003) 120.

²¹² *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 136(2)(a).

²¹³ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 136(2)(b)-(e).

²¹⁴ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 3A(a).

²¹⁵ *Environment Protection and Biodiversity Conservation Act 1999 (Cth)* s 3A(b). See *Nicholls v Director-General of National Parks and Wildlife* (1994) 84 LGERA 397. See further *Leatch v National Parks and Wildlife Service* (1993) 81 LGERA 270; *Bridgetown/Greenbushes Friends of the Forest Inc v Executive Director of the Department of Conservation and Land Management* (1997) 18 WAR 102; *Tuna Boat Owners Association of SA Inc v Development Assessment Commission* (2000) 77 SASR 369. See also John Frangos, 'Environmental Science and the Law' (1999) 16 *Environmental and Planning Law Journal* 175. See generally Adrian Deville and Ronnie Harding (eds), *Applying the Precautionary Principle* (1997); C Barton, 'The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine' (1998) 22 *Harvard Environmental Law Review* 509; Bates, above n 1, 129-35.

²¹⁶ *Gene Technology Act 2000 (Cth)* s 4(aa).

²¹⁷ Tranter, 'A question of confidence. An appraisal of the operation of the Gene Technology Act 2000', above n 86, 247.

equity described in the 1992 Inter-Governmental Agreement on the Environment.²¹⁸

Also of relevance here, other Commonwealth Ministers²¹⁹ may be invited to comment on an approval including commenting in relation to economic and social matters relating to the action which the Environment Minister is considering. Those comments must be considered by the Minister when making a decision as to approval.²²⁰

The Environment Minister may also take into account whether the releaser is a suitable person to be granted approval in light of their environmental record²²¹ but cannot take into account any other matters.²²² There is no explanation of 'environmental record'. However, given the broader understanding of 'environment' in the EPBC Act,²²³ as compared with the GT Act, it is submitted that offences under the State moratorium legislation are more clearly relevant here.

The contents of any assessment report provided to the Minister will reflect the above relevant matters. Indeed, such information could already have been provided as part of the preliminary information on the likely impacts of the proposed action given to the Minister to decide the assessment method to be used. That preliminary information includes the economic impact that action is likely to have on the local and broader community²²⁴ and the views of those communities about the action.²²⁵

Campbell concludes that the legislation means the Environment Minister can make decisions with primary weight given to the positive economic effects a project would have on a local community.²²⁶ This will be of advantage in respect of many GMOs where, for example, there are economic benefits to adopting GM technology. However, the Minister may also take into account negative effects of a GMO release. Opponents of GM could, for example, point to potential effects on non-GM agriculture to put pressure on the Environment Minister to refuse to grant approval to a GMO releaser.

F Penalties and Rights of Review

Contravention of the EPBC Act can result in criminal, civil and administrative penalties.²²⁷ For example, undertaking an action to which the legislation applies

²¹⁸ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 3A(c).

²¹⁹ If that Minister has administrative responsibilities relating to the proposed action: *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 131(1)(a).

²²⁰ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 136(2)(f).

²²¹ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 136(4).

²²² *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 136(5).

²²³ See section C2 above.

²²⁴ See Department of the Environment and Heritage, *Preliminary Information Form*, Part 9.

²²⁵ Department of the Environment and Heritage, *Preliminary Information Guide*, Part 1(9).

²²⁶ Campbell, above n 208, 299.

²²⁷ Campbell claims that the reality is that 'environmental offence provisions are enforced and used in the rarest of instances, and that these, on balance, do not negatively alter industry's exposure.' Campbell, above n 208, 302. See also Auditor-General Audit Report No 38, above n 196, [40].

without approval may incur a penalty of up to \$5.5 million²²⁸ or imprisonment for up to seven years.²²⁹ Further, releasers' GMOs can be removed if the Minister suspects there has been a contravention of the EPBC Act, whether or not an offence has been committed.²³⁰ This includes the destruction of organisms inadvertently contaminated by a GMO if GMO releases are controlled actions. Unlike pursuant to the GT Act, contraveners of the EPBC Act, whether convicted of an offence under the Act or not, are also liable to compensate any person suffering loss or damage because of the contravention, including repaying the Commonwealth its expenses for remediation action.²³¹ The compensatory provisions of the EPBC Act are not limited to property damage. They include expenses reasonably incurred in repairing or removing conditions arising from the contravention that relates to the environment.²³² Given the definition of environment in the legislation this would include, for example, the costs of recertification of an organic farm. Contraventions of the EPBC Act may also be publicised by the Minister in anyway that the Minister thinks appropriate.²³³

