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WHICH LITTLE PIGGY TO MARKET?

LEGAL CHALLENGES TO THE COMMERCIALISATION OF AGRICULTURAL GENETICALLY MODIFIED ORGANISMS IN AUSTRALIA

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ABSTRACT

Genetically modified organisms ('GMOs') are being commercialised in Australia. It is the central thesis of this study that whilst a national regulatory scheme specifically for GMOs has been introduced, considerable and significant legal uncertainty continues. Legal uncertainty arises because GMOs are 'different' to other commodities. Like other living organisms they are animate and can escape from their intended place to live and reproduce without human assistance. But they are also different to other organisms because of the human intervention involved in their creation. This combination of animate traits and their method of creation has caused a range of responses to GMO commercialisation. One concern that has recently become particularly important is the social and economic impacts of agricultural GMO releases.

This study analyses the more significant legal challenges relevant when selecting agricultural GMOs for commercialisation in Australia. Some of these challenges are heightened because the law is asked to respond to society's concerns about the social and economic impacts of GMO releases. The main aim of this thesis is to identify where uncertainties and other legal challenges may arise and where possible predict how those challenges will or should be resolved.

Three legal issues are of particular importance at the selection stage. These are the implications of the applicable regulatory regimes to the selection of GMOs, whether GMOs and their products will be protected by Australia's intellectual property ('IP') laws and thirdly, possible liability of those releasing agricultural GMOs or their products into the environment.

In regard to the first issue the thesis seeks to demonstrate that the regulatory regimes, whilst creating expected hurdles for commercialisers, also create unnecessary confusion and uncertainty. Further, such regimes have implications for commercialisers' liability for harm arising following the organisms' release into the environment.

With respect to the second issue the thesis argues that GMOs and their products will be protected by Australia's IP laws although the value of that protection may be limited. In particular, GMOs' ability to reproduce without human assistance presents legal challenges for IP protection.

The third issue is considered by exploring commercialisers' potential liability in both tort and pursuant to environmental legislation. It will be demonstrated that, as expected, commercialisers can be liable both in tort and pursuant to statute. However, with respect to liability in tort it is argued that the most significant challenge for commercialisers is predicting how a court will classify the impacts of GMO releases. The implications of the regulatory regimes on such liability are also analysed. With respect to the expected liability under environmental legislation, it will be demonstrated that the interplay of the national and State regulatory regimes with environmental legislation creates important legal challenges for commercialisers.

The thesis concludes by submitting that if commercialisation of agricultural GMOs is to proceed, Parliament must act now to clarify the legal position of commercialisers and provide some protection for those releasing GMOs in compliance with regulatory requirements.

The law in this thesis is as at 12 May 2004.

STATEMENT BY CANDIDATE

This thesis contains no material which has been previously accepted for the award of any other degree or diploma in this or any other university or institution.

This thesis contains no material previously written or published by another person, except where reference or acknowledgement is made.

No other person has collaborated in the preparation of this thesis.

Signed [redacted].....

Dated: 9 Sept 2004

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ARTICLES PUBLISHED

Material in Chapters 2, 3 and 4 of this thesis has largely been published in the following:

- 'Some Legal Aspects of Commercialisation of Transgenic Crops' in McLean, G D et al (eds), *Commercialisation of Transgenic Crops: Risks, Benefit and Trade Considerations* Proceedings of a workshop held in Canberra 11-13 March 1997 (AGPS, Canberra, 1997), pp 225-37 (approximately 7,500 words).

- 'Genetically Modified Organisms and Their Products as Patentable Subject Matter in Australia' [1999] *European Intellectual Property Review* 298-312 (approximately 15,000 words).

- 'Cultivating Chaos: State Responses to Releases of Genetically Modified Organisms' (2004) 9 *Deakin Law Review* 1-40 (approximately 10,400 words).

Material drawn from Chapter 6 has also been submitted for publication although as at the date of submission of this thesis, the referees' reports have not been received. Those articles are:

- 'Cross with Care: The Intersection of the *Gene Technology Act 2000* (Cth), State Moratorium Legislation and the *Environment Protection and Biodiversity Conservation Act 1999* (Cth)'.

- 'Genetically Modified Organisms and Pollution in Victoria'.

TABLE OF ABBREVIATIONS

AAT	Administrative Appeals Tribunal
ACT	Australian Capital Territory
ADJR Act	*Administrative Decisions (Judicial Review) Act 1977* (Cth)
ALRC	Australian Law Reform Commission
ANZFA	Australia New Zealand Food Authority (now FSANZ)
AQIS	Australian Quarantine and Inspection Service
ASCORD	Academy of Science Committee on Recombinant DNA Molecules
Aust	Australia
AVCC Act	*Agricultural and Veterinary Chemicals (Control of Use) Act 1992* (Vic)
BFA	Biological Farmers of Australia Co-op Ltd
CCI	Confidential commercial information
Cth	Commonwealth of Australia
Dept	Department
Designated Areas Policy Principle 2003	Gene Technology (Recognition of Designated Areas) Policy Principle
DIR licence	Licence granted under the *GT Act* for a dealing involving the intentional release of a GMO into the environment
DNA	Deoxyribonucleic acid
DNIR licence	Licence granted under the *GT Act* for a dealing not involving the intentional release of a GMO into the environment
DPI	Victorian Department of Primary Industries

EP Act	*Environment Protection Act 1970* (Vic)
EPA	Victorian Environment Protection Authority
EPBC Act	*Environment Protection and Biodiversity Conservation Act 1999* (Cth)
EPC	European Patent Convention
FSANZ	Food Standards Australia New Zealand (formerly ANZFA)
GM	Genetically modified or genetic modification, as the case requires
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically modified organism
GMOs	Genetically modified organisms
GT	Gene technology
GT Act	*Gene Technology Act 2000* (Cth)
GT Agreement	Gene Technology Agreement
GT Bill	Gene Technology Bill 2000 (Cth)
GTCCC	Gene Technology Community Consultative Committee
GTGC	Gene Technology Grains Committee
GTMC	Gene Technology Ministerial Council
GTR	Gene Technology Regulator
GTTAC	Gene Technology Technical Advisory Committee
IOGTR	Interim Office of the Gene Technology Regulator
IP	Intellectual property
LMO	Living GMO
NSW	New South Wales

NT	Northern Territory
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PBR	Plant breeder's right
PIC	Plant Industries Committee, a subcommittee of the Commonwealth Primary Industries Ministerial Council
PIRS Committee	Commonwealth House of Representatives Standing Committee on Primary Industries and Regional Services
Qld	Queensland
RA&RMP	Risk assessment and risk management plan under the *GT Act*.
RDMC	Recombinant DNA Monitoring Committee
RNA	Ribonucleic acid
S&IP system	Segregation and identity preservation system
SA	South Australia
States	Includes all Australian States and Territories unless otherwise indicated
Tas	Tasmania
TRIPS Agreement	*Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organisation)*, 1995 ATS 8
UK	United Kingdom
US	United States
Vic	Victoria

VLRC	Victorian Law Reform Commission
WA	Western Australia

CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION

Genetically modified ('GM')[1] pigs are ready for market several weeks earlier than their 'ordinary' counterparts. Their pork is almost fat-free. Such pigs were an Australian invention, ready for market in 1995. The pigs may have been better than their counterparts, at least in some respects, but they were also 'different'. Due to uncertainty about the legal consequences of that difference, the pigs never got to market. It is the central thesis of this study that even following the introduction of a regulatory scheme specifically for GM pigs and other GM organisms ('GMOs') considerable and significant legal uncertainty continues. Moratoria on GMO releases imposed recently by the majority of States makes an investigation into that uncertainty all the more timely.

Legal uncertainty arises because GMOs are 'different' to other commodities. They are living organisms. Like other organisms they are animate and can escape from their intended place to live and reproduce without human assistance. But they are also different to other organisms because of the human intervention involved in their creation.[2] This combination of animate traits and their method of creation has caused a range of responses to their commercialisation. Responses range from welcoming their commercialisation to anxiety over certain applications of the technology, particularly in food, to total opposition to any GM.[3] One concern that has recently become an important issue for government is the social and economic impacts of GMO releases.[4]

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[1] GM is used in this study to refer to 'genetically modified' or 'genetic modification' as the case may require. The technology is also sometimes called 'genetic manipulation', 'genetic engineering' or 'bioengineering'. The terms mean essentially the same thing. See section 1.3.1 below for further information on the technology.

[2] See section 1.3.1 below.

[3] With respect to concerns about GM crops, see UK, Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (Latimer Trend & Co, Plymouth, UK, 1999) (http://www.nuffieldfoundation.org/fileLibrarypdf/gmcrop.pdf) (copy on file with author). Re GM animals see R 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 AEBC* (2002) (http://www.aebc.gov.uk/aebc/animals-report.html) (copy on file with author). For further general discussion see, eg, Law Reform Commission of Victoria, *Genetic Manipulation* Report No 26 (Melbourne, June 1989), Chap 1; Aust, House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (AGPS, Canberra, 1992) ('*Threat or the Glory* Report'), Chap 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, *The Social Management of Genetic Engineering*

The next Part of the Chapter, Part 1.2, describes the scope of the thesis. Part 1.3 then briefly explains the science used to create GMOs to illustrate the human intervention involved in their creation. The three case studies used in this study are also introduced in that Part. The socio-economic impacts relevant to the study are identified in Part 1.4. Finally, Part 1.5 provides an outline of the thesis chapters.

1.2 SCOPE OF THESIS

1.2.1 *Relevant Issues*

It is impossible to comprehensively review all legal issues relevant to the commercialisation of all GMOs in this study.[5] Accordingly the study focuses on one sector in which GMOs are being developed, agriculture,[6] and one stage of commercialisation, selection of appropriate GMOs for commercialisation in Australia.[7] The application of GM to agriculture has been chosen because it is seen to be a strength of Australia's biotechnology industry.[8] The study considers only higher life-forms, namely

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(Ashgate Publishing Ltd, England, 1998), Chap 15; Canada, The Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. An Expert Panel Report on the Future of Food Biotechnology* (Ontario, January 2001) ('Canada *Elements of Precaution* Report').

[4] For eg, addressing potential socio-economic effects of biotechnology is a key strategy objective of the Cth National Biotechnology Strategy. Aust, Biotechnology Ministerial Council, *National Biotechnology Strategy* (Canberra, 2000), p 10. See also, for eg, S Wright, 'Uproar as GM canola approved' *The Age* (Melbourne), 19-20 December 2003, News p 10; M Marino, 'GM ruling sparks fears' *The Sunday Age* (Melbourne), 5 January 2003, p 3.

[5] Commercialisation of research and development has been described as the 'generation of net wealth by the firm through the sale of products and processes incorporating new ideas, [requiring] the manufacture, distribution and servicing of novel products and processes with a subsequent benefit flowing to the commercialising company'. Task Force on the Commercialisation of Australian Research, *Bringing the Market to Bear on Research* (AGPS, Canberra, 1991), p 7. This thesis adopts this understanding of the term.

[6] Horticultural organisms are included in the term 'agricultural' for the purposes of this study.

[7] The level of GM research in Aust is unknown but it is estimated that about $100 million a year is spent on agricultural GM research in Aust. Aust, House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with caution. Primary Producer Access to Gene Technology* (Canberra, June 2000) ('*Work in Progress* Report'), [5.2].

[8] Cth of Aust, Ernst & Young and Freehills, *Australian Biotechnology Report 2001* (Canberra, 2001) ('*Biotech Report 2001*'), p 7. There is evidence of governmental support for biotechnology generally. See, for eg, the Cth's creation of Biotechnology Australia and the National Biotechnology Strategy. See also the recently announced Commercial Ready Program. Many States also have government organisations or strategies to encourage or accelerate the biotechnology industry. See, eg, Bio Innovation SA (http://www.bioinnovationsa.com.au accessed 26/2/04); Qld, Dept of Innovation and Information Economy *Queensland BioIndustries Strategy* (2001) (http://www.iie.qld.gov.au/biotechnology/bioindustries/index.html accessed 26/2/04); NSW, BioFirst Strategy (http://www.biofirst.nsw.gov.au/aboutus/ accessed 26/2/04); Victoria, Dept of Innovation, Industry and Regional Development *Biotechnology Strategic Development Plan for Victoria* (http://www.biotechnology.vic.gov.au accessed 23/4/04).

plants and non-human animals.[9] It also considers only domestic commercialisation. The law is as on 12 May 2004.[10]

The investigation is made from the perspective of those wanting to commercialise GMOs. This perspective has been chosen as a useful contrast to the government and academic analyses already available.[11] Such analyses are from the perspective of government or the public. Studies of GM regulation have also been done overseas.[12] However, Australia's GM regulatory regimes, environmental statutes and common law[13] are different to that in other countries.[14] A study of the legal challenges facing commercialisers under the present Australian law is therefore appropriate. The selection stage of the commercialisation process has been chosen because it is a part of the process where an analysis of the law with respect to GMOs can justifiably focus on the commercialiser rather than consumers.[15]

It is not the object of this thesis to judge whether the commercialisation of agricultural GMOs is in Australia's interests or whether concerns regarding either the technology or its uses are justified. Rather, it is intended to analyse the more significant legal challenges relevant when commercialisers select agricultural GMOs for development in Australia. Some of those challenges are heightened because the law will be asked to respond to society's concerns about the implications of commercialisation of GMOs such as the socio-economic impacts of GMO releases. This thesis is not a study of those concerns. Nor does

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[9] Microorganisms and, to a very limited extent, humans are also being 'genetically modified' but are not considered here.

[10] This date is referred to as the 'completion date' of this study.

[11] These analyses are discussed in Chapter 2.

[12] Relevant recent reports include: New Zealand Royal Commission on Genetic Modification, *Report of the Royal Commission on Genetic Modification* (Wellington, 2001); New Zealand, Law Commission, *Liability for Loss Resulting From the Development, Supply, or Use of Genetically Modified Organisms* Study Paper 14 (Wellington, 2002); New Zealand, Ministry of Economic Development, *A Review of the Patents Act 1953: Boundaries to Patentability: A Discussion Paper* (2002) (http://www.med.govt.nz/buslt/int_prop/patentsreview/index.html) (copy on file with author); New Zealand, Ministry for the Environment, *Public Discussion Paper: Improving the Operation of the HSNO Act for New Organisms* (2002); Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (OECD, Paris, 2002); UK, Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (Nuffield Council on Bioethics, London, 2002) (http://www.nuffieldbioethics.org) (copy on file with author); Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (Canadian Biotechnology Advisory Committee, Ottawa, 2002) and UK, Agriculture and Environment Biotechnology Commission, *GM Crops? Coexistence and Liability* (Dept of Trade and Industry, London, 2003). See also UK, Dept for Environment, Food and Rural Affairs et al, *The GM Dialogue: Government response* (2004).

[13] For eg, it seems that Australian negligence law allows for a greater range of recovery for pure economic loss than is available in the UK. See J L R Davis, 'Liability for careless acts or omissions causing pure economic loss: *Perre v Apand Pty Ltd*' (2000) 8 *Tort Law Journal* 123, 131.

[14] For links to foreign regulatory requirements go to http://www.affa.gov.au/agbiotech.

[15] Non-GMOs are of course also commercialised. This thesis uses the term 'commercialiser' only in respect of those commercialising GMOs unless otherwise clearly stated.

it address how judgments on social and economic matters should be made. Such studies need to be made by those skilled in such matters. However, it is one task of this thesis to explore the possible heightening of the legal challenges facing commercialisers by the existence of such concerns. The main aim of this thesis is therefore to identify where uncertainties and other legal challenges may arise and where possible predict how those challenges will or should be resolved.

Three legal issues are of particular importance at the selection stage: [16]

- the implications of the applicable regulatory regimes to the selection of GMOs;
- whether the proposed new organism or product will be protected by Australia's intellectual property ('IP') laws; and
- the potential liability of commercialisers releasing GMOs or their products into the environment.

These issues are the subject of this study.[17]

1.2.2 *Significance of Legal Challenges*

(a) Introduction

Uncertainty as to the law is detrimental to commercialisers.[18] For example, commercialisers will be reluctant to release GMOs in field trials,[19] a step necessary for selection and ultimately commercialisation in most cases, if they are uncertain of their

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[16] Non-legal issues are also important during selection. These include marketability, in part determined by public acceptance of the organism, and anticipated profitability. As noted by the ACCC '[e]ventually it will be the consumers who decide if GM products survive in the market'. A Asher and S Bhojani, Forum, 'Accuracy in the labelling of genetically modified foods' (2000) 31 *ACCC Journal* 1, 1. Scientific matters are also important. All such issues are outside the scope of this thesis.

[17] Other legal issues are relevant to the commercialisation of new GMO or products, including laws with respect to occupational health and safety issues, public health and animal welfare. These are beyond the scope of this study.

[18] For eg, the WA Government considers that legal uncertainty is responsible for the reluctance of multinational companies to make their gene technology available to Australian companies. *Work in Progress* Report, [5.64].

[19] Field trialling involves 'a deliberate release of a genetically manipulated organism into the open environment on a restricted scale, for a limited period, and under conditions which minimise or reduce the potential for dissemination or persistence of the organism or its genetic material into the environment.' Aust, Genetic Manipulation Advisory Committee ('GMAC'), *Guidelines for the Deliberate Release of Genetically Manipulated Organism* (1998). Also Aust, Interim Office of the Gene Technology Regulator ('IOGTR'), *Fact Sheet 4: System for Overseeing Genetic Manipulation Work* (1999), p 2. Although the *Gene Technology Act 2000* (Cth) uses the term field trial it does not define the term. Field trials are undertaken, prior to general commercial release, to test GMOs outside the laboratory environment and in the environment in which they will be used.

regulatory responsibilities, IP rights or legal liabilities.[20] Uncertainty with respect to such matters creates additional problems when obtaining insurance and adequate capitalisation. Both can be difficult to obtain when insurers and investors are unclear as to what the commercialiser can actually protect as an asset or when potentially overwhelming liability is perceived as a possible outcome.[21] Certainty in the application of legal principles, on the other hand, can assist in these matters. It can also lessen litigation by providing a better basis for resolving disputes.[22] Additionally, it can better influence the conduct of those wanting to commercialise GMOs.[23] Finally, clarification of the relevant law provides a better basis on which to decide whether the existing regulatory scheme and recent actions by the States are appropriate.

(b) Regulatory responsibilities

A uniform national regulatory scheme for GMOs was introduced in 2001. It will be submitted that the scheme creates unintended and unnecessary legal challenges for commercialisers. Furthermore, relevant regulation is currently undergoing significant change. Most States have recently legislated to prevent at least some GMO releases. Those laws, whilst creating intended legal hurdles, also add yet another layer of unnecessary legal challenges through uncertainty and complexity. Finally, the interaction of the national scheme and the State legislation with each other and with other laws, such as the common law and environmental legislation, creates a third layer of legal challenges.

It is assumed here that commercialisers will seek to comply with the law. For that reason alone, there should be certainty about the requirements and effect of regulations relevant to selection through field trialling.

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[20] The implications of IP rights on commercialisation and determining legal liability for consequences of GM contamination have recently been described by the Cth Government as challenging emerging issues for the biotechnology industry in Aust. Dept of Agriculture, Fisheries and Forestry - Australia, *Biotechnology Strategy for Agriculture, Food and Fibre* (Cth of Aust, August 2003) (http://www.affa.gov.au/agbiotech accessed 19/6/03), Appendix 1, p 14.

[21] J M Merry, 'The Bioengineering Revolution: Genesis of a Compromise Solution' (1988) 20 *Pacific Law Journal* 163, 165.

[22] N D Hamilton, 'Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms' (2001) 6 *Drake Journal of Agricultural Law* 81, 109.

[23] N D Hamilton, 'Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms' (2001) 6 *Drake Journal of Agricultural Law* 81, 109.

(c) IP protection

Before releasing a GMO into the environment, adequate IP protection is essential.[24] As with other inventions, release may mean loss of physical control of the GMO by the commercialiser. IP rights are not lost upon the release of the invention. Instead, IP rights mean that the IP owner can in many instances continue to control the invention even after it has left their hands.

Whilst the need for IP protection is not unique to GMOs, their unique traits mean it is necessary for successful commercialisation. GMOs and their products are particularly susceptible to copying and exploitation by others because many can replicate without human intervention. Further, competitors can often reproduce the relevant article using genetic material taken from the original organism or product. Competitors then do not need to undertake the same level of research and development as the original creator.[25] This may mean competitors unfairly benefit from the commercialiser's efforts and may deprive the commercialiser of the opportunity even to recover their costs. The gene technology ('GT') regulatory scheme does not deal with the availability of IP protection. Instead the availability of such protection, or lack thereof, is left to pre-existing IP laws. It is uncertain whether GMOs' unique traits affect the availability of IP protection and the scope of that protection.

(d) Tort and environmental liabilities

Commercialisers will also be reluctant to release GMOs in field trials necessary for selection if they do not know their potential liabilities. Uncertainty with respect to liability for GMO releases may cause commercialisers to believe that it is necessary to take greater precautions to avoid spread than is actually necessary.[26] The perceived need for such

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[24] See, eg, *Work in Progress* Report, [6.1] and [6.10]; Organisation for Economic Co-operation and Development, *Intellectual Property, Technology Transfer and Genetic Resources. An OECD Survey of Current Practices and Policies* (OECD Publications, France, 1996), p 16; G Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Ashgate Publishing Ltd, England, 2003), p 153.

[25] This point was clearly noted by a US court in relation to the breeding and sale of new varieties of chrysanthemums. Judge Goldberg in *Yoder Brothers, Inc. v California-Florida Plant Corporation* 537 F. 2d 1347, 193 USPQ 264 at 270 (5th Cir 1976) said:

> Theoretically, once the first plant of a new variety is sold, it is impossible for a breeder ever again to be compensated for his efforts in developing it... [A]nyone can take a cutting from the new plant, propagate a number of cuttings from the first cutting, and obtain an infinite supply of the plant...

[26] Cf Agriculture WA which it seemed took the approach of not seeking Crown Law advice in relation to its liability in the event of contamination of non-GM crops when it started trials of GM crops in WA. WA,

precautions and concerns regarding liability may cause some commercialisers not to pursue commercialisation of GMOs.[27] For example, the commercialiser of the GM pig case study decided not to proceed 'because of concerns about legal liability'.[28]

Field trial releases of GMOs must be authorised under the GT regulatory scheme and State legislation. However, the scheme does not provide immunity from either common law liability or penalties under other statutes. The State legislation on GMO releases also provides little protection for those who comply with it. Liability instead depends upon how the courts apply generally applicable laws and environmental legislation to GMOs. This creates uncertainty. Further uncertainty and challenges come from the differing standards used in the regulatory regimes, environmental legislation and by tort law to assess the legality of commercialisers' activities.

1.3 GM AND CASE STUDIES

The following sections provide a brief background on, and describe the commercial significance of, GM generally and the case studies. Three case studies are used as illustrations to focus the investigation. These are GM carnations, canola and pigs. All are GMOs that have been developed, at least in part, in Australia. They are or could be therefore of economic significance to this country. Two plants have been chosen because they provide useful contrasting illustrations. The GM carnation is visually different to its non-GM counterparts; GM canola is not. Nevertheless, as will be discussed in Part 1.4 below, it is the release of GM canola into the environment that is causing the most concern in Australia. The third case study is the GM pig. It has been chosen because, as noted above, its commercialisation was terminated because of uncertainty of Australian laws. It is a real example of the adverse consequences that legal uncertainty has on GMO commercialisation in Australia. It is also, of course, an animal in contrast to the other two organisms.

1.3.1 *Genetic Modification*

GMOs are essentially organisms modified by GT and their progeny that inherit such modification.[29] GT, or GM as it is more commonly known, is broadly any technique for

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Parliamentary Debates, Legislative Council, 14 September 1999, 1080 [184] (Criddle, Minister for Transport).

[27] This is particularly the case for small Australian producers. *Work in Progress* Report, [5.112].

[28] *Zoffanies Pty Ltd v Commissioner of Taxation* [2002] AATA 758 (Unreported, Mr Handley, 4 September 2002) at [12]. See further section 1.3.4 below.

the modification of genetic material other than, amongst other things, sexual reproduction and standard plant breeding techniques.[30]

It has been known since 1952[31] that a particular chemical substance is the basic stuff of heredity in all organisms. That chemical substance is deoxyribonucleic acid ('DNA').[32] DNA carries the genetic information of the cell. That is, the instructions for the replication of the cell as well as replication of the DNA itself and also the information needed for the production of other molecules. The activities of such molecules are in turn responsible for the total structure, function and growth of the cell, and therefore the organism, which contains them.

DNA occurs in the form of chromosomes. Segments of chromosomes are known as genes.[33] A particular gene affects a particular trait of the organism, such as the colour of its flowers. When a new generation is produced the parent(s)' genes are passed onto the progeny. Where there are two parents,[34] the genes of the parents are usually randomly sorted[35] resulting in new combinations of genetic material.

Since the 1940s organisms, particularly microorganisms, were subject to deliberate attempts to alter their genetic makeup.[36] This generally involved the application of agents, known as mutagens, in the hope that some change would be made to the organism's DNA. It is now possible to locate and identify individual genes on the DNA of living organisms. The genes can then be altered or removed from one cell and inserted into another, including into a cell of a different species.[37] For example, a gene from a petunia could be moved to a carnation; a gene from a bacterium to a canola plant.[38] Alternatively genes can be wholly or partly synthetically created and then inserted into organisms.[39] Once the modification has occurred, the modified cell can be made to obey the new genetic material

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[29] *Gene Technology Act 2000* (Cth) s 10(1) (definitions of 'GMO' and 'genetically modified organism'). See also definition of 'organism'.
[30] *Gene Technology Act 2000* (Cth) s 10(1) (definition of 'gene technology'). See further Chapter 2.
[31] Through the work of Alfred Hershey and Martha Chase.
[32] A limited number of organisms, particularly viruses, use ribonucleic acid (RNA) rather than DNA as their genetic material.
[33] Chromosomes also contain other DNA segments that are not genes as well as protein which holds the DNA in a completed form.
[34] Not all organisms require two individuals to reproduce. For eg, some plants, such as carnations, can be vegetatively reproduced (such as by cuttings) from one parent.
[35] This sorting is not entirely random.
[36] Aust, Dept of Industry, Technology and Commerce, *Monitoring Recombinant DNA Technology: A Five Year Review* by Recombinant DNA Monitoring Committee (AGPS, Canberra, 1986), p 26.
[37] The transfer of genes from one species to another is sometimes called transgenics.
[38] These are some of the modifications made to the case studies. See subsections (b)-(d) below.
[39] Even if synthetically created, the gene must still be based on a naturally occurring gene.

as desired. The technology used to accomplish these various changes is one particular type of biotechnology.[40] It is known as 'genetic modification'.[41]

Changes to the genetic makeup of organisms have always occurred in nature.[42] Such changes have been partially directed by humans for centuries through selective breeding of plants and animals with particular traits. However, in September 1980 the first demonstration of the GM of an animal in a deliberately and directly controlled manner occurred.[43] Plants were subject to successful controlled GM even later than animals.[44]

GM has been applied to, and is said to have enormous further potential for, commercial applications in a wide variety of industries.[45] In agriculture, plants and animals are being modified to make them herbicide-tolerant, pest-resistant,[46] improve their nutritional value,[47] change their usual growth pattern[48] or reduce their environmental impact.[49] Although assessing the potential benefits and risks of agricultural GMOs is difficult, two

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[40] Biotechnology is a general term referring to the industrial use of biological processes. The 1992 Convention on Biological Diversity defines biotechnology as 'any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use.' Convention on Biological Diversity ATS 1993 No 32 Article 2. Examples of traditional biotechnology include winemaking, beer brewing and cheese-making. See also *Biotech Report 2001*, p 3.

[41] For further explanation of the techniques involved in GM, see Australian Government Analytical Laboratories, *Review of Technologies for Detecting Genetically Modified Materials in Commodities and Food*, prepared for the Dept of Agriculture, Fisheries and Forestry – Australia (undated, circa 2002); B J Glick and J J Pasternak, *Molecular Biotechnology. Principles and Applications of Recombinant DNA* (3rd ed, ASM Press, Washington DC, USA, 2003).

[42] This most commonly occurs when, as noted in the text above, the genetic material of both parents is randomly mixed to produce a unique individual but can also occur, for eg, as a result of bacterial or viral infection.

[43] The first successful GM of a mammal was reported as occurring in laboratory mice. See J M Massey, 'Animal Production Industry in the Year 2000 A.D.' (1990) 41 *Journal of Reproduction & Fertility (Supplement)* 199, 203. Production of GM livestock quickly followed. B Seamark, 'Transgenesis: Prospects and Limitations' [1991] *Intellectual Property Forum* 6.

[44] The first GM plants were created in 1985 although GM in the important cereal crops was only first achieved in early 1991.

[45] Such industries include health care, therapeutic goods production (such as insulin and human growth factor), mining and agriculture. For a description of the benefits GM brings to agriculture see *Work in Progress* Report, pp 7-16. See pp 16-26 with respect to the risks and disadvantages.

[46] Including resistance to viral, bacterial, fungal and nematode attack.

[47] For eg, by reducing lactose content in milk or reducing fat content in meat.

[48] For 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.

[49] There are other commercial applications of GM to agriculture. See, for eg, SA, Dept of Human Services, Environmental Health Branch, Genetically Modified Food Unit, Discussion Paper, *Preserving the Identity of non-GM Crops in South Australia* (September 2001) (http://www.health.sa.gov.au/publns/id-non-gm-crops.htm accessed 10/6/03) ('SA *Preserving non-GM Identity Paper*'); Dept of Agriculture, Fisheries and Forestry - Australia, *Biotechnology Strategy for Agriculture, Food and Fibre* (Cth of Aust, August 2003) (http://www.affa.gov.au/agbiotech accessed 19/6/03), Appendix 1, pp 5-7.

recent Commonwealth agency reports have concluded that it may be detrimental to Australia's agricultural trade if GM crop production does not proceed.[50]

1.3.2 *Carnation*

The GM carnation first went on sale in Australia in late 1996.[51] It was the first GM flower to be commercialised in the world.[52] An Australian company, Florigene Pty Ltd,[53] had noted that carnations were the biggest selling flower in the world. It also noted that blue flowers were amongst the most popular sellers. However, no blue carnations were available.[54] To meet the expected demand, the company genetically modified carnations to alter petal colour to produce a blue carnation.[55] Two genes were taken from blue petunia flowers and inserted into the carnation's genetic material.[56] A selectable marker gene[57] was also inserted into the carnation's DNA. Plants and cut flowers are being sold to the public.[58]

1.3.3 *Canola*

The gross value of canola production in Australia in the financial year 1999/2000 was estimated to be $699 million.[59] It is estimated that GM canola will add $135 million a year

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[50] Aust, Productivity Commission, *Modelling Possible Impacts of GM Crops on Australian Trade* by S Stone et al, Staff Research Paper (Melbourne, 2002) (http://www.pc.gov.au/research/staffres/gmcrops/gmcrops.pdf) (copy on file with author); Aust, Grains Research and Development Corporation, *GM Canola: What are its Economics under Australian Conditions?* by M Foster, ABARE (Canberra, 2003) (http:/www.abareonlineshop.com/product.asp?prodid=12526) (copy on file with author).

[51] E Huttner, '1996: Transgenic Crops Debut on the World Stage' in G D McLean et al (eds), *Commercialization of Transgenic Crops: Risks, Benefit and Trade Considerations* Proceedings of a workshop held in Canberra 11-13 March 1997 (AGPS, Canberra, 1997) 1, 10.

[52] Aust, Department of Foreign Affairs and Trade, Trade Development Branch, *Trade Outcomes and Objectives Statement* (February 1999), p 307.

[53] As it then was. The company has since listed on the Australian Stock Exchange.

[54] Other than carnations dyed that colour.

[55] For details on the GM made to the carnation see Aust, Office of the Gene Technology Regulator ('OGTR'), *Risk Assessment and Risk Management Plan. Application for licence for dealings involving an intentional release into the environment. DIR 030/2002 Commercial release of colour modified carnations (replacement of deemed licence GR-2)* (June 2003) ('Carnation RA&RMP'), Appendix 1.

[56] The genes are involved in the biosynthesis of anthocyanins (flower pigments). They produce certain enzymes essential for the production of delphinidins (blue pigments). Aust, OGTR, *Early-Bird Notification re risk assessment and risk management plan for a dealing involving the intentional release of genetically modified carnations DIR 030/2002* (December 2002), p1.

[57] A selectable marker gene is a gene whose presence is easily detectable. It is inserted into a GMO along with the desired gene. The presence of the marker gene allows scientists to know that the insertion of the genes has been successful. (From CSIRO, Gene Technology in Australia, Glossary of Terms (undated) (http://genetech.csiro.au/glossary.htm accessed 7/6/04).

[58] Carnation RA&RMP, s 1.1 [5].

[59] Dept of Agriculture, Fisheries and Forestry - Australia, *Draft Biotechnology Strategy for Agriculture, Food and Fibre* (Cth of Aust, September 2002) (http://www.affa.gov.au/content/output.c...tID=2A5EBB5D-0C62-45F5-96048D331D8E6F967 accessed 19/6/03) ('DAFF *Draft Biotech Strategy*'), p 6.

to Australia's harvest.[60] Canola has two distinct products. The first is canola oil for human consumption. The second market is canola meal, the by-product of oil extraction. Canola meal is predominately used as a stockfeed in the livestock industry.[61]

Bayer CropScience Pty Ltd[62] ('Bayer') has developed a GM canola, commonly known as 'InVigor Canola'.[63] The GM canola has been modified to include three new genes.[64] One gene results in the plant being herbicide tolerant.[65] Herbicide tolerance means that the plant can be sprayed with herbicide that would otherwise kill it, to destroy weeds growing in the same field. The ability to spray crops with herbicide provides farmers with an additional weed control option when the crop is being grown. Two other genes result in the GM canola being a hybrid variety. Hybrids have improved agronomic performance.[66] Hybrid varieties are common in many plant species but previously had only been created using conventional techniques. In this case, the hybrid was created using GM. Bayer claims that GM canola will give Victorian farmers an average seed yield increase of 15 percent over conventional canola and other benefits substantially increasing farm incomes.[67]

GM canola has been trialled in Australia under limited and controlled conditions both before and after the introduction of the GT regulatory scheme.[68] However, canola, GM or not, is often associated with a potential to escape from cultivation.[69] That means there is a risk of spread to other properties or to the wild. The proposed commercial release of GM canola in Australia has therefore generated perhaps unprecedented controversy because of

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[60] A Bolt, 'Modify your ideas, Bracks' *Sunday Herald Sun* (Melbourne), 28 March 2004, 21 quoting Dr R Norton, University of Melbourne, School of Agriculture and Food Systems.

[61] WA, Dept of Agriculture, *International Market Trends for Genetically Modified Crops* (Perth, February 2002) ('WA *Market Trends Paper*'), p 27.

[62] Formerly known as Aventis.

[63] A second GM canola has also been approved for commercial use in Aust. It was developed by Monsanto Australia Ltd to be resistant to Monsanto's more widely used broadacre herbicide, glyphosphate, commonly sold as 'Roundup' or 'Roundup Ready'. See Aust, OGTR, *Risk Assessment and Risk Management Plan. Final Version. Application for licence for dealings involving an intentional release into the environment DIR 020/2002 General Release of Roundup Ready canola* (Brassica napus) *in Australia. Monsanto Australia Ltd* (December 2003).