Injunctions to restrain GMO releases which contravene the legislation can also be obtained by 'any interested party'.²³⁴ Neighbours would be interested persons for these purposes if they are Australian citizens or residents because their interests will have been, are or will be affected by the releaser's conduct.²³⁵ Similarly, opponents to GM will have standing to sue even if they are not neighbours provided they are Australian and have engaged in environmental protection, conservation or research in the two years immediately before the GMO release.²³⁶ The court cannot require an undertaking as to damages in actions with respect to interim injunctions which may assist neighbours or opponents in taking such actions.²³⁷

Of further concern to GMO releasers is that, unlike the GT Act, the EPBC Act expressly extends the meaning of a 'person aggrieved' in the ADJR Act.²³⁸ As with the GT Act, a person must be a person aggrieved to seek judicial review of decisions made under the EPBC Act. However, the term is expressly extended by the EPBC Act to include individuals²³⁹ who have engaged in environmental

²²⁸ See, eg, *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 12(1).

²²⁹ See, eg, *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 15A.

²³⁰ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 499.

²³¹ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 500(1).

²³² *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 500(2)(a).

²³³ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 498(1).

²³⁴ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 475(1). 'Interested party' is defined in ss 475(6), (7), 528. Injunctions can also be sought by the Minister or a person acting on behalf of an unincorporated organisation that is an interested person.

²³⁵ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 475(6). In the case of organisations, the organisation must be Australian: *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 475(7). Its objects or purposes must include environmental protection, conservation or research and the organisation must be engaged in such activities in the two years immediately before the conduct or its interests must have been, are or would be affected by the conduct: *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 475(7). The environmental activities need not have been in Australia.

²³⁶ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 475(6).

²³⁷ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 478.

²³⁸ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 487.

²³⁹ Including organisations.

protection, conservation or research in Australia in the two years preceding the decision they wish to challenge.²⁴⁰ Many opponents to GM may have standing for these purposes. They therefore, together with landowners and residents adjoining or near the releaser's land as in the case of the GT Act, clearly have standing to challenge the Minister's decision that a particular GMO release is not a controlled action or to approve an action.²⁴¹ However, no merits review of a Ministerial decision on approval of an action is possible.

Releasers are also entitled to challenge the Minister's decisions regarding whether a release is a controlled action and whether to approve an action. However, they are only entitled to written reasons for the Minister's determination about whether a proposal requires approval if they did not state in any referral made by them that they believe the proposal is a controlled action.²⁴² Such reasons can make challenging a decision simpler because they should include all matters, relevant and irrelevant, considered by the Minister. Inability to get such reasons where the releaser has made particular comments at the beginning of the process means that decisions made very early in the process by releasers may have significant repercussions.²⁴³ Reasons for approval or otherwise are not available.

G Summary

GMO releases into the environment can in some cases be considered to have or be likely to have a significant impact on a matter of national environmental significance or on the environment in a Commonwealth area and therefore a controlled action. Whether or not there will be a significant impact will depend on the particular GMO and the circumstances of its release. If the EPBC Act is amended as discussed in section C above so that GMOs are expressly included in a definition of invasive species in the Act, it is even more likely that dealings with them will be found to have a significant impact. From the releaser's perspective, the possible application of the EPBC Act is of concern for a number of reasons.

GMO releases will, in appropriate circumstances, require approval under the EPBC Act whether or not licensed under the GT Act and authorised under State moratorium legislation. A licence under the GT Act and compliance with State moratorium legislation is no defence to proceedings under the EPBC Act.

²⁴⁰ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ss 487(1), (2). In the case of organisations, the organisation's objects or purposes must also include environmental protection, conservation or research: *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 487(3). See also *Booth v Bosworth* (2001) 114 FCR 39; *Schneiders v State of Queensland* [2001] FCA 553 (Unreported, Dowsett J, 4 May 2001); *Nathan Dam Case* [2003] FCA 1463 (Unreported, Kiefel J, 19 December 2003).

²⁴¹ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ss 487, 488. Although see *Tasmanian Conservation Trust Inc v Minister for Resources (Gunns [No 2])* (1996) 65 FCR 25 (with respect to earlier legislation) which illustrates that challenging such a decision may be difficult because of the broadness of the discretion to decide whether an EIA is required. See also A Fleming, 'Commonwealth Assessment of Forest Operations After Gunns (No 2)' (1996) 13 *Environmental and Planning Law Journal* 309, 314.

²⁴² *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 77(5).

²⁴³ Hughes, above n 171, 456.

An assessment of risks additional to those considered by the Regulator under the GT Act is relevant under the EPBC Act. The Acts both include the protection of the environment in their objects.²⁴⁴ They both also define 'environment'.²⁴⁵ However, the definitions differ. The definition of environment in the EPBC Act is much broader than that in the GT Act in that it includes reference to people and communities as well as to the social, economic and cultural aspects of those things included in the definition of environment such as places and areas. This arguably includes matters such as the effect on trade and agricultural implications of GMO releases and some social objections to the technology or its products.

Relevant considerations under the EPBC Act are also much broader than the matters considered by the Regulator under the GT Act. The Commonwealth Environment Minister is expressly required to consider economic and social matters in reaching a decision as to whether to approve the taking of a controlled action under the EPBC Act. Such matters are irrelevant under the GT Act and when the Minister is commenting on licence applications under the GT Act. Further, neither environmental or socio-economic considerations under the EPBC Act are limited by a requirement that they be due to gene technology as is the case, at least with respect to environmental considerations, in the GT Act.

The EPBC Act also requires principles of ecologically sustainable development be taken into consideration in decision-making.²⁴⁶ This reflects the policy set down in the 1992 *Inter-Governmental Agreement on the Environment*.²⁴⁷ That principle is irrelevant under the GT Act and State moratorium legislation. Further, the precautionary principle in the EPBC Act²⁴⁸ is not limited by reference to cost-effective measures as is the case in the GT Act. These differences enable the Minister to take a broader perspective in administering the EPBC Act than is possible under the Regulator's current approach pursuant to the GT Act.

There will also be overlap in the operation of the EPBC Act and State moratorium legislation. Given that the Environment Minister will be engaged in a weighing up of the socio-economic impacts of a GMO release in making approval decisions under the EPBC Act, many of the same considerations relevant under the State moratorium legislation will be relevant here. Exactly what the overlap is though is unclear because of the lack of detail in the State legislation. Nevertheless it gives rise to the possibility that a State Minister²⁴⁹ may determine that a GMO release may proceed but the Commonwealth Environment Minister may refuse approval. This can be explained in some cases on the basis that the Commonwealth Minister is acting in the interests of the environment. However,

²⁴⁴ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 3(1)(a); *Gene Technology Act 2000* (Cth) s 3.

²⁴⁵ See *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 528; *Gene Technology Act 2000* (Cth) s 10(1).

²⁴⁶ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ss 136(2)(a), 3A (with respect to decisions as to approval of actions).

²⁴⁷ The Agreement is a schedule to the *National Environment Protection Council Act 1994* (Cth).

²⁴⁸ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 3A(b). See also s 391(2).

²⁴⁹ Secretary of the Department for Primary Industries and Water in the case of Tasmania.

in other cases the same socio-economic consequences assessed by the State Ministers under the State legislation may be the cause for the Commonwealth Environment Minister's decision under the EPBC Act.

In light of the above, that a release has been licensed by the Regulator and is in compliance with State moratorium legislation is unlikely to constrain a court determining whether the EPBC Act applies and has been contravened.

VII CONCLUSION

The application of the EPBC Act and introduction of the State moratorium legislation is of concern for those wanting to release GMOs for many reasons. First, doubts as to whether or not the EPBC Act and/or State moratorium legislation applies adds to the uncertainty regarding their legal position. The application of the EPBC Act to GMO releases also means releasers, like other proponents under the Act, have the problem of predicting what environmental assessment process will be used by the Minister.²⁵⁰ An environmental assessment is necessary whenever approval is sought for a controlled action. This makes it difficult to accurately predict what the approval process will cost or what data is required.²⁵¹ Such uncertainty has been noted by the peak body representing the biotechnology industry in Australia as a deterrent to GMO use.²⁵² Similar uncertainties arise regarding whether and how the State moratorium legislation will apply.

Secondly, the application of the EPBC Act and/or State moratorium legislation means another layer of regulation that must be complied with adding to the expense and difficulty of GMO use. Many activities require licences or approvals from more than one regulator with respect to different aspects of the activity and the courts consider this valid. However, the more government agencies involved, the greater the cost,²⁵³ complexity and possible inconsistency between regulations. The penalties for contravention of the EPBC Act and State moratorium legislation are serious involving substantial fines and jail terms. Adverse publicity may also result under the EPBC Act, of significance given the importance of consumer acceptance to successful commercialisation of GMOs.