[64] As with the GM carnation, a selectable marker gene is also included in the plant.

[65] The herbicide is known as glufosinate ammonium.

[66] Known as hybrid vigour.

[67] Vic, *Report of the Independent Reviewer to the Government of Victoria. Review of Market Impacts of Genetically Modified Canola and Industry Preparedness* by P J Lloyd (undated, circa 2004) ('Lloyd Report'), Executive Summary, p v.

[68] See subsection 2.11.2(b) below.

[69] It has many characteristics causing it to spread easily. These include high seed production, its volunteers (that is, plants from seed that has been left in or near a field after harvesting) frequently appear especially along roadsides near crop production fields and it is able to survive burial for long periods through induced dormancy. A J Conner et al, 'The release of genetically modified crops into the environment. Part II. Overview of ecological risk assessment' (2003) 33 *The Plant Journal* 19, 24.

fears of damage that could be done to the environment and other farmers by its release into the environment. As discussed in Chapter 2, GM canola has been approved for commercial release in Australia and its oil approved for use as human food by the relevant regulators.[70] Nevertheless, commercial release is unlikely for some years following a series of bans and moratoria by individual States.[71]

1.3.4 *Pigs*

Work on developing a GM pig was begun in 1982 by a research group at Adelaide University.[72] The pigs were ready for market in mid 1995. Extra copies of the pig's own growth hormone gene were included in the pig's DNA. Included with the extra hormone gene copies was a special switch (known as a promoter[73]) originally from a human gene[74] which enabled the farmer to switch on or off the extra growth hormone genes using dietary supplementation.[75] The modification reportedly resulted in a faster growing and leaner pig. Pigs reportedly reached market weight up to seven weeks earlier than their conventional litter mates without any adverse effect on the pigs' health. They also yielded almost fat-free pork because the inserted genes increased the food-conversion efficiency of the pigs.[76] Due to regulatory uncertainty the pigs were never sold in Australia.[77] If commercialisation was to proceed now, either the pigs themselves and/or products from the animals such as bacon and pork could be sold subject to regulatory approval. The gross value of Australian pig production in 2001-2002 was $963 million.[78] The industry provides 33,863 Australian jobs.[79]

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[70] See subsection 2.11.2(b) below.
[71] See Chapter 3.
[72] *Zoffanies Pty Ltd v Commissioner of Taxation* [2002] AATA 758 (Unreported, Mr Handley, 4 September 2002) at [28]. The group later became Bresatec Ltd and in 1999, after listing on the stock exchange, changed its name to Bresagen Ltd. With respect to breaches of the then applicable guidelines during and at the completion of the project, see *Threat or the Glory* Report, pp 190-3.
[73] This is a DNA sequence at the start of a gene that controls where and when that gene is expressed and at what expression level. Australian Government Analytical Laboratories, *Review of Technologies for Detecting Genetically Modified Materials in Commodities and Food*, prepared for Dept of Agriculture, Fisheries and Forestry – Australia by K Griffiths et al (undated, circa 2002), p 100, Appendix 5.
[74] *Threat or the Glory* Report, [5.333].
[75] By adding zinc to the pigs' diet to turn it on or withholding it to turn it off. This meant if the pigs escaped to the wild, the new genes would not function because it was unlikely the pigs would get access to the amount of zinc needed.
[76] By about thirty percent.
[77] *Zoffanies Pty Ltd v Commissioner of Taxation* [2002] AATA 758 (Unreported, Mr Handley, 4 September 2002) at [45] and [57]. See Part 2.3 below for further discussion of this project's termination.
[78] Australian Pork Ltd (the national representative body for Australian pig producers), Australian Pig Industry Handbook, *Pig Stats 2002* (http://www.australianpork.com.au/ accessed 5/4/04), p 136.
[79] Australian Pork Ltd (the national representative body for Australian pig producers), Australian Pig Industry Handbook, *Pig Stats 2002* (http://www.australianpork.com.au/ accessed 5/4/04), p 136.

1.4 SOCIO-ECONOMIC IMPACTS

GMO releases may have socio-economic impacts for the community and for individuals. Possible social impacts of GMO releases are described in section 1.4.1.[80] The second section, 1.4.2, describes possible economic impacts of such releases, including an explanation of GM contamination.

1.4.1 *Social impacts*

Social impacts for the purposes of this thesis are the effects of GMO releases on other's way of life. GMO releases may cause third parties distress because of the third party's personal attitudes to GMOs. 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.[81] For example, a commonly raised possible social impact is that contamination or threatened contamination by GMOs will make non-GM agriculture impossible. All such concerns can arise whether or not GMOs have spread to another's land.

1.4.2 *Economic impacts*

'Contamination' for the purposes of this study refers to 'the unintentional and/or unwanted presence of a substance, organism or part of an organism in a particular environment, including within organisms. In the context of [GMOs], contamination is the unintended/ unwanted presence of a GMO, or the genetic material of a GMO or product of a GMO in an organism, environment or product.'[82]

There are two types of GM contamination – physical and genetic. Genetic contamination is really a subset of physical contamination but is treated separately here. Physical contamination occurs when GMOs or their parts move from the commercialiser's land to

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[80] Other socio-economic consequences besides those discussed in this Part are also possible, although more distantly removed from field trialling by the commercialiser than the ones described in the text. For eg, 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 study.

[81] For further discussion see, eg, Law Reform Commission of Victoria, *Genetic Manipulation* Report No 26 (Melbourne, June 1989), Chap 1; *The Threat or the Glory* Report, Chap 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, *The Social Management of Genetic Engineering* (Ashgate Publishing Ltd, England, 1998), Chap 15; Canada *Elements of Precaution* Report; Tasmania, Parliamentary Joint Select Committee, *Report on Gene Technology* (2001) ('Tasmanian Gene Technology Report'), Chap 6.

[82] Aust, Senate Committee on Community Affairs, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report on the Gene Technology Bill 2000* (November 2000) Tabled 1/11/00 PP No 263/00, [6.2].

other land.[83] For example, pollen or seed from GM plants may spread,[84] or GM animals stray, onto neighbours' land. Once there the GMO may begin growing or feeding on that land. Physical contamination may also occur when a third party's livestock or honeybees feed on GMOs that have spread from the commercialiser's land. Feeding on a GMO does not cause an animal to become GM itself.[85] However, it may cause the animal to lose, for example, organic certification.[86]

Genetic contamination is the contamination of the genetic makeup of other organisms. For example, cross-pollination may occur between the GMO and a third party's organisms;[87] a GM animal may mate with a wild counterpart.

Genetic contamination is not a significant concern for all GMOs. Many crops are obligatory self-pollinators and no cross-pollination occurs.[88] Where crops are vegetatively produced or in other ways sexually sterile, gene transfer through cross-pollination is also impossible.[89] For example, cross-pollination is unlikely to occur in GM carnations.[90] The carnation is a domestic, cultivated species which produces little or no pollen. During commercial production of cut-flower crops, setting of seed does not occur.[91] Even for some sexually propagated crops the likelihood of cross-pollination is very small because of the physiological characteristics of the plant and crop-management, such as where a particular crop is surrounded by unrelated crops.[92] There is also a minimal risk of many

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[83] Contamination may also occur through, for eg, physical intermingling in the supply chain during processing, transport or distribution. However, this would usually occur after field trialling.
[84] Dispersal could occur, for eg, through wind, bees or other animals or insects.
[85] For eg, food legislation does not require meat from such organisms to be labelled as GM and the *Gene Technology Act 2000* (Cth) does not apply to such animals. See Chapter 2.
[86] Australian Quarantine and Inspection Service, Organic Produce Export Committee, *National Standard for Organic and Bio-Dynamic Produce* (3rd ed, December 2002), Standard 3.13.1. See also Standard 3.13.7d. Organic certification is discussed further in subsection 5.2.3(b) below.
[87] For a summary of factors relevant to cross-pollination see SA *Preserving non-GM Identity Paper*, p 18. For scientific assessment of literature on cross-pollination in Aust and overseas see Aust, Bureau of Rural Sciences Australia, *Gene flow study: Implications for GM crop release in Australia* by J Glover (Canberra, 2002).
[88] Vic, Dept of Natural Resources and Environment, *Genetic Engineering-free Zones. Report of the Victorian Government Consultation* (December 2001), p 12.
[89] Vic, Dept of Natural Resources and Environment, *Genetic engineering-free zones* Consultation Paper (March 2001), submission by Florigene Ltd.
[90] Both the GTR and her predecessor GMAC have concluded that the probability of gene dispersal from cultivated carnations is very low. See Aust, OGTR, *Risk Assessment and Risk Management Plan for Intentional Release of a GMO Into the Environment: Application No. DIR 030/2002 Executive Summary* (14 March 2003), p 2 and Aust, GMAC, *Annual Report 1997-8* (Cth of Aust, Canberra, 1998), p 19 'Proposed PR-84' respectively.
[91] For this reason carnations are vegetatively propagated (by cuttings) but do not spread vegetatively under natural conditions.
[92] Nonsexual transfer is possible from one unrelated organism to another by virus or bacteria via horizontal transfer. G N Mandel, 'Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of

GM animals contaminating another's land or organisms because it is unlikely that such valuable animals would be kept in conditions from which they could easily escape.

Nevertheless some GMOs are considered to pose a high risk of contamination. For example, certain GM fish are reported to be high risk because of the likelihood of escape from containment. The widespread cultivation of some GM crops is also considered likely to have a major impact on existing forms of agriculture[93] and cross-pollination of neighbouring sexually compatible crops inevitable.[94] For example, there is considered to be a significant risk of contamination of land and organisms by GM canola. Australian research published in *Science* found pollen from a new canola plant[95] could travel up to three kilometres away, borne by wind and insects.[96] However, the amount of cross-pollination was minimal.[97]

GM contamination or threatened contamination following a GMO release may cause a range of economic impacts for third parties. These include the loss of market advantage, need to take precautionary measures, need to comply with regulatory requirements, infringement of patent rights and general agricultural implications. Each of these is considered below.

The third party may be a non-GM farmer, growing conventional or organic organisms.[98] Agricultural markets can be divided into three categories.[99] 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

Genetically Modified Plants and Animals' (19 June 2003) (http://ssrn.com/abstract=418221) (copy on file with author), p 21.

[93] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 518. But cf G Brookes and P Barfoot, *Co-existence of GM and non GM arable crops: case study of the UK*, Research paper (PG Economics Ltd, UK, May 2004) which claims that GM crops can co-exist with conventional and organic crops, at least in the UK, without causing any economic or marketing problems and that claims by anti-GM groups that GM and non-GM crops cannot co-exist are exaggerated.

[94] See *Work in Progress* Report, [4.18].

[95] The plant was not GM but was created with human intervention through mutagenesis.

[96] M A Rieger et al, 'Pollen-mediated movement of herbicide resistance between commercial canola fields' (2002) 296 *Science* 2386. See also E Stokstad, 'A little pollen goes a long way' (2002) 296 *Science* 2314.

[97] E Stokstad, 'A little pollen goes a long way' (2002) 296 *Science* 2314, 2314. About 63 percent of the fields tested turned up some plants with modified genes although the highest rate of modified plants in non-modified fields was only 0.2 percent. M A Rieger et al, 'Pollen-mediated movement of herbicide resistance between commercial canola fields' (2002) 296 *Science* 2386, 2386.

[98] In 2000 there were 2000 producers certified organic in Aust. I Gilfillan, SA Member of Parliament, Media Release, *GM Moratorium Plan Gathers Support* (20 June 2000).

[99] The following categories are from Aust, Gene Technology Grains Committee, *A strategic framework for maintaining coexistence of supply chains* (draft-for-discussion) (31 July 2002), p 6.

material. Finally, identity 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.[100] Actual or threatened GM contamination may cause the invaded party to lose access to a particular market.[101] Contamination may also mean the third party no longer satisfies contractual warranties provided by them regarding the GM status of their organisms.[102]

Even on the assumption that all GMOs grown in Australia have regulatory approval, not all will have the same status with respect to overseas markets.[103] 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.[104] Loss of such access could in turn cause the loss of some premium available in the relevant market.[105]

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[100] Australian anti-GM activist groups, Australian GeneEthics Network and Greenpeace Australia-Pacific, have reportedly been unable to find organic canola farmers in Aust. G O'Neill, 'Melbourne University report positive on GM Canola varieties' (26/3/03) *Australian Biotechnology News* (http://www.biotechnews.com.au/index.php?id=1387312272&taxid=5 accessed 26/3/03).

[101] See R 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.

[102] Dept of Agriculture, Fisheries and Forestry - Australia, *Liability Issues Associated with GM Crops in Australia* by Science and Economic Policy Branch, Scoping study (September 2003) ('DAFF *Liability Issues Study*'), p 6.

[103] For a summary of GM legislation and labelling issues concerning the export of Australian produce to 15 overseas countries see WA *Market Trends Paper*, pp 62-3 Table 21.

[104] T P Redick and C G Bernstein, 'Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date With Damocles' (2000) 30 *Environmental Law Reporter* 10328 text re fn 11. See also R A Repp, 'Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift' (2000) 36 *Idaho Law Review* 585, 591 where Repp describes events leading to rejection of shipment of organic tortilla chips worth US$500,000 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 B 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 LA International & Comparative Law Review* 453, 456 and 482.

[105] 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. Vic, Dept of Natural Resources and Environment, *Genetic Engineering-free Zones. Report of the Victorian Government Consultation* (December 2001), p 10. See also WA *Market Trends Paper* and Australian Bureau of Agricultural and Resource Economics, *Market Access Issues for GM Products: Implications for Australia* by M Foster et al, ABARE *e* Report 03.13 to the Dept of Agriculture, Fisheries and Forestry – Australia (Canberra, July 2003); Lloyd Report for a discussion of premiums paid on non-GM crops by overseas markets; Aust, Grains Research and Development Corporation, *GM Canola: What are its Economics under Australian Conditions?* by M Foster, ABARE (Canberra, 2003) (http://www.abareonlineshop.com/product.asp?prodid=12526) (copy on file with author) which concluded that there was no clear trend emerging for significant premiums for differentiated (GM and non-GM) products.

Threatened contamination could cause third parties to take precautions to prevent spread onto their properties.[106] Actual contamination may also cause third parties to have to change normal agricultural practices.[107] It has been claimed GM contamination may even cause crops to fail.[108] Costs may also be incurred trying to eradicate the invading organism.[109]

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. For example, '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 status can be substantiated'.[110] 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 national GT scheme and State moratorium legislation.[111] Invaded parties will then have to comply with the scheme and relevant State legislation where they otherwise did not have to.[112] As discussed in Chapters 3 and 6, GM contamination may even result in the destruction of the contaminated crop under State or environmental legislation and restrictions being imposed on the future use of the land under State legislation.

Patent legislation may also mean the third party is not able to use their contaminated organisms or save and use seed from a contaminated crop. As discussed in Chapter 4,

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[106] 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.

[107] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 530. For eg, 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.

[108] See R A Repp, 'Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift' (2000) 36 *Idaho Law Review* 585, 595.

[109] Remediation of the contaminated property can be extremely difficult and expensive. See, eg, *Monsanto Canada Inc v Schmeiser* 2001 FCT 256 [59] (discussed in subsection 4.3.6(c) below) 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 ACT, Legislative Assembly, Standing Committee on Health, *Inquiry into the Gene Technology Bill 2002. Report No 2* (December 2002), [2.30] referring to case in Tasmania where GM-canola appeared on land five years after a trial was held on the site.

[110] Tasmanian Gene Technology Report, p 108.

[111] Discussed in Chapters 2 and 3 respectively.

[112] Rogers suggests that knowing of herbicide resistant characteristics in a crop might well be knowledge that the crop is a GMO through contamination. N 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, 5.

patent laws may mean contaminated parties are liable to GMO patent owners if contaminated organisms are used or seeds are saved.

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.[113]

1.5 THESIS OUTLINE

There are five substantive chapters. The thesis begins, in Chapter 2, with a brief description of the history of GM regulation in Australia. Prior studies of both that regulation and the legal issues relevant to this thesis are outlined in the course of that description. The Chapter then summarises the national GT regulatory scheme pursuant to which the selection of GMOs now occurs. A recent government paper noted that '[s]ince the implementation of the *Gene Technology Act 2000* (Cth), there does not appear to be new evidence or direct experience demonstrating any inadequacies in the existing regime'.[114] However, it will be submitted that the scheme has created unintended difficulties for commercialisers. For example, the risks and impacts relevant under the scheme are unclear. In particular, it is unclear wnether socio-economic impacts of GMO releases are relevant when licensing decisions are made. Such uncertainties and the way the scheme is currently being operated will be investigated. Finally, there is a brief outline of the end product regulatory scheme relevant to the case studies. The ramifications of the operation of the national and end product schemes on selection of GMOs and their products for commercialisation are considered. An assessment is made as to whether the new regime is an improvement for commercialisers when compared with the 'regime' in place prior to its introduction. It will be submitted that the new scheme is generally an improvement for commercialisers.

The very recent introduction by many States[115] of moratoria on GMO releases is a further significant change to the regulatory environment in which GMOs are selected for commercialisation. These changes are described and analysed in Chapter 3. The relevance

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[113] R Bratspies, 'Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco' (2003) 27 *William & Mary Environmental Law & Policy Review* 591, 600. For eg, Bt GM crops may lead to the loss of effectiveness of BT, a natural bacterial pesticide used by organic farmers to control caterpillars.
[114] DAFF *Liability Issues Study*, p 15.
[115] 'States' is used here to include all States and Territories unless stated otherwise.

of these changes for each of the case studies is also addressed. It will be submitted that the State legislation has added considerably to the legal challenges facing commercialisers.

Chapter 4 concerns the availability of IP protection for GMOs and their products. IP protection depends upon GMOs satisfying generally applicable legal requirements. These are described in Chapter 4. How the availability and usefulness of IP protection is affected by the unique characteristics of GMOs and their products is examined. For example, in respect of each of the three IP regimes considered, the ability of GMOs to self reproduce will be relevant to the scope of protection given by the regime. In each case the relevance or irrelevance, as the case may be, of socio-economic impacts is also assessed. It will be submitted that IP protection will be available; socio-economic impacts of GMO releases will not result in protection being denied. However, the scope and value of that protection will be limited because of the unique traits of GMOs and their products.

Commercialisers' liability in tort arising from GMO releases during field trials is the subject of Chapter 5. As with IP protection, liability largely depends upon the application of legal principles not specifically created for the purposes of GMOs. The implications of the unique characteristics of GMOs on such liability are unclear. Relevant legal principles are described. They are then applied to the likely socio-economic impacts described in Part 1.4 above. As expected, commercialisers can be liable in tort. However, one of the most significant challenges for commercialisers will be predicting how the court will classify such impacts. It will be demonstrated that there is uncertainty in that regard. It will be submitted that classification should be based on regulatory or legislative standards rather than standards set by groups or organisations such as organic farmers. The interactions of the national regulatory scheme and new State restrictions with tort law are also analysed. It will be submitted that whilst the national regulatory scheme will be of little assistance to commercialisers defending themselves in tort proceedings, the State legislation discussed in Chapter 3 is of considerable relevance. Interestingly, it is those States with legislation prohibiting certain GMO releases where commercialisers of non-prohibited GMOs are least likely to be liable in tort.

Statutory liability under environmental legislation is considered in Chapter 6. Once again liability will be determined by laws not created specifically for GMOs. Examples of those laws are described and applied to GMO releases. It will be demonstrated that, as expected, commercialisers will be liable under environmental legislation. However, the overlap of the regulation of agricultural GMOs by the national regulatory scheme, State moratorium

legislation and environmental legislation has implications for commercialisers. It will be submitted that the need for approval under Commonwealth environmental legislation means third parties may be able to use the legislation to the detriment of commercialisers. With respect to State environmental legislation it will be submitted that deference by State authorities to decisions under the GT regulatory scheme is legally questionable.

Conclusions are then brought together in Chapter 7 and possible reforms suggested.

CHAPTER 2

SETTING THE SCENE

2.1 INTRODUCTION

Until recently there were no specific regulatory controls on the development and release of GMOs or their products in Australia. A voluntary and self-regulatory system had existed since the mid-seventies but there were no direct legal repercussions where those 'regulations' were not adhered to. Commercialisation of GMOs' end products was also not specifically regulated. Some end products were subject to general regulation which applied regardless of whether GM was used in their production.[1] Other GM end products were not regulated at all.

An example of a GMO developed and then sold without regulation is the GM carnation. The carnation first went on sale in Australia in late 1996.[2] When it was first developed and released for sale, no Australian regulatory agency had statutory power over the organism's development, the end use of cut flowers or ornamental plants or responsibility for approving initial commercial release. The research and development of the product was conducted under the voluntary system referred to above and the first sale of the 'new' carnation required no prior regulatory approval. This was the case whether the carnation was sold as cut flowers or whole plants.

In contrast to the GM carnation, the lack of regulation prevented the introduction of some GMOs destined for the food market. The GM pigs were ready for market in mid 1995.[3] However, when the commercialiser, at the time called Bresatec Ltd, approached a meatworks regarding the slaughter of 120 pigs the meatworks required some form of formal certification for the sale of what would have been the first GM wholefood on the

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[1] For eg, pharmaceutical products were and are still regulated under the *Therapeutic Goods Act 1989* (Cth) and agricultural and veterinary chemicals are regulated under the Agvet Code. See *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) s 5(1). See also Part 2.10.

[2] E Huttner, '1996: Transgenic Crops Debut on the World Stage' in G D McLean et al (eds), *Commercialisation of Transgenic Crops: Risks, Benefit and Trade Considerations* Proceedings of a workshop held in Canberra 11-13 March 1997 (AGPS, Canberra, 1997), p 1, p 10.

[3] P Quiddington, 'New, lean porkers have the regulators hamstrung' *The Australian Financial Review* (Sydney), 24 November 1995, p 19.

Australian market.[4] The Authority overseeing the voluntary regulatory system in place at that time, the Genetic Manipulation Advisory Committee ('GMAC'), was approached although it had no jurisdiction over sales. GMAC suggested that the commercialiser advertise its intention to release the meat onto the market. It advertised in a food industry journal and a national newspaper in May and July 1995 but got no response.

The meatworks was still not satisfied. Therefore the commercialiser sought authority from the National Food Authority (as it then was). The Authority denied that it had jurisdiction in the matter but suggested that as there was no code in the area the pork should be 'appropriately labelled'. The Food Authority gave no advice as to what the label should say or where in the retail chain it should appear: that is, whether the label should appear only on the carcasses delivered to butchers, or also on meat sold to the public, or also on processed foods containing the pork.[5] The commercialiser shelved all plans to sell the pork.[6]

The lack of specific regulation of GM ended in 2001 with the introduction of the national regulatory scheme for GT. The centrepiece of that scheme is the *Gene Technology Act 2000* (Cth) ('*GT Act*'). GMOs are now regulated throughout the entire commercialisation process – that is, from the earliest research to sale of end products. The new scheme regulates all research, field trials, commercial releases and post-release management of GMOs and dealings with GM products not already regulated by other pre-existing regulatory schemes. Pre-existing regulatory schemes that applied to GM end products before the introduction of the new scheme continue to apply. They were, though, amended to coordinate them with the *GT Act* and to better deal with GMOs and their products. Some GMOs and their products therefore need to satisfy regulatory requirements in addition to those of the GT regulatory scheme. For example, GM food must meet specific requirements under food regulations.

This Chapter concerns the national regulatory background against which commercialisers must field trial and select new GMOs and their products. It begins in Parts 2.2 to 2.5 with

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[4] Although see *Zoffanies Pty Ltd v Commissioner of Taxation* [2002] AATA 758 (Unreported, Mr Handley, 4 September 2002) at [45] where evidence was given that a few GM pigs had been sold into the food chain in 1988.

[5] P Quiddington, 'New, lean porkers have the regulators hamstrung' *The Australian Financial Review* (Sydney), 24 November 1995, p 19.

[6] About 300 pigs were destroyed and the germplasm retained by storing semen from the best boars in liquid nitrogen. *Zoffanies Pty Ltd v Commissioner of Taxation* [2002] AATA 758 (Unreported, Mr Handley, 4 September 2002) at [12].

the history of GM 'regulation' and prior Australian studies of that regulation. Part 2.6 describes the establishment of the new national regulatory scheme for GT. An outline of the application and administration of the *GT Act* is then given in Part 2.7. The most important part of the Act for commercialisers is the prohibition of dealings with GMOs. Part 2.8 examines that prohibition and the exceptions to it. In particular it analyses the risks addressed by the GTR when making licensing decisions. Other matters which may be of particular relevance to commercialisation dealt with in the *GT Act* are considered in Part 2.9. Part 2.10 describes the end product regulatory scheme relevant to two of the case studies, that of food regulation. That regulation is important to discussion in Chapters 5 and 6. The Chapter concludes with a discussion of the implications of the scheme for commercialisers of the case studies and GMOs generally in Part 2.11.

2.2 1974 - 1987

The regulation of recombinant DNA research (as GM was then often called) was first considered by the Australian Academy of Science in 1974.[7] In 1975 it established a Committee on Recombinant DNA Molecules ('ASCORD').[8] That Committee was responsible for, amongst other things, monitoring recombinant work. As commercial applications of the technology became more likely, the Commonwealth Government established a further Academy committee to review surveillance of the technology.[9] Professor Frank Fenner was its chair.[10] The Recombinant DNA Monitoring Committee ('RDMC') was established in 1981 as a result of the Committee's report.[11]

The RDMC was to be established for five years. It was then to report to the Commonwealth Government on the need for the monitoring of recombinant DNA activities to continue beyond that term. The Committee, however, operated until 1987 when its successor, the GMAC, was established. The RDMC's objective was to ensure that the use of recombinant DNA techniques did not endanger workers involved with

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[7] Australian Academy of Science, *Recombinant DNA: An Australian Perspective* (Canberra, 1980) ('Fenner Committee Report'), p iii.
[8] Aust, RDMC, *Report for the period October 1981 to October 1982*, Dept of Science and Technology (AGPS, Canberra, 1983) ('RDMC 1981-1982 Report'), p 2.
[9] Fenner Committee Report, p iii.
[10] Formerly Director, Centre for Resource & Environmental Studies, Australian National University, Canberra.
[11] The RDMC was a non-statutory federal monitoring body in the Dept of Science and Technology. ASCORD transferred its records to the RDMC's secretariat upon creation of the RDMC. RDMC 1981-1982 Report, p 1.

recombinant DNA, the general community and the environment.[12] However, the system was a voluntary one. Compliance with the system was not legally enforceable.

The earliest Government studies on GM in Australia, such as the Fenner Committee Report in 1980 and the Five Year Review[13] by the RDMC published in 1986, concentrated on the use of the technology for the purposes of research.[14] Both Reports include a brief and now very out of date section on the law applicable where harm is caused by GMOs.[15] The Five Year Review summarises the results of the Barker Report discussed below. There is no discussion of the social or economic repercussions of releases or their relevance to legal liability in either Report.[16] With respect to IP protection, the Five Year Review merely notes patents are available for artificial entities offering some economic advantage.[17] The Fenner Committee Report does not consider the issue.

The RDMC, together with the Commonwealth Department of Science and Technology, commissioned a consultancy study by Michael Barker. That study resulted in the publication of a report in 1984.[18] One of the three broad objectives of the Report was 'the identification and description of major Commonwealth, State and Territory laws having relevance to the monitoring and regulation of recombinant DNA work in Australia'.[19] The Report was completed 20 years ago and before the introduction of the GT regulatory scheme. It is therefore considerably out of date. The study also resulted in, by its own admission, only a brief description of the major laws.[20] It did not discuss the outcome of common law application to such technology in detail[21] or consider IP protection at all. More importantly, the performance of Australia's regulatory system was the focus. The

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[12] RDMC 1981-1982 Report, p 4.
[13] Aust. RDMC, *Monitoring Recombinant DNA Technology: A Five Year Review*, Dept of Industry, Technology and Commerce (AGPS, Canberra, 1986) ('Five Year Review').
[14] The Fenner Committee Report, for eg, expressly excluded consideration of GM of higher organisms for the purposes of agriculture. Fenner Committee Report, pp xi and 38.
[15] Fenner Committee Report, Chap 7; Five Year Review, Part Three, section 4.
[16] With respect to the Five Year Review, this may be because the RDMC considered its expertise as being limited to the 'genetic aspects' of a release. Five Year Review, p 48.
[17] Five Year Review, p 45.
[18] M L Barker, *The Recombinant DNA Technique and the Law: A Review of Australian Law which may be relevant to the Regulation of Recombinant DNA Research and Applications. A Report to the Recombinant DNA Monitoring Committee and the Commonwealth Department of Science and Technology* (Dept of Science and Technology, Canberra, 1984) ('Barker Report').
[19] Barker Report, p 1.
[20] Barker Report, p viii.
[21] See Barker Report, pp 88-90 for the brief outline of the common law causes of action in the Report. This essentially consists of a brief description of the elements of various torts. The discussion is limited to personal injury and property damage. Pure economic loss is not considered.

needs of commercialisers of the technology were not taken into account. Nor was the relevance of socio-economic implications of GMOs considered.[22]

2.3 1987 - 1990

In light of the great advances in the technology, the Commonwealth Government established GMAC in 1987. GMAC replaced the RDMC and expanded the RDMC's work.[23] In particular all innovative genetic manipulation techniques rather than only research involving breaking and recombining DNA were included in GMAC's monitoring role.[24] The name of the new committee reflected the change in role.

However, like the RDMC, GMAC was a non-statutory body with no direct legal power to enforce its decisions. Persons wanting to use GMOs submitted a proposal to GMAC. GMAC then did a risk assessment and provided advice on management conditions for the particular research or use.[25] There was no statutory obligation to provide proposals to GMAC before dealing with GMOs. Nor was there any statutory obligation to comply with recommended conditions. GMAC had no power to take action where there was non-compliance. Nevertheless, compliance with GMAC recommendations was said to be high.[26]

GMAC was concerned generally with monitoring research. Legal responsibility for regulation of the sale of GM outcomes rested with various Commonwealth and State Government agencies. Which, if any, agency was responsible depended upon the end use proposed for the product. GMAC, however, advised these agencies on the environmental and safety implications of GMOs. Some GMOs such as the carnation were commercialised during this time.[27]

Not everyone saw such regulation as ideal. Many criticisms of the system were raised. Some of these concerned the commercialisation of GMOs and their products. One such criticism concerned the system's lack of transparency and responsiveness. Although the

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[22] Barker Report, p x.
[23] GMAC was a part-time body of mainly scientific experts.
[24] A second body was created by the Cth Government which worked with the GMAC in the more recent past. It was called the Interim Office of the Gene Technology Regulator ('IOGTR'). See Part 2.4 below.
[25] Aust, Office of the Gene Technology Regulator ('OGTR'), *Comparison between the Gene Technology Act 2000 and the system overseen by the Genetic Manipulation Advisory Committee* Information Sheet (undated).
[26] Aust, OGTR, *Voluntary System* (undated) (http://www.health.gov.au/ogtr/voluntary/background.htm accessed 5/9/01). But see, for eg, the breaches of GMAC recommendations listed in B Bennett and G Williams, 'Gene technology regulation: the Australian approach' (2001) 1 *Biotechnology Law and Policy Reporter* 29, 30-31.
[27] Eg, the GM carnation was first commercially released with GMAC 'approval'.

majority of the relevant government agencies were required to engage in public consultation at some stage in their regulatory procedure, there were claims that insufficient regard was being had to social and ethical issues arising with respect to the sale of GM outcomes. There were calls for the establishment of an ethics committee to review such issues. Such a committee could take into account, amongst other things, public concerns associated with the potential release of a product, whether the product would benefit the community and the likely impact of the product's release on the market. Additional concerns were that the work of the various agencies may be uncoordinated or repetitive, with agencies repeating investigations already undertaken by other agencies. Further, some products did not fall within the mandate of existing regulators[28] and GMAC, which was established to regulate research rather than commercialisation, could not act as a 'stop-gap'.

In March 1988 the Law Reform Commission of Victoria ('VLRC') released its Discussion Paper *Genetic Manipulation*.[29] Its Final Report, also called *Genetic Manipulation*, was tabled in Parliament in 1989.[30] The study was undertaken in the context of the Commission's Standing Reference on Medicine, Science and the Law. This required the Commission to '"monitor new developments in the field of medicine and science which raise complex ethical and moral issues" and to advise the Government on changes to the law that may be necessary to provide adequate controls'.[31] Amongst other things, the Report considered the rights of people suffering personal injury or property damage because of GMOs and environmental concerns following GMO releases. The VLRC recommended that there be no special remedy for people injured or suffering property damage as a result of GMO releases other than the usual common law remedies.[32] It noted though that recovery may be difficult because of the need to establish the reasonable foreseeability of the harm and that it was caused by the GMO.[33] It concluded that there were doubts about the 'applicability of the existing common law remedies to injuries caused by [GMOs]'.[34] In regard to environmental legislation, it concluded that releases

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[28] Regulation Impact Statement for the Gene Technology Regulations 2001 (Cth), Part 2, Attachment to Explanatory Statement to the Gene Technology Regulations 2001 (Cth).
[29] Law Reform Commission of Vic, *Genetic Manipulation* Report No 11 Discussion Paper (Melbourne, 1988).
[30] Law Reform Commission of Vic, *Genetic Manipulation* Report No 26 (Melbourne, June 1989) ('VLRC Final Report').
[31] VLRC Final Report, p 39.
[32] VLRC Final Report, Recommendation 12. See also Recommendation 11.
[33] VLRC Final Report, p 22.
[34] VLRC Final Report, p 22. The VLRC says (at p 22) '...the Commission is not convinced that recombinant DNA work presents unique risks that require the creation of a special right to compensation for injuries or

could be an offence under certain legislation.[35] It also noted that confusion as to whether environmental legislation applied to GMO releases 'might also deter potential investors'.[36]

The Report was the result of very wide consultation and is comprehensive in so far as it goes. However, as with the Barker Report, the Commission's Report is now considerably out of date. It was written before the introduction of the GT regulatory scheme and the States' responses to GM crop releases. Relevant environmental legislation and negligence law in particular have also changed considerably since the Report. The investigation was also from the perspective of the Government or third parties rather than that of commercialisers. Furthermore, where the application of the common law or other regulations is discussed there is no explanation for the predicted outcome making it difficult for readers to assess the correctness of any conclusions. Finally, neither IP protection nor the legal relevance of socio-economic repercussions of GMO releases is discussed.

On 12 June 1990 Senator John Button, the then Commonwealth Minister for Industry, Technology and Commerce, wrote to the House of Representatives Standing Committee on Industry, Science and Technology proposing an inquiry into the issues arising from, and the regulation of, GMOs.[37] In October of the same year, a special Premiers' Conference agreed 'to the development of a national approach to assessment and control of GMOs'.[38]

In July 1990 the Standing Committee began its inquiry. The inquiry resulted in the publication of a report in February 1992 called *Genetic Manipulation: The Threat or the Glory?*[39] The broad thrust of the Report was that legal force be given to the GMAC Guidelines and procedures. It also recommended the establishment of a central statutory authority to oversee GMO releases. That authority, according to the Committee, could also

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property damage. Common law remedies are available and although their applicability ... is not entirely clear, that applies also to some remedies for other injuries.'