²⁵⁰ A study by the Bureau of Industry Economics, supported by the Business Council of Australia, found that delay was the most substantial cost element of the EIA process for new major resource projects and a substantial disincentive to future projects. Reasons included the number of authorities involved; lack of coordination between responsible authorities; and lack of uniform standards leading to conflicting demands: Australian Bureau of Industry Economics, *Environmental Assessment – Impact on Major Projects Research Report* (1992).

²⁵¹ See submission by the Australian Biotechnology Association, n 145 above, Point 4.

²⁵² *Ibid.* Hughes has also noted that if a proponent needs to 'complete EIAs in different States for different projects, and for the Commonwealth in others, this can strain resources, can create confusion and uncertainty, and therefore cost.' Hughes, above n 171, 452.

²⁵³ Australian Bureau of Industry Economics, *Environmental Assessment – Impact on Major Projects Research Report* (1992).

The EPBC Act and some State moratorium legislation also allows third persons who suffer loss or damage because of a contravention of the legislation to obtain compensation from the releaser. The GT Act does not provide for this.

Thirdly, both the GT Act²⁵⁴ and EPBC Act²⁵⁵ require licence holders to be a 'suitable person'. An offence under these Acts, State moratorium legislation or other environmental legislation could mean that they are not such persons and therefore affects releasers' ability to secure licences needed for future commercialisation.

Finally, and most importantly, application of the EPBC Act where the GT Act and State moratorium legislation already apply means third parties can take advantage of the overlap to in effect nullify State or Regulator decisions under the State moratorium legislation or GT Act as the case may be by complaining to the Department of the Environment and Heritage that a release has not been approved under the EPBC Act or by seeking an injunction pursuant to the EPBC Act, taking advantage of the increased standing provisions in that Act.

The State moratorium legislation, except for the New South Wales Act, does not provide for the issuing of injunctions even where the legislation has been contravened. The New South Wales Act limits the availability of injunctions to the Minister.²⁵⁶ Whilst injunctions are also available under the GT Act, they may be available to a wider class of people under the EPBC Act. More importantly, they will be available in the wider circumstances controlled by the EPBC Act. For an injunction under the EPBC Act, the third party must satisfy certain conditions, including showing that the releaser has or will contravene the EPBC Act.²⁵⁷ A court in deciding this will therefore consider the socio-economic impacts of the release which would, at least in part, have already been assessed by the State Minister. Further, those environmental consequences arising from the GMO assessed by the Regulator would also be reconsidered by the court. However, how the discretion will be used is difficult to predict creating uncertainty for releasers. In *Booth v Bosworth* Branson J commented on the use of this discretion. She said that, with respect to harm being done to a World Heritage Area:

In weighing the factors which support an exercise of the Court's discretion in favour of the grant of an injunction ... against those factors which tell against the grant of such an injunction, it would be a rare case in which a Court could be satisfied that the financial interests of private individuals, or even the interests of a local community, should prevail over interests recognised by the international community and the Parliament of Australia as being of international importance.²⁵⁸

²⁵⁴ *Gene Technology Act 2000* (Cth) s 58.

²⁵⁵ *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth) reg 17.02.

²⁵⁶ *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 32(1).

²⁵⁷ *Environment Protection and Biodiversity Conservation Act 1999* (Cth) s 475(2).

²⁵⁸ (2001) 114 FCR 39, 68.

This comment could be expected to also apply to cases involving threats to other matters of national environmental significance under the Act. However, it is uncertain how the court would approach an application for injunction on the basis of socio-economic harm caused by a controlled action where the action has socio-economic benefits for others.

It is suggested that GMO releasers would be best served by the Regulator assessing socio-economic risks arising from GMOs when undertaking the risk assessment process under the GT Act rather than having two separate legislative regimes dealing with environmental and socio-economic repercussions respectively. This would reintroduce the uniformity in regulation of GMOs throughout Australia intended to be achieved by the introduction of the GT Act. However, it is unlikely that the States will surrender their power to regulate GMOs to protect their local trade. Accordingly, it is submitted that if it is decided that socio-economic repercussions of GMO releases are best assessed at a State rather than national level then, in addition to the obviously advantageous but unlikely introduction of nationally uniform State moratorium legislation, State moratorium legislation should be improved by clarification of the issues relevant to decisions under the legislation and how those issues are to be assessed. The EPBC Act should also be amended to exclude from the assessment and approval process both environmental and socio-economic matters arising because of the use of gene technology in the creation of the organism concerned. Such changes ensure that whilst all relevant considerations arising from GMO releases are still assessed by Commonwealth or State government regulators as the case may be, those wanting to release GMOs in Australia have greater certainty with respect to their legal position.