[35] VLRC Final Report, pp 27-9.

[36] VLRC Final Report, p 31.

[37] Aust, GMAC, *Annual Report 1993-94* (AGPS, Canberra, 1994), p 51.

[38] Aust, House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (AGPS, Canberra, 1992) ('*Threat or the Glory* Report'), [1.73] citing submission by the Dept of Industry Technology and Commerce: Submission 126.1 p1.

[39] Aust, House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (AGPS, Canberra, 1992).

consider social and ethical issues.[40] GMAC was to continue to oversee the area until the new arrangements were implemented.[41]

In accordance with its Terms of Reference, the inquiry was very broad.[42] Philosophical, social and ethical issues were considered together with legal issues.[43] Whilst the Report is extremely useful so far as its objectives are concerned, it is not particularly useful for those wanting to commercialise GMOs today. The Committee noted that an action in trespass or nuisance would enable an injunction to be sought against a party releasing[44] GMOs which cause or threaten to cause damage.[45] Additionally it said that an action in trespass, private or public nuisance or negligence may enable a person to receive financial compensation for loss or damage suffered as a result of a GMO release into the environment.[46] However, its analysis of whether such actions would succeed is scant.[47] It relies for much of its conclusions on the Barker Report, which on the Committee's own admission is only a brief description of the major laws.

The Committee recommended that strict liability be imposed for damage arising from the deliberate and unauthorised release of GMOs.[48] If the GMO release which resulted in loss or damage was authorised, the Committee believed that legal liability of the releasing party should be mitigated.[49] A state of the art defence to protect those who, acting with due diligence, authorise releases was also recommended.[50] The Report was prepared before the

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[40] *Threat or the Glory* Report, Recommendations 33, 40 and 44.
[41] GMAC's response to the Report's recommendations are in GMAC, *Annual Report 1991-2* (AGPS, Canberra, 1992).
[42] The Committee was required to:

- 'identify and report on any national issues unique to the contained development and use of genetically manipulated organisms and their release into the environment; and
- inquire into and report upon the adequacy of the current arrangements, and advise on future desirable legislative frameworks for the regulation of the contained development and use of genetically manipulated organisms, and their release into the environment, including imported material.'

Threat or the Glory Report, p xii.
[43] See *Threat or the Glory* Report, Chap Four with respect to philosophical, ethical and social issues.
[44] Whether accidentally or deliberately.
[45] *Threat or the Glory* Report, p 254.
[46] *Threat or the Glory* Report, p 254. The Committee also referred to a possible action under *Rylands v Fletcher* (1868) LR 3 HL 330 but that is no longer available in Aust. See *Burnie Port Authority v General Jones Pty Ltd* (1994) 179 CLR 520.
[47] See *Threat or the Glory* Report, pp 175-8. In its' own words, this discussion is really only a 'mention' of the common law actions which might apply. See pp 254-6 and 260.
[48] *Threat or the Glory* Report, Recommendation 33.
[49] *Threat or the Glory* Report, p 256.
[50] *Threat or the Glory* Report, p 256.

introduction of the GT scheme. None of these recommendations were adopted in the scheme.[51]

With respect to the protection of the investment made by GMO commercialisers the Committee considered only the patent regime in any detail.[52] Nevertheless, its consideration of the patentability of GMOs is superficial.[53] There is little consideration of the effect of the unique traits of GMOs on such protection. The availability of trade secrets and plant variety rights under the predecessor to the current legislation are only briefly noted.[54] Moreover, as in the earlier studies, the Committee adopts the perspective of the national interest. The perspective of those wanting to commercialise GMOs was largely ignored. Finally, the legal repercussions of socio-economic concerns arising from GM contamination were not considered.[55]

All of the above Reports were prepared before the introduction of the GT regulatory scheme. Further, none considered the relevance of areas designated as GM-free on commercialisers' liability. Nor did the Reports consider the relevance of the socio-economic impacts of the introduction of GMOs on other farmers in considering the common law or statutory liability of GMO commercialisers.[56] Little consideration is given to IP protection of GMOs.

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[51] Other recommendations, such as the introduction of a Genetically Modified Organisms Release Authority (*Threat or the Glory* Report, Recommendations 40-48), were taken up in the scheme.

[52] On this matter it concluded that there was no justification for denying the biotech industry the opportunity to use the *Patents Act* to seek a reward for effort. It also decided that only human beings should be excluded from the patents legislation and not other life forms. See *Threat or the Glory* Report, Chap 7.

[53] See *Threat or the Glory* Report, pp 224-6. See also pp 229-42 with respect to objections to the patenting of GMOs.

[54] *Threat or the Glory* Report, p 224.

[55] Although the Committee does note that 'there may be strong public feeling that the social consequences of some particular application of genetic manipulation technology are such that it should not proceed'. *Threat or the Glory* Report, p 113. It therefore recommends that concerns about the social impacts of particular releases of GMOs or their products be considered by the body granting approvals to release. See *Threat or the Glory* Report, Recommendation 9.

[56] The Standing Committee did consider the possibility of the transfer of genes between plants but in the context of the creation of weeds. See *Threat or the Glory* Report, pp 155-6.

2.4 TOWARDS A STATUTORY REGULATORY BODY

In October 1992 the Commonwealth Government announced, in its response to the *Threat or the Glory* Report, that it would establish a statutory body to replace GMAC.[57] The Commonwealth and State Governments began negotiations with each other in 1993 to establish a GT authority.[58] Negotiations soon stalled.

In October 1997 the proposal for a national legislative regulatory scheme for GT was revived and a Commonwealth-State Consultative Group on Gene Technology was formed.[59] That body prepared a paper, *Regulation of Gene Technology*, in November 1998 seeking views on the broad policy principles that might underpin the scheme.[60] In May 1999 the Interim Office of the Gene Technology Regulator ('IOGTR') was established to oversee the development of the legislation implementing the national scheme and to work with GMAC.[61] The Consultative Group in collaboration with the IOGTR prepared a further discussion paper entitled *Proposed national regulatory system for genetically modified organisms. How should it work?* in October 1999.[62] Using the responses to that paper, the IOGTR drafted a GT Bill.[63]

The draft Bill together with a plain language explanatory guide was released for public consultation in late December 1999.[64] Following a subsequent consultative process,[65] changes were made to the Bill before it was introduced into the House of Representatives on 22 June 2000.[66] Upon introduction to the Senate, the Bill was referred to the Senate Committee on Community Affairs which delivered its report, *A Cautionary Tale: Fish*

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[57] Aust, GMAC, *Annual Report 1993-4* (AGPS, Canberra, 1994), p 12. As to whether a regulatory system is sufficient to protect the public, see Note, 'Designer Genes That Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products' (1987) 100 *Harvard Law Review* 1086.
[58] P Quiddington, 'New, lean porkers have the regulators hamstrung', *The Australian Financial Review* (Sydney), 24 November 1995, p 19.
[59] Aust, Senate Committee on Community Affairs, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report on the Gene Technology Bill 2000* (November 2000) Tabled 1/11/00 PP No 263/00 ('*Cautionary Tale* Report'), [1.8].
[60] *Cautionary Tale* Report, [1.10].
[61] *Cautionary Tale* Report, [1.11] fn 3.
[62] *Cautionary Tale* Report, [1.11].
[63] *Cautionary Tale* Report, [1.12].
[64] *Cautionary Tale* Report, [1.12].
[65] See Aust, First Australian Consensus Conference, *Gene Technology in the Food Chain, Lay Panel Report* (National Museum of Aust, Canberra, 1999); Aust, House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with caution. Primary Producer Access to Gene Technology* (Canberra, June 2000) ('*Work in Progress* Report').
[66] *Cautionary Tale* Report, [1.13]. An amended Explanatory Memorandum and Explanatory Guide dated July 2000 were also released.

Don't Lay Tomatoes. A Report on the Gene Technology Bill 2000 on 1 November 2000.[67] Following further amendments in light of that report the Bill was enacted and took effect as the *GT Act* on 21 June 2001.[68]

As noted above, reports on GT were released during the development of the regulatory scheme. These took into account the impact of the scheme. However, they focused on the development and details of the scheme. Few comments relevant to the issues raised by this study were made. The civil liability of people using GT was mentioned in the paper produced jointly by the Commonwealth-State Consultative Group on Gene Technology and the IOGTR. They concluded that there were statutory and common law actions available to those injured because of actions by the GTR, commercialisers or others. They also noted that the GT legislation would not affect available common law avenues for redress.[69] No further investigation or discussion of how these conclusions were reached or in what circumstances they are correct was made.

The *Cautionary Tale* Report examined liability issues relating to the deliberate and accidental contamination of non-GM crops by GM crops.[70] IP concerns were not within its Terms of Reference. The Committee noted that the Bill did not provide for a statutory right of action or compensation fund for those affected by a breach of the legislation.[71] It also noted that there was no immunity for those who inadvertently use GMOs.[72] The Committee reviewed the submissions made to it on the issue and the range of solutions open to it. The Committee acknowledged the uncertainties of common law.[73] There is no investigation of whether liability would be imposed at common law or under environmental legislation. Nor is there consideration of the Bill's impact on such liability. There is also no consideration of the relevance of socio-economic impacts on liability. No recommendation is made for any change to clarify the liability of commercialisers acting under the Act or to provide for compensation for those affected by GMO releases. The

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[67] See also draft Gene Technology Regulations 2000 and accompanying Explanatory Guide, August 2000; revised draft Gene Technology Regulations January 2001 and Explanatory Guide in relation to the development of the scheme.

[68] Two other associated Cth Acts also came into force on that day which are also considered part of the national scheme: the *Gene Technology (Consequential Amendments) Act 2000* (Cth) and *Gene Technology (Licence Charges) Act 2000* (Cth). No fees or charges are currently imposed for licences and other approvals or actions under the regulatory scheme although this is being reviewed.

[69] Aust, IOGTR and the Cth-State Consultative Group on Gene Technology, Discussion Paper, *Proposed national regulatory system for genetically modified organisms. How should it work?* (Draft for discussion) (October 1999), p 34.

[70] *Cautionary Tale* Report, Terms of Reference (i).

[71] *Cautionary Tale* Report, [6.21].

[72] *Cautionary Tale* Report, [6.21].

[73] See, for eg, *Cautionary Tale* Report, [6.22] and [6.30].

Committee, however, recommended that the Bill be amended to allow the Gene Technology Regulator ('GTR') to consider whether licensees hold suitable insurance.[74] As a result, the GT Bill was amended so applicants can be required to have suitable insurance cover before being granted a licence.[75] The Committee also noted that the regulatory regime should 'ensure that the strictest controls are in place to ensure that organic farms and other non-GM farming systems are not' contaminated by GMOs.[76] It therefore recommended that the Bill be amended to require that the GTR should not issue a licence to release without conditions ensuring as much as possible that GM contamination of non-GM produce or land cannot occur.[77] However, it is not mandatory under the Act that such conditions be imposed.

The one exception to this scant regard to the legal challenges facing commercialisers is the report called *Work in Progress: Proceed with Caution. Primary Producer Access to Gene Technology*.[78] The Report was the outcome of a Parliamentary inquiry into primary producer access to GT.[79] The inquiry took place while the GT Bill was being prepared, the draft Bill being released only shortly before the inquiry ended.[80] The final details of the regulatory scheme were not known to the Committee.[81] The Report considered, amongst other things, two matters said to be the important underpinning elements of the commercialisation process and ongoing use of GMOs. These were: the protection of IP and regulation of their use.[82] The Committee noted the risk that genes may spread from GMOs into organic or non-GM crops growing nearby.[83]

In relation to IP protection for GMOs and their products, the Committee considered only patent and plant breeders' rights in detail.[84] Even then there was no independent

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[74] When prescribing licence conditions. *Cautionary Tale* Report, [6.32].
[75] See section 2.8.6 below.
[76] *Cautionary Tale* Report, [4.119].
[77] *Cautionary Tale* Report, Recommendation at [4.119].
[78] *Work in Progress* Report.
[79] Referred to the Cth House of Representatives Standing Committee on Primary Industries and Regional Services on 30 March 1999 by the Minister for Agriculture, Fisheries and Forestry.
[80] *Work in Progress* Report, [7.2] and [7.8].
[81] *Work in Progress* Report, [7.32].
[82] *Work in Progress* Report, [1.13].
[83] *Work in Progress* Report, [2.48] and [7.58]-[7.68].
[84] The Report notes that other forms of protection existed but does not consider whether they would be available or how useful they would be to commercialisers. *Work in Progress* Report, [6.3] and [6.63]-[6.68]. The other forms of protection expressly noted were trade secrets, private know how agreements and technologies restricting the use of GMOs such as hybridisation and terminator (which produces sterile seeds) and verminator (which ensures growers use particular proprietary chemicals with the crop) technologies.

assessment by the Committee of whether GMOs would be protected. Advice from the relevant government department that they would be protected was simply accepted.[85]

With respect to liability for contamination of another's crop, the Committee said:

> It is ... important for organic farmers that, if their crops are contaminated by GM products, they can seek compensation for the damage done. The reverse situation might also occur in the future, for example, if GM crops are developed for specific nutritional qualities; they might be contaminated by neighbouring organic or non GM crops.[86]

However, after noting that several submissions debated where liability should rest if contamination by GMOs of other crops occurred,[87] that the issue had not been tested in Australian courts and that there was no specific legislation relating to the issue,[88] the Committee concluded that:

> Common law provides a means for redressing problems arising from GMOs. Remedies might also be sought through environmental protection and pollution control legislation, and legislation relating to wild animals and abnormally dangerous activities.[89]

There is no explanation for this conclusion and there is no analysis of law leading to it.[90]

2.5 STUDIES FOLLOWING THE INTRODUCTION OF THE GT REGULATORY SCHEME

Since the introduction of the regulatory scheme, there have been government reports regarding the establishment of areas designated free from GMOs (also known as GM-free areas or zones).[91] However, these give little, if any, real consideration to the issues raised

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[85] *Work in Progress* Report, [6.8].
[86] *Work in Progress* Report, [7.104].
[87] *Work in Progress* Report, [7.105].
[88] *Work in Progress* Report, [7.106].
[89] *Work in Progress* Report, [7.106].
[90] There is a footnote reference to advice and references used by the Committee. See *Work in Progress* Report, [7.106] fn 140.
[91] See, for eg, Vic, Dept of Natural Resources and Environment, *Genetic engineering-free zones* Consultation Paper (March 2001); SA, Dept of Human Services, Environmental Health Branch, Genetically Modified Food Unit, Discussion Paper, *Preserving the Identity of non-GM Crops in South Australia*, (September 2001) (http://ww.health.sa.gov.au/publns/id-non-gm-crops.htm accessed 10/6/03); Vic, Dept of Natural Resources and Environment, *Genetic Engineering-free Zones. Report of the Victorian Government Consultation* (December 2001)('Vic *GE-free Zones Report*'); WA, Dept of Agriculture, *Genetic Modification-Free Zones* Discussion Paper (December 2001) (http://www.agric.wa.gov.au/biotechnology/gmzones/index.htm accessed

here.[92] This is despite the introduction of such areas coming about primarily because of concerns about the impact of GMO releases on non-GM and organic agriculture.[93]

The exception to this is a Tasmanian report on GT prepared by a Tasmanian Parliamentary Joint Select Committee in 2001.[94] The Report described the results of an assessment of issues surrounding the use of GT in Tasmanian primary industries. It considered, amongst other things, the economic costs and benefits for Tasmanian and individual primary industry sectors. This included the legal concerns of producers.[95] The Committee noted that one expert witness had suggested that the main course of action where a party suffered loss or damage from GM contamination would be negligence.[96] There is, however, little discussion by the Committee of how successful such an action would be.[97] The discussion considers only liability with respect to pure economic loss. There is no discussion of whether and why the loss caused by contamination would be property or pure economic loss for the purposes of negligence. Further, other than reference to a recent High Court decision[98] there is no explanation of how the principles of negligence law would apply.

Finally, there has been a recent Commonwealth Department paper on the potential legal risks associated with the commercial release of GM crops in Australia.[99] It superficially discusses the common law causes of action available following contamination, concluding successful actions are possible. It notes that compliance with the *GT Act*, licence conditions and industry standards such as S&IP systems is a method of risk minimisation. It does not consider the effect of regulation on the outcome of common law actions or whether the *GT Act* therefore helps or hinders commercialisation in that regard.

11/3/02); ACT, Legislative Assembly, Standing Committee on Health, *Inquiry into the Gene Technology Bill 2002 Report No 2* (December 2002).

[92] For eg, the Victorian Report notes that the issue of liability of those dealing with GMOs to other agricultural producers was dealt with by the *Cautionary Tale* Report. It summarises the findings of that Report and provides no views of its own. IP protection is not considered at all. Vic *GE-free Zones Report*, p 13.

[93] Designated areas are considered further in Chapter 3.

[94] Tas, Parliamentary Joint Select Committee, *Report on Gene Technology* (2001) ('Tasmanian Gene Technology Report').

[95] Tasmanian Gene Technology Report, pp 105-12.

[96] Tasmanian Gene Technology Report, p 107.

[97] Except for a brief discussion of the difficulties for plaintiffs in proving contamination had actually occurred and the source of contamination. See Tasmanian Gene Technology Report, p 107.

[98] *Perre v Apand Pty Ltd* (1999) 198 CLR 180 at Tasmanian Gene Technology Report, p 108.

[99] Aust, Dept of Agriculture, Fisheries and Forestry - Australia, *Liability Issues Associated with GM Crops in Australia* by Science and Economic Policy Branch, Scoping study (September 2003).

2.6 NATIONAL SCHEME

2.6.1 *Type of Scheme*

A preliminary issue when the GT regulatory scheme was being created was whether to have central Commonwealth control or State based control. It was generally agreed that it was better to have a centrally controlled scheme rather than eight potentially different State based schemes together with a Commonwealth scheme. However, the Commonwealth does not have the constitutional power to regulate all dealings with GT. Therefore for a national system to operate, it was essential that there be complementary Commonwealth and State legislation. This is what has been done.

Implementation of the new system occurred through two parts. The first, a national cooperative scheme of Commonwealth and State legislation, such legislation being essentially the same.[100] The second an inter-governmental agreement called the Gene Technology Agreement ('GT Agreement'), to which the Commonwealth and States are all party. These two parts are described in more detail below.

2.6.2 *Cooperative Legislative Scheme*

Each State must effectively adopt the *GT Act* into its own law for the national scheme to apply. By virtue of the State Acts the national regulator, the GTR, established under the Commonwealth Act is recognised and granted power to act in each State. All jurisdictions except WA[101] and the NT have introduced the necessary complementary legislation.[102] Four States also have accompanying Regulations.[103]

Pursuant to the GT Agreement, the States need not adopt identical legislation and may choose not to adopt particular sections of the Commonwealth Act.[104] For example, the

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[100] See *GT Act* s 5.
[101] A Bill has been introduced to the WA Parliament. Gene Technology Bill 2001 (WA).
[102] *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).
[103] Gene Technology Regulation 2002 (Qld); Gene Technology Regulations 2002 (SA); Gene Technology Regulations 2003 (Tas); Gene Technology Regulations 2001 (Vic). The Gene Technology Regulations 2004 (ACT) became effective on 5 June 2004, after the completion date of this thesis.
[104] Any variation, however, must be consistent with those allowed by the GT Agreement.

NSW legislation[105] prohibits the GTR from licensing actions prohibited by a moratorium order made under other NSW legislation.[106]

2.6.3 *GT Agreement*

The GT Agreement took effect from 11 September 2001.[107] It sets out the understandings between the participating Governments. The Agreement provides for the amendment of the GT legislation. The roles and responsibilities of each of the Governments in the administration and enforcement of the scheme are also described.[108] Further, the Agreement provides for the review of the implementation and effectiveness of the national scheme as soon as possible after four years operation of the *GT Act*. Finally, it establishes the Gene Technology Ministerial Council ('GTMC').[109]

2.7 *GT 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 [GT], and by managing those risks through regulating certain dealings with GMOs'.[110] It does this by prohibiting all 'dealings'[111] with GMOs in Australia unless authorised under the *GT Act*.[112] If the organism concerned is not a GMO or the proposed activity is not a 'dealing' for the purposes of the legislation, the *GT Act* does not apply. The Act focuses on living and viable GMOs rather than the products of such organisms because it was decided that the health and environmental risks associated with most non-living, non-viable GM products were already adequately controlled by other regulators.[113] GM products can nevertheless also be regulated under the new scheme.[114]

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[105] *Gene Technology (New South Wales) Act 2003* (NSW) s 6(1).
[106] That other legislation being the *Gene Technology (GM Crop Moratorium) Act 2003* (NSW). That legislation is discussed in Chapter 3. See also Genetically Modified Organisms Control Bill 2004 (Tas) Sch 1.
[107] Aust, OGTR, *Quarterly Report of the Gene Technology Regulator for the period 1 October to 31 December 2001* (13 May 2002), p 10.
[108] Including arrangements for the reimbursement of costs incurred by jurisdictions for services provided as part of the legislative scheme.
[109] These points are from Aust, OGTR, Handbook on the Regulation of Gene Technology in Australia (2001) ('OGTR Handbook'), pp 22-4. The GTMC is discussed further in Chapter 3.
[110] *GT Act* s 3.
[111] See *GT Act* s 10(1) (definition of 'deal with') and the discussion in section 2.7.1 below.
[112] *GT Act* ss 32(1) and 33(1).
[113] Aust, IOGTR and the Cth-State Consultative Group on Gene Technology, Discussion Paper, *Proposed national regulatory system for genetically modified organisms. How should it work?* (Draft for discussion) (October 1999), p 14.
[114] See section 2.7.2 below.

The discussion below refers to the Commonwealth Act and GT Regulations 2001 (Cth).[115] As discussed above, adopting State legislation should largely mirror the provisions of the Commonwealth legislation and therefore essentially be the same.

The next section discusses the important definitions relevant to the application of the Act. Section 2.7.2 then describes how GM products are affected by the scheme. The final section of this Part, section 2.7.3, briefly describes the administrator of the scheme.

2.7.1 *Definitions*

A GMO [116] is defined as:

> (a) an organism that has been modified by GT; or
>
> (b) an organism that has inherited particular traits from an organism (the **initial organism**), being traits that occurred in the initial organism because of GT; or
>
> (c) anything declared by the regulations to be a GMO, or that belongs to a class of things declared by the regulations to be GMOs;
>
> but does not include:
>
> (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
>
> (e) an organism declared by the regulations not to be a GMO, or that belongs to a class of organisms declared by the regulations not to be GMOs.

'Organism' is defined as:

> any biological entity that is:
>
> (a) viable; or
>
> (b) capable of reproduction; or
>
> (c) capable of transferring genetic material.[117]

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[115] See also Cth, Gene Technology Regulations 2001 Explanatory Statement and attached Regulation Impact Statement for the Gene Technology Regulations 2001 (Cth) with respect to the Regulations generally.
[116] *GT Act* s 10(1) (definitions of 'GMO' and 'genetically modified organism').
[117] *GT Act* s 10(1) (definition of 'organism').

'Gene technology' for the purposes of the legislation means:

> any technique for the modification of genes or other genetic material, but does not include:
>
> (a) sexual reproduction; or
>
> (b) homologous recombination; or
>
> (c) any other technique specified in the regulations for the purposes of this paragraph.[118]

Although the definitions are broad, they were not intended to result in the regulation of every organism that has had its genetic material altered. Many 'altered' organisms are not caught by the definitions. The *GT Act* therefore does not regulate any dealings with such organisms. Organisms not regulated include those described in paragraphs (d) and (e) of the definition of GMO. Paragraph (d) refers to human beings who have undergone some types of gene therapy and is not relevant to this study. Paragraph (e) reflects the capacity for the Regulations to declare that certain organisms or classes of organisms are not GMOs.[119] This allows those organisms not considered to be GMOs prior to the creation of the scheme to continue to be treated as non-GMOs under the new scheme.[120] Such organisms generally are those that can occur in nature and/or commonly used in biological research and/or have a long history of usage in Australia and overseas.[121] For example, plants formed by protoplast fusion,[122] a standard technique used for many years by plant breeders, are not GMOs for the purposes of the Act.[123]

Other organisms not regulated by the legislation are those not produced by GT as defined above. The definition of 'gene technology' provides that techniques may be specified in

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[118] *GT Act* s 10(1) (definition of 'gene technology').
[119] Those organisms declared not to be GMOs are set out in the Gene Technology Regulations 2001 (Cth) Sch 1, Part 1. For egs of such organisms see OGTR Handbook, pp 34-5, Box 1.
[120] Cth, Regulation Impact Statement for the Gene Technology Regulations 2001, Part 4, attachment to Gene Technology Regulations 2001 Explanatory Statement.
[121] Cth, Regulation Impact Statement for the Gene Technology Regulations 2001, Part 4, attachment to Gene Technology Regulations 2001 Explanatory Statement.
[122] Protoplast fusion occurs when the outer cell walls are removed from single cells from two types of plant (the cells having been grown in tissue culture). The resulting 'protoplasts' are then fused and some genetic exchange between the two nuclei may occur. Plants can then be regenerated from the fused cells, which may have newly acquired characteristics.
[123] Gene Technology Regulations 2001 (Cth) Sch 1, Part 1.

the Regulations as not being GT. The Regulations provide that somatic cell transfer[124] is not GT if GM material is not involved. Accordingly many types of cloning are not included.[125] This is because cloning does not require the modification of genes or other genetic material but instead involves the replication or duplication of existing genetic material.[126]

The case studies are GMOs for the purposes of the legislation. The initial or parent organism in each case would be organisms as defined in the Act modified by GT. They therefore fall within paragraph (a) of the definition of GMO. Progeny of the parent organisms can also be GMOs if they fall within paragraph (b) of that definition. As to products derived from the case studies, as discussed in section 2.7.2 below, the GTR has power pursuant to the legislation to regulate 'things (other than a GMO) derived or produced from a GMO'.[127] Such things are referred to as 'GM products' in the legislation.

It is only 'dealings' with GMOs that are regulated. 'Deal with' in relation to GMOs for the purposes of the Act means:

(a) conduct experiments with the GMO;

(b) make, develop, produce or manufacture the GMO;

(c) breed the GMO;

(d) propagate the GMO;

(e) use the GMO in the course of manufacture of a thing that is not the GMO;

(f) grow, raise or culture the GMO;

(g) import the GMO;

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[124] A somatic cell is any cell in a multicellular organism that is not a gamete (that is, not an egg or sperm cell). Somatic cell transfer is the process by which the nucleus from a somatic cell is fused with an egg cell from which the nucleus has been removed. After fusion, the cell can go on to develop, even into an entire organism.
[125] Gene Technology Regulations 2001 (Cth) reg 4. Note though that cloning of human beings is prohibited pursuant to the *Prohibition of Human Cloning Act 2002* (Cth) and complementary State legislation.
[126] OGTR Handbook, p 32.
[127] *GT Act* s 10(1) (definition of 'GM product').

> and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (g).[128]

Most uses of the case studies are dealings with GMOs for the purposes of the legislation. For example, the raising of GM pigs and use of their meat in the manufacture of other products, such as quiche, are dealings for these purposes. Importantly for this study, developing and field trialling the case studies are dealings pursuant to the Act. However, if the user does not know that their organism is, or had been, contaminated by a GMO there is no offence.[129] Further, the GTR's enforcement powers do not apply to such users.[130]

2.7.2 *GM Products*

The GTR has the power to regulate dealings with GM products whether or not such products are already regulated under other schemes. Such regulation could occur in two ways. First, a particular product of a GMO could itself be declared a GMO for the purposes of the legislation.[131] No products have been declared GMOs thus far.

Secondly, the GTR can regulate GM products through the process of licensing dealings with the GMO from which they are derived. An application for a licence for dealings involving an intentional release of a GMO into the environment must provide information about proposed uses of the GMO or of products derived or produced from it.[132] The GTR considers potential risks posed not only by the GMO but also by its products. In light of those risks, limitations on how the products may be used may be imposed as licence conditions if thought necessary.[133] The GTR will usually not consider it necessary to impose a condition if another regulator of the same product has or will impose the same or similar condition.[134]

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[128] *GT Act* s 10(1) (definition of 'deal with').
[129] *GT Act* ss 32(1)(a) and 33(1)(a).
[130] See *GT Act* Part 10. See also section 2.9.4 below.
[131] *GT Act* s 10(1) (definition of 'genetically modified organism' para (c)).
[132] *GT Act* s 43(2) and Gene Technology Regulations 2001 (Cth) reg 7 and Sch 4.
[133] *GT Act* s 62(1).
[134] See, eg, Aust, OGTR, *Commercial release of InVigor canola* (Brassica napus) *for use in the Australian cropping system DIR 021/2002 Bayer CropScience Pty Ltd. Licence conditions and reasons for the conditions* (undated), p 1. In many cases the commercialiser will already have obtained approval from other relevant regulators but this is not a prerequisite for GTR approval and will not always be the case.

2.7.3 *Gene Technology Regulator*

The national scheme is administered by the GTR.[135] The GTR is appointed by the Governor-General with the agreement of the majority of Australian jurisdictions[136] and heads the national Office of the Gene Technology Regulator.[137]

The GTR is an independent statutory office-holder.[138] She[139] is not subject to direction from anyone in the performance or exercise of her functions or powers, subject to the limitations provided for in the Act.[140]

The Act describes the functions and powers of the GTR.[141] The GTR has power to do all that is necessary or convenient to perform her functions.[142] One of the GTR's key functions is to authorise dealings with GMOs.[143]

2.8 APPROVED DEALINGS

Four categories of dealings are exempted from the general prohibition on dealings with GMOs. Such dealings are authorised provided certain conditions and requirements are met. These categories are: Exempt dealings; Notifiable low risk dealings ('NLRDs'); Dealings listed on the GMO Register; and Licensed dealings.

Each category is discussed below. The position of the case studies is described in the conclusion in Part 2.11. Only the last two categories can involve GMO releases into the environment. They are therefore the most relevant to this study. As yet, no GMO has been approved for inclusion on the GMO Register. Therefore the last category, licensed dealings, is the main focus of this study. Section 2.8.5 considers the risk assessment

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[135] See *GT Act* s 10(1) (definition of 'Regulator'). The Cth Senate Committee on Community Affairs had recommended that the GTR be a statutory authority consisting of a Board of three people. See *Cautionary Tale* Report, p xiv. Nevertheless, the GTR is an individual.
[136] *GT Act* s 118.
[137] The Office is a Cth regulatory agency within the Therapeutic Goods Administration of the Aust Dept of Health and Ageing.
[138] *GT Act* s 30.
[139] The present GTR is Dr Sue Meek.
[140] *GT Act* s 30.
[141] See *GT Act* Part 3.
[142] *GT Act* s 28.
[143] The GTR's other functions include: assessing any risks posed by GMOs; informing and advising other regulatory authorities and the public about GMOs and GM products; developing draft policy principles and guidelines requested by the GTMC; developing codes of practice and technical and procedural guidelines; harmonising risk assessments for GMOs and GM products by regulatory authorities; monitoring international practice; and maintaining links with relevant international organisations. *GT Act* s 27.

required before a licence can be granted. The final section of the Part, section 2.8.6, describes the licence form and conditions.

2.8.1 *Exempt Dealings*

A dealing can be specified in the Regulations as an 'exempt dealing'.[144] Exempt dealings are those that have been assessed over time as posing negligible risks. They are undertaken within contained facilities and do not involve commercialisation of the GMO for human or animal use.[145]

If a dealing is an exempt one, no licence or other approval from the GTR is needed provided the required precautionary measures are met.[146] However, if a precautionary measure is not met, the dealing is not an exempt dealing and an offence will in most circumstances be committed if no licence or other approval is obtained from the GTR.[147]

2.8.2 *Notifiable Low Risk Dealings*

NLRDs[148] are, like exempt dealings, dealings which have been demonstrated to pose a minimal risk to the public or environment provided certain risk management conditions set out in the Regulations are met.[149] The Regulations may declare a dealing with a GMO to be a NLRD[150] provided the dealing does not involve the intentional release of a GMO into the environment[151] and the other matters listed in the legislation are satisfied.[152]

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[144] *GT Act* s 32(3) and (4) and Gene Technology Regulations 2001 (Cth) reg 6 and Sch 2 Part 1.
[145] For example, all dealings with gene-knockout mice are exempt dealings pursuant to the Regulations. This is provided that no advantage is conferred by the modification on the adult animal over wild type unmodified mice. Therefore a researcher may transport the mice, store the mice, conduct experiments (not involving GT) with the mice and so on without seeking the GTR's approval. However, the researcher cannot do any other GM on the mice. If that is proposed then a licence must be obtained from the GTR. Example from OGTR Handbook, p 44.
[146] *GT Act* s 32(3). The precautionary measures that must be met, in addition to the dealing being listed in the Regulations, are that the dealing must: not involve GM other than a modification described in the Regulations; be conducted in accordance with Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for physical containment Level 1; and not involve an intentional release of the GMO into the environment. Gene Technology Regulations 2001 (Cth) reg 6(1).
[147] *GT Act* ss 32(1) and 33(1). See also Gene Technology Regulations 2001 (Cth) reg 6(2).
[148] Defined in *GT Act* s 10(1) (definition of 'notifiable low risk dealing') as having the meaning given by s 74.
[149] OGTR Handbook, p 38. See generally *GT Act* Part 6 and Gene Technology Regulations 2001(Cth) regs 12 and 13.
[150] *GT Act* s 74(1).
[151] *GT Act* s 74(2). See also Gene Technology Regulations 2001 (Cth) reg 12(1).
[152] *GT Act* s 74(3). See also Gene Technology Regulations 2001 (Cth) reg 12(1).

As with exempt dealings, risk management conditions described in the Regulations must be met.[153] It is an offence not to meet all of these conditions unless a licence or other approval is obtained from the GTR.[154]

2.8.3 *Dealings Listed on GMO Register*

Dealings are also authorised when included on the GMO Register.[155] The Act provides for matters on which the GTR must be satisfied before including a dealing on the GMO Register and matters the GTR must have regard to in making that decision.[156] Dealings may be entered on the GMO Register once they have been licensed for a certain period of time.[157] The GTR must also be satisfied that they are sufficiently safe that they can be undertaken by anyone (even someone without a licence), and that safety does not depend on oversight by a licence holder.[158]

Alternatively a dealing with a GMO can be included on the GMO Register without having been previously licensed if the GMO is actually a GM product. Such a product must have been declared to be a GMO pursuant to Regulations made under paragraph (c) of the definition of GMO.[159] The GTR must still be satisfied as to the same matters discussed above. Once a dealing (or GM product) has been included on the Register no licence need be held by anyone in order to undertake future dealings.[160] Such use though would be

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[153] The Act provides that the Regulations may prescribe different requirements for different situations and different persons. *GT Act* s 75(2). Pursuant to the Regulations the risk management conditions that must be met by anyone undertaking a NLRD are that the NLRD must: be assessed by an Institutional Biosafety Committee to be a NLRD, the Institutional Biosafety Committee forwarding, if appropriate, the information to the GTR and notifying the project supervisor that the information has been sent; be notified to the GTR; be conducted within a contained facility certified to be at least physical containment Level 2 (or as otherwise specified by the GTR) and of appropriate design; be properly supervised (for eg, undertaken with an Accredited Organisation) with a record of dealing details kept; if GMOs are to be transported they must be transported in accordance with guidelines issued by the GTR; and if the dealing involves organisms that may produce disease in humans, the NLRD must be conducted in accordance with the vaccination requirements set out in Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology). OGTR Handbook, pp 70-1. See Gene Technology Regulations 2001 (Cth) reg 13.

[154] *GT Act* s 32(1). See also Gene Technology Regulations 2001 (Cth) reg 12(2).

[155] *GT Act* s 76(1). The Gene Technology Bill did not provide for a GMO Register.

[156] *GT Act* ss 78-79. The GMO Register is maintained by the GTR (*GT Act* s 76(2)). It may be kept in a computerised form (*GT Act* s 76(3)) and is open to public inspection (*GT Act* s 81).

[157] Inclusion on the Register can be on the GTR's invitation or application of a licence holder. *GT Act* s 78(2).

[158] Aust, OGTR, *Questions and Answers on the Gene Technology Act 2000* Information Sheet (undated), p 5.

[159] *GT Act* s 78(1)(b).

[160] For eg, a GM flower may have been grown in Aust for a long period of time, used by a large number of people and been demonstrated to be safe. It is then arguably unreasonable to expect one company to continue to hold a licence to enable the flowers to be grown, sold and used by millions of people. This would particularly be the case if there were no conditions necessary to manage any risks posed by the flower and so no direct oversight by the licence holder was necessary. In such a case, dealings with the flower could be entered on the GMO Register. Anyone could then use or otherwise deal with the flower without any approval from the GTR. Example taken from OGTR Handbook, p 113.

subject to other legal rights in the organism or product such as plant breeders rights and patent rights.

2.8.4 *Licensed Dealings*

The GTR can licence dealings under the *GT Act*. When the GTR receives a licence application, an initial screening of the application for completeness is carried out. This includes checking that all required information is included[161] and that the application is not inconsistent with any policy principles issued by the GTMC.[162]

If the application is satisfactory, the GTR must then assess the application. The GTR can, at any time, request further information from licence applicants to assist in decision making and can refuse to consider an application if this is not complied with.[163]

There are two types of licences – those *not* involving intentional release of a GMO into the environment ('DNIR licences') and those that *do* involve such release ('DIR licences'). An 'intentional release of a GMO into the environment' is defined in the 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.[164]

Licence applications must specify whether any of the proposed dealings involve the intentional release of a GMO into the environment.[165] This determines the next steps taken by the GTR. There are separate assessment processes for each of the two types of licence application.[166] A more rigorous process is required for DIR licence applications. No distinction is made in the legislation on the basis of why the release is being made.[167] For example, whether the release is to be made as part of a field trial or for general commercial release purposes.

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[161] *GT Act* s 43(2). See Gene Technology Regulations 2001 (Cth) reg 7. Schedule 4 of the Regulations sets out the prescribed information required in licence applications.
[162] *GT Act* s 43(2)(e). See also s 57(1). See further Chapter 3.
[163] *GT Act* ss 42 and 43(2)(d).
[164] *GT Act* s 11.
[165] *GT Act* s 40(3).
[166] *GT Act* Part 5.
[167] However, the actual assessment processes and licence conditions finally imposed will differ in those cases. For eg, for a licence relating to the commercial release of a GMO, the GTR will most likely require to be satisfied that the GMO's safety has already been tested *in Australia* through licensed field trials. OGTR Handbook, pp 91-2. This will not be necessary for applications in respect of limited release for field trial purposes.

(a) DNIR licence

The process followed by the GTR in assessing DNIR licence applications is simpler than that required for DIR licence applications. Public consultation by the GTR is not mandatory. Nor is consultation with any other entity required although in both cases, such consultation is discretionary.[168] Information regarding the intended commercialisation of the organism's products must be given to the GTR regardless of the type of licence sought.[169] This may result in the same licence conditions being imposed on the commercialisation of these products as would have been the case if the second process had been followed.

The GTR prepares a risk assessment and a risk management plan ('RA&RMP')[170] taking into account the risks posed by the proposed dealings, in particular risks to the health and safety of people or to the environment.[171] 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'.[172] The risk management plan details how any risks posed by the GMO may be 'managed to ensure that unacceptable risks are not realised'[173] and describes any proposed licence conditions.

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[168] The GTR has discretion to consult the States, as well as the Gene Technology Technical Advisory Committee and other relevant Cth authorities, and appropriate local councils and persons in relation to the application. *GT Act* s 47(4).

[169] See, for eg, Gene Technology Regulations 2001 (Cth) reg 7 and Sch 4 Part 1 item 1.1.1(f). Cf Part 2 item 2.1.4(k) which specifically requires details of proposed uses of, amongst other things, things derived or produced from the GMO or GMOs following release into the environment.

[170] *GT Act* s 47(1).

[171] *GT Act* s 47(2) and (3). For a critique of risk assessment under the *GT Act* see C 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.

[172] OGTR Handbook, p 79. See also Aust, OGTR, *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator* (January 2002) ('OGTR *Risk Analysis Framework*') which provides general guidance to applicants, evaluators and other stakeholders when identifying and assessing the risks posed by dealings with GMOs and to assist in determining the measures necessary to manage any such risks.

[173] OGTR Handbook, p 79.

(b) DIR licence

Where a DIR licence is being sought the process to be followed by the GTR is as follows.

1. Where the GTR considers that one or more of the proposed dealings the subject of the application may pose significant risks to the environment or the health and safety of people,[174] public submissions on the application must be called for.[175]

2. The GTR prepares the RA&RMP.[176]

3. The GTR *must consult* (rather than it being discretionary as it is for DNIR applications) with the States, the Gene Technology Technical Advisory Committee ('GTTAC'),[177] all Commonwealth authorities listed by the Regulations,[178] the Commonwealth Environment Minister and any local council the GTR considers appropriate[179] in preparing the RA&RMP. That advice must be taken into account when preparing the documents.[180] The GTR must also take into account those matters prescribed by the Regulations.[181]

4. A copy of the application (excluding certain confidential information discussed in section 2.9.2) must be given by the GTR to anyone requesting a copy.[182] This must be done whether the application was advertised or not.

5. When the RA&RMP have been prepared, the GTR is required to advertise this fact. Public comment is sought and must be considered.[183] The GTR must seek such public comment whether or not she has already sought public comment on the application itself.[184]

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[174] As to determining whether a significant risk is posed, see *GT Act* s 49(2). For a discussion of the factors which influence the GTR in making particular decisions, see, for eg, Aust, OGTR, *Quarterly Report of the Gene Technology Regulator for the period 1 October to 31 December 2001* (13 May 2002), p 16.
[175] *GT Act* s 49. See also OGTR Handbook, p 101. This is done by advertisement in newspapers (*The Australian* and certain regional press), *The Commonwealth Government Notices Gazette* and through notices on its website.
[176] *GT Act* s 50(1). See also s 51.
[177] One of three advisory committees established by the Act, it provides expert scientific and technical advice to the GTR and GTMC at their request (*GT Act* s 101). See also *GT Act* s 100 and Gene Technology Regulations 2001 (Cth) Part 4 with respect to this Committee.
[178] Gene Technology Regulations 2001 (Cth) reg 9.
[179] *GT Act* s 50(3).
[180] *GT Act* s 51.
[181] *GT Act* ss 51(1)(g) and 51(2)(g). See also Gene Technology Regulations 2001 (Cth) reg 10.
[182] *GT Act* s 54.
[183] *GT Act* s 56(2)(c).
[184] *GT Act* s 52.

6. The GTR must seek input on the RA&RMP from the same bodies as described in step 3.[185]

7. The GTR may take any other action she considers necessary for the purposes of deciding the application.[186]

Relevantly here, the 'precautionary principle', a well established principle of environmental law,[187] is included in the *GT Act* as one method by which the Act's object is to be achieved.[188] The principle 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.[189]

There is uncertainty as to the meaning of many of the terms used in this section.[190] Of particular relevance here, 'the government did not articulate the meaning or intention of "cost effectiveness"' in this scheme.[191]

2.8.5 *Risk Assessment and Licence Approvals*

The following subsections describe the GTR's approach to licensing decisions and assess the implications of that approach for commercialisers. The scientific assessment undertaken by the GTR is not considered. Rather, the general character of the issues considered relevant by the GTR are the focus of the section. An important issue for commercialisers is the risks considered by the GTR. In particular, is the risk of GM contamination of non-GMOs and the socio-economic consequences of such contamination relevant?

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[185] *GT Act* s 52(3).
[186] *GT Act* s 53.
[187] 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 ATS 1993 No 32 Preamble; Cartagena Protocol on Biosafety to the Convention on Biological Diversity Article 11.8.
[188] *GT Act* s 4(aa). The inclusion of this principle was recommended in the *Cautionary Tale* Report, p xiv.
[189] *GT Act* s 4(aa).
[190] C 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.
[191] C 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.

(a) GTR's approach

The GTR must decide, after following the above procedures, whether to grant the licence and, if so, on what conditions.[192] Licences cannot be granted to an applicant who is not a 'suitable person'.[193] Suitability depends, in part, on whether they have any 'relevant convictions'.[194] 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 $5000 or more or imprisonment of one year or more.[195]

The GTR may consult with the Gene Technology Ethics Committee on ethical issues and/or the Gene Technology Community Consultative Committee on matters of general concern.[196] Whilst the licensing decisions of the GTR could be restricted on the basis of the socio-economic impacts of GMOs' release, the steps necessary for this to occur have not been taken.[197] Accordingly, socio-economic objections to GMO releases seem to be considered only in so far as they are relevant to the scientific assessment of the human health and safety or environmental hazards referred to below.

The GTR is prohibited from issuing a licence unless satisfied that risks posed by the proposed dealings can be managed in a way that protects public health and safety and the environment.[198] The regulatory regime created by the *GT Act* therefore accepts that there are risks in allowing GMO releases. If those risks can be *managed* the release may occur subject to conditions thought necessary to address them. Where the GTR considers that there is an unacceptable risk in a GMO release, approval to release may be refused or licence conditions may be imposed to limit such risk to an acceptable level. The imposition of such conditions does not, though, eliminate the risks.

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[192] *GT Act* s 55. Even if the necessary conditions are met, the legislation does not require the GTR to issue the licence although a review of a decision to refuse a licence or impose particular conditions on a licence can be sought by an applicant. *GT Act* Part 12 Div 2. This is discussed in section 2.9.6 below.
[193] *GT Act* s 57(2) and see also s 58.
[194] *GT Act* s 58. Other matters include the applicant's 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 and the applicant's capacity to meet the conditions of the licence. This presumably includes matters such as the applicant's financial capacity.
[195] *GT Act* s 58(3).
[196] Two of the three statutory advisory committees established under the *GT Act*. See *GT Act* Part 8, Divs 4 and 3 respectively.
[197] This would require the making of a policy principle (or mandatory guideline) by the GTMC. This has not been done. Policy principles are discussed further in section 3.2 below.
[198] *GT Act* s 56.

Because of the definition of environment and the object of the legislation,[199] the GTR considers that she is limited in the risks, or consequences, that she can consider and attempt to control.[200] The risks addressed by the GTR are only those that adversely affect the health and safety of people or the environment.[201] 'Environment' is defined in the Act as including 'the qualities and characteristics of locations, places and areas'.[202] A narrow approach is taken by the GTR with respect to the meaning of environmental risks. Environmental risks assessed by the GTR with respect to agricultural GM crops include hazards to the flora and fauna, habitat and biodiversity of the receiving environment posed because of contamination by, or gene transfer from, the GMO to other organisms.[203] Accordingly GM contamination causing death or illness to other organisms would be an environmental risk. Trade and marketing ramifications of GMO releases though, such as impacts on domestic and export markets and impacts on organic status, are not evaluated or addressed.[204] Nor does the GTR consider the possible costs of GMOs to the agricultural industry an environmental risk.[205] For example, when releasing the draft RA&RMP for the commercial release of GM canola, the GTR made the following comments.[206]

> There has been considerable media and written communications about the possible impact of the uptake of GM canola on non-GM crops and markets. Evaluation of trade, marketing and cost-benefit issues has been intentionally excluded from the *Gene Technology Act 2000* assessment process. ... Therefore, this RARMP focuses on the protection of human health and safety and the environment, and does not draw

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[199] The consultation draft of the Gene Technology Bill circulated in 1999 referred to the regulation of dealings with GMOs in a way consistent with Australia's national interests as a secondary object of the legislation. This does not appear in the Act.

[200] There is some support for the GTR's view that she cannot consider the economic ramifications of the commercial production of GM crops on neighbouring farmers. See N 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 M 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; C McGrath, 'A system under strain: The Regulation of Gene Technology' (2003) 2 *National Environmental Law Review* 32, 35.

[201] Aust, OGTR, *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'.

[202] *GT Act* s 10(1).

[203] OGTR *Risk Analysis Framework*, p 20.

[204] Aust, OGTR, *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 10 [702] and [704].

[205] Aust, OGTR, *Risk Assessment and Risk Management Plan for Commercial Release of Bayer GM Canola into the Environment: Application No DIR 021/2002* (1 April 2003).

[206] Aust, OGTR, *Risk Assessment and Risk Management Plan for Commercial Release of Bayer GM Canola into the Environment: Application No DIR 021/2002* (1 April 2003). The GTR also noted that she had consulted with the authorities prescribed in the Act. Aust, OGTR, *Invitation to Comment on the Risk Assessment & Risk Management Plan for Commercial Release of Bayer Genetically Modified Canola* (1 April 2003).

any conclusions about the possible costs or benefits of GM canola to farmers or the agricultural industry.

During risk assessment, risks posed by GMOs are considered 'in the context of the risks posed by the non-modified parental organisms in the receiving environment'.[207] For example, in the case of canola, risk was judged by considering the adverse effects that may arise from the new characteristics of the GM canola caused by the GM which are different to those effects threatened by non-GM canola.[208] The potential hazards to the environment which were considered as part of the assessment of GM canola included whether the new genes in the GM canola might transfer to non-GM canola crops or other organisms with any adverse consequences for the environment.[209] The GTR concluded that there would be some contamination of non-GM canola.[210] Nevertheless she decided that the 'risks' posed by the proposed commercial release of the GM canola were no greater than those posed by conventional (non-GM) canola because conventional canola also contaminates other crops.[211]

(b) Analysis of approach

How the GTR reaches decisions under the *GT Act* is uncertain as is the nature of the risks that justify refusal of a licence. Uncertainty with respect to how the GTR reaches her decisions arises first because, as Lawson has pointed out, the GTR does not acknowledge inherent value judgments in making decisions.[212] The GTR claims there is no balancing of risk and benefit by her.[213] Yet the terminology used by the GTR often refers to whether the level of risk is 'acceptable' but does not clarify how acceptability is to be judged.[214]

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[207] OGTR *Risk Analysis Framework*, p 16.
[208] Aust, OGTR, *Full Risk Assessment and Risk Management Plan Application for licence for dealings involving an intentional release into the environment DIR 021/2002 Commercial release of genetically modified (InVigor hybrid) canola* (25 July 2003), pp 9-10.
[209] Aust, OGTR, *Risk Assessment and Risk Management Plan for Commercial Release of Bayer GM Canola into the Environment: Application No DIR 021/2002* (1 April 2003).
[210] Aust, OGTR, *Full Risk Assessment and Risk Management Plan Application for licence for dealings involving an intentional release into the environment DIR 021/2002 Commercial release of genetically modified (InVigor hybrid) canola* (25 July 2003), p 11.
[211] Aust, OGTR, *Risk Assessment and Risk Management Plan for Commercial Release of Bayer GM Canola into the Environment: Application No DIR 021/2002* (1 April 2003).
[212] C 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, 202 and 211. See also N 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, 9.
[213] OGTR *Risk Analysis Framework*, p 15.
[214] For eg, OGTR *Risk Analysis Framework*, p 14.

There is no explanation, as Lawson says, of 'why a particular risk is worth taking'.[215] Secondly, the width of the basis for licence refusal is unclear. The Act does not provide that a licence can be refused *only* if the health and safety of people or the environment cannot be protected.[216] It provides that where risks to those two things cannot be satisfactorily managed a licence *must* be refused. Arguably a licence could be refused on other grounds. However, it is unlikely that a court would agree with such an argument in light of the object of the Act.

With respect to the uncertainty regarding the nature of risks justifying refusal of licence, it is submitted that the GTR's narrow approach to risk assessment described in subsection (a) above is wrong. Some social or economic consequences of GMO releases may justify refusal of a licence under the current legislation. This submission is made on two grounds.

First, the Act requires that RA&RMPs be considered by the GTR when DIR licensing decisions are made.[217] It is submitted that any risk, including risk to other forms of agriculture and trade in and marketing of their products, can and should be considered by the GTR when preparing RA&RMPs. The Act provides that the risks posed by proposed dealings '*including* any risks to the health and safety of people or risks to the environment' must be taken into account in preparing a risk assessment.[218] The inclusive phrasing of this section indicates that risks other than those to people or the environment are relevant. This is supported by the wording of the section concerning when a licence must be refused. It says that if the health and safety of people and the environment cannot be protected by the management of '*any* risk posed by the dealings proposed to be authorised' then the licence must be refused.[219]

No further guidance on what risks are to be considered is given in the Act or the Regulations. For example, there is no explanation as to whether the GTR must take into account the effect of a release on neighbouring non-GM crops. Due to the lack of

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[215] C 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, 202. See also M Tranter, 'A question of confidence: an appraisal of the operation of the Gene Technology Act 2000' (2003) 20 *Environmental and Planning Law Journal* 245, 253-4.

[216] See also *GT Act* s 57 which requires a licence to be refused if it would be contrary to a policy principle or the applicant is not a suitable person.

[217] *GT Act* s 56(2)(a) and (b). Cf DNIR applications where although RA&RMPs must be prepared (s 47) they are not required to be considered in approval decisions (s 56). This does not mean the GTR cannot take DNIR RA&RMPs into account. As observed by Tranter, this appears to be an omission. M Tranter, 'A question of confidence: an appraisal of the operation of the Gene Technology Act 2000' (2003) 20 *Environmental and Planning Law Journal* 245, 249.

[218] Emphasis added. *GT Act* s 47(2) (re DNIR applications) and s 51(1)(a) (re DIR applications).

[219] Emphasis added. *GT Act* s 56(1).

guidance in the statute, the GTR released the *Risk Analysis Framework for Licence Applications*.[220] Importantly, it defines 'risk management' as incorporating 'scientific, technological, social and economic information and community values'.[221] 'Risk' is also defined broadly as '[t]he probability that, in a certain time frame, an adverse outcome will occur in a person, group of people, plants, animals and/or the ecology of a specified area that is exposed to a GMO'.[222] The Framework also refers to the GTR addressing 'the impact of GMOs on agroecosystems and the measures necessary to manage the risks'.[223] However, the Framework is a guide only and is not mandatory or enforceable.[224]

The Explanatory Memorandum accompanying the *GT Act* identified the risk to Australia's capacity to maintain diverse farming practices because of the impact of contamination on traditional or organic crops as one that caused concern to the community.[225] However, that risk is not explicitly referred to in the Act, Regulations or Framework.[226] Nor does the Framework expressly refer to possible effects on neighbouring non-GM farmers.[227] The Framework does note, though, that it is not a comprehensive list of every possible risk that could be considered by the GTR.[228]

The second reason why the GTR's narrow approach to risk assessment is wrong is because of the *GT Act's* definition of environment. It is submitted that that definition means the effect and implications of GM crops on non-GM crops are part of the relevant environmental risks.[229] This means that such effects and implications should be assessed by the GTR and included as factors in her decision-making. 'Environment' as noted above is defined as including 'the qualities and characteristics of locations, places and areas'.[230] It is submitted that, as McGrath asserts, 'environment' for the purposes of the *GT Act*

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[220] OGTR *Risk Analysis Framework*.
[221] OGTR *Risk Analysis Framework*, Appendix 1 p 70.
[222] OGTR *Risk Analysis Framework*, Appendix 1 p 70. See also definition of 'hazard'.
[223] OGTR *Risk Analysis Framework*, p 13.
[224] For an evaluation of some of the concerns expressed with respect to the *GT Act* generally, see M Hain et al, 'Regulating Biosciences: the Gene Technology Act 2000' (2002) 19 *Environmental and Planning Law Journal* 163.
[225] Explanatory Memorandum accompanying the *Gene Technology Bill 2000*, p 6 n 4. *Work in Progress* Report, p 150 [7.77] notes that the interim arrangements immediately before the GTR was established required GMAC to examine the risks posed by each application to public health, the environment or *the sustainability of agricultural systems* (emphasis added).
[226] Explanatory Memorandum accompanying the *Gene Technology Bill 2000*, p 6.
[227] Although information which could be used to assess risks in that regard is required from the applicant. For eg, information on where the GMO is to be released, cross-pollination between the parent plant and the GMO and 'other possible adverse consequences' is required. OGTR *Risk Analysis Framework*, pp 43, 47-8.
[228] OGTR *Risk Analysis Framework*, p 28.
[229] See M 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.
[230] *GT Act* s 10.

arguably includes non-GM crops in the area of release. Further, as McGrath has concluded, by failing to 'view the issue of non-GM crops and areas where they are grown as *part of the environment and take those into account*' there has been a failure to carry out the object of the Act.[231] These submissions are made on the following three grounds.

First, amongst the matters the GTR must consider when preparing the risk assessment for DIR applications are the matters listed in paragraphs 49(2)(a) to (f).[232] Two of these are 'provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment'[233] and 'the potential for spread or persistence of the GMO or its genetic material in the environment'.[234] Matters prescribed by the Regulations must also be taken into account.[235] Regulation 10 provides that, inter alia, the potential of the relevant GMO to be harmful to other organisms, adversely affect any ecosystems, transfer genetic material to another organism or spread or persist in the environment must all be taken into account.[236] Arguably all of these matters are particularly relevant if environment is given the broad interpretation suggested and may support a wide interpretation. However, they are also relevant even if the GTR's narrow understanding of environment as not including such matters is used. Therefore their inclusion is not particularly helpful.

Secondly, during the Bill's passage through the Senate, attempts to include measures dealing with ecologically sustainable development in addition to the precautionary principle were rejected.[237] The reason given was that the Senate did 'not consider a separate definition [of ecological sustainability] is required, because ecological sustainability is not separate and distinct from the environment'.[238] The Senate therefore considered environment to include ecological sustainability considerations. Non-GM

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[231] C McGrath, 'A system under strain: The Regulation of Gene Technology' (2003) 2 *National Environmental Law Review* 32, 35.
[232] *GT Act* s 51(1)(a).
[233] *GT Act* s 49(2)(c).
[234] *GT Act* s 49(2)(d).
[235] *GT Act* s 51(1)(g).
[236] Gene Technology Regulations 2001 (Cth) reg 10(1)(b)(i)-(iv).
[237] Cth, *Parliamentary Debates*, Senate, 7 December 2000, Amendment 'to promote ecological sustainability', Amendment 1, Sheet 2049, 21181-2 and 21203-7 (Stott Despoja, SA – Deputy Leader of the Australian Democrats).
[238] Cth, *Parliamentary Debates*, Senate, 7 December 2000, 21204 (Tambling, NT – Parliamentary Secretary to the Minister for Health and Aged Care). See C 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, 209-10.

crops, as part of the ecosystem, should therefore be protected.[239]

Finally the conditions that are or can be imposed on licences include conditions that, whilst minimising risks to the environment in a narrow sense, also minimise risk to other farmers and forms of agriculture. For example, buffer zones can be required around GM crops. The PIRS Committee in its report concerning, in part, GM contamination described the steps government could take or was taking to limit contamination of non-GM crops. It listed the GTR setting conditions to prevent contamination and policing compliance as one measure that could be taken.[240] The Committee therefore arguably interpreted the then to be enacted legislation as capable of reacting to such risks.

2.8.6 *Licence Form and Conditions*

The licence period may be definite or indefinite.[241] The licence form (or extent) depends upon the scope of the application. That scope includes the dealings authorised and the people who may undertake such dealings. Applications should deal with both aspects. For example, in relation to the dealings authorised, the application may seek authorisation for all dealings with one particular GMO or with GMOs in a specific class. Alternatively it may relate to one specified dealing, or specified class of dealings, with a GMO or specified class of GMOs.[242]

In regard to the people licensed to undertake dealings, authorisation can be sought for a specified person or class of person or for all persons.[243] For example, the licence for the commercial release of the GM carnation covers the licence holder (the commercialiser, Florigene Ltd) and the project supervisor and all persons who have authorisation from the project supervisor or Florigene Ltd.[244] It authorises all such people to deal with the carnations in any way covered by the legislation.[245] Therefore, florists who sell the flowers

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[239] C McGrath, 'A system under strain: The Regulation of Gene Technology' (2003) 2 *National Environmental Law Review* 32, 35.
[240] *Work in Progress* Report, [7.66].
[241] *GT Act* s 60. Licences can also be suspended, cancelled or varied in certain circumstances. *GT Act* Part 5 Div 7.
[242] *GT Act* s 40(4).
[243] *GT Act* s 40(5).
[244] Aust, OGTR, *Conditions of the Advice to Proceed (Deemed Licence) – GR2 (Florigene – Carnations)* (undated). This would seem to be the case also with the replacement licence DIR 030/2002 although it is not entirely clear. See Aust, OGTR, *Conditions of licence – DIR 030/2002 Florigene Ltd – Colour modified carnation* (undated, circa June 2003) (http://www.ogtr.gov.au/ir/dir030.htm) (copy on file with author), cl 2, Part 1.
[245] Subject only to the licence conditions. Aust, OGTR, *Conditions of licence – DIR 030/2002 Florigene Ltd – Colour modified carnation* (undated, circa June 2003) (http://www.ogtr.gov.au/ir/dir030.htm) (copy on file with author), cl 3.

and propagators who grow them are all authorised to deal with the carnation through the same licence. They are referred to as persons 'covered by the licence'. Florigene Ltd, as licence holder, is responsible for making the application and providing all necessary information to the GTR.

All licences are subject to conditions, some of which are specified in the legislation.[246] For example, the Act requires that the licence holder inform the GTR of any additional information that becomes available regarding risks to public health or the environment, any contraventions of the licence or any unintended effects of the dealings.[247]

Additional conditions can also be imposed pursuant to the Regulations or as the GTR decides either when issuing the licence or after it has been issued.[248] For example, the GTR may limit where the organism is to be used. Conditions requiring the licence holder to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment by the licensed dealings can also be imposed.[249] The GTR has said that as a matter of policy the following additional conditions will usually be imposed on DIR licences:[250]

- the licence holder must be an Accredited Organisation;[251]
- conditions relating to the transport of the GMO will be imposed if transport is relevant;
- the licence holder must provide the GTR with an annual report about the licensed dealings.

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[246] *GT Act* s 61. See also ss 63, 64 and 65.
[247] *GT Act* s 65(1). Other persons covered by the licence 'may' do so. *GT Act* s 66. Note also s 67 which provides that if such person gives information to the GTR, they do not incur any civil liability in respect of loss, damage or injury of any kind suffered by another person because that information was given.
[248] *GT Act* ss 61(b), (c) and (d), 62 and 71. At this time, no conditions are prescribed by the Regulations. See Gene Technology Regulations 2001 (Cth) reg 11.
[249] *GT Act* s 62(3).
[250] OGTR Handbook, pp 105-6. See also s 62.
[251] See *GT Act* s 10(1) (definition of 'accredited organisation'). The application form for a licence for dealings with a GMO, whether release is intended or not, requires an accreditation number. In summary, accreditation is the method used to ensure that organisations undertaking gene technology have basic quality assurance systems in place. To be accredited the organisation must have, amongst other things, its own or access to an Institutional Biosafety Committee and comply with the requirements of the GTR's guidelines for accreditation. For more information on accreditation see *GT Act* Part 7 Div 3. As to the technical and procedural processes for accreditation, see Cth, OGTR, *Guidelines for Accreditation of Organisations* (June 2001).

An additional condition will be imposed where the release is for a field trial. The licence holder will be required to notify all neighbouring property owners that a field trial of GMOs is to be conducted on neighbouring land.

It should be noted that if the GTR's narrow understanding of environment is correct, the Act could not require insurance in respect of liability for harm only to the economic interests of others. Uncertainty as to the breadth of 'environment', discussed in subsection 2.8.5(b), therefore results in uncertainty as to what can be imposed as licence conditions on commercialisers.

2.9 OTHER MATTERS DEALT WITH IN THE *GT ACT*

After a brief summary of the other matters dealt with by the Act, the protection of information given to the GTR is examined in section 2.9.2. Offences, penalties, monitoring and enforcement under the legislation are then described in sections 2.9.3 and 2.9.4. Finally, in section 2.9.5 commercialisers' rights of review with respect to actions by the GTR and GTMC and the actions that may be taken by members of the public who may be opposed to a commercialiser's intended actions are outlined.

2.9.1 *Summary*

In addition to regulating dealings with GMOs, the *GT Act* also:

- regulates the accreditation of organisations and certification of facilities for particular types of work for the purposes of GT;[252]
- provides for reporting requirements for accredited organisations[253] and licence holders[254] as well as by the GTR;[255]
- provides that an independent review of the Act's operation is to be undertaken as soon as possible after four years of operation;[256]

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[252] *GT Act* Part 7. The purpose of certification is to satisfy the GTR that the facility, used to contain the GMO, meets the GTR's requirements for physical containment as described in the GTR's certification guidelines. See Aust, OGTR, *Guidelines for the Certification of Facilities/Physical Containment Requirements* (August 2003), Appendix 3 to OGTR Handbook.
[253] Reporting requirements may be imposed as a condition of accreditation. *GT Act* s 94.
[254] Reporting requirements may be imposed as a licence condition. *GT Act* s 62.
[255] *GT Act* Part 9 Div 5.
[256] *GT Act* s 194.

- describes transitional provisions to assist in the transition of the previous voluntary arrangements overseen by GMAC to the new system;[257]
- creates a centralised, publicly available database[258] of all GMOs and GM products approved in Australia called the Record of GMOs and GM Product Dealings;[259]
- provides for limited methods to protect confidential commercial information ('CCI') provided to the GTR for the purposes of the Act;[260]
- provides for offences, enforcement and penalties for the purposes of the legislation; and
- provides for rights of review by users of the scheme.[261]

The final three matters above are particularly relevant to the commercialisation of GMOs and their products. They are discussed below.

2.9.2 *Confidential Commercial Information*

As discussed in subsection 2.8.4(b) above, members of the public must be given upon request a copy of any DIR licence application and RA&RMP.[262] Licence applications will include, inter alia, comprehensive information regarding the GMO and how it was created.[263] That information may be confidential. As discussed in Chapter 4, commercialisers may rely on confidential information as a method of IP protection for their GMOs or products. Additionally, information may need to be kept secret until patent protection has been secured. Disclosure to the public will destroy confidentiality and novelty for the purposes of confidential information and patent protection respectively.

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[257] *GT Act* Part 12 Div 5.
[258] The Record can be inspected by any person (*GT Act* s 139) and is accessible through the GTR's website.
[259] It records all approved dealings in Australia involving GMOs and GM products. It includes dealings authorised by the GTR and GM products approved by regulatory agencies other than the GTR where those products are mentioned in designated notifications given to the GTR under the Acts listed in s 138(5). *GT Act* s 138(5). See also s 138(9).
[260] *GT Act* Part 12 Div 3.
[261] The Act used to regulate the cloning of human beings and associated techniques in ss 192B, 192C and 192D. Those sections have now been repealed following the enactment of the *Prohibition of Human Cloning Act 2002* (Cth) and complementary State legislation.
[262] *GT Act* s 54(2).
[263] *GT Act* s 40(2). See also Gene Technology Regulations 2001(Cth) reg 7 and Sch 4, Part 2. It is a criminal offence to give false or misleading information or documents when making an application to the GTR or otherwise complying with the Act. *GT Act* s 192.

If the commercialiser can satisfy the GTR that information is a trade secret or commercial or valuable information that would be destroyed or diminished if the information was disclosed, the GTR must declare the information CCI.[264] It is then not to be made available to the public,[265] disclosed during public consultations[266] or recorded on the Record discussed above.[267] It is also not to be used by the GTR when considering licence applications by anyone other than the person who supplied the CCI.[268] The unauthorised disclosure of CCI by anyone who has CCI because of their duties or functions under the scheme and who knows the information is CCI is an offence.[269]

'Trade secrets' is not defined in the legislation. However, given the potential value of the information commercialisers should be able to establish in some cases that disclosure of certain information in such circumstances would destroy or diminish the information and that that information should be declared CCI.[270] Use only by the OGTR of the CCI, not being public use, would not destroy novelty under patent law[271] and should not destroy confidentiality for the purposes of confidential information protection.

However, the GTR can refuse to declare information CCI where the public interest in disclosure outweighs the prejudice that disclosure would cause.[272] No guidance is given on what 'public interest' means in this context or the matters relevant to such decisions.[273] Kelly has submitted that public interest is in favour of 'non-disclosure of confidential information ... as an essential part of the technology commercialisation process which, if successful, leads to the development of beneficial new products and growth of the Australian economy'.[274] The GTR, though, considers that 'the GT Act is premised on the

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[264] *GT Act* s 185(1). Declarations may be revoked. *GT Act* s 186. Information concerning the lawful commercial or financial affairs of a person, organisation or undertaking where its disclosure would unreasonably affect that entity can also be protected in this way. See also Aust, OGTR, *Application for declaration that specified information is confidential commercial information* (undated).
[265] *GT Act* 54(2)(a).
[266] *GT Act* s 53(2). See also s 54(2).
[267] *GT Act* s 138.
[268] *GT Act* s 45. Subject to written consent by owner.
[269] *GT Act* s 187. Some disclosure is still permitted under the Act even if information is declared CCI. See *GT Act* s 187.
[270] N Atkinson and B Sherman, 'Intellectual Property and Environmental Protection' [1991] *European Intellectual Property Review* 165, 166 make this point with respect to UK legislation.
[271] *Patents Act 1990* (Cth) ss 9(a)–(d) and 24(2)(a). See also *Azuko Pty Ltd v Old Digger Pty Ltd* (2001) 52 IPR 75.
[272] *GT Act* s 185(2).
[273] Although the OGTR website referred (as at 16 February 2004) to a Confidential Commercial Information guide, no such guide exists (personal communication, OGTR, 23/2/04). The OGTR Handbook does not clarify the meaning of this term.
[274] D Kelly, 'Gene Technology Act 2000' (2001) 1 *Biotechnology Law and Policy Reporter* 1, 6.

RELEASE of as much information about dealings with GMOs as possible'.[275] Nevertheless, some information has been declared CCI. For example, the commercialiser of the GM canola has had detailed technical information on the precise gene constructs and molecular characteristics data of its organism declared CCI.[276]

Information about field trials locations, which also must be included in licence applications, is dealt with differently to other CCI. Commercialisers are concerned that the public disclosure requirements of the Act may jeopardise research and endanger the properties of farmers who have agreed to conduct trials.[277] Some industry participants have sought to avoid disclosure of the location of GM crop trials by having them classified as CCI.[278] Such applications have been unsuccessful. To declare information relating to field trial locations CCI, in addition to being the type of information described above with respect to CCI generally, the GTR must be satisfied that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed.[279] There is no explanation of what significant damage or property is for these purposes.[280]

2.9.3 *Offences and Penalties*

It is a criminal offence to deal with GMOs otherwise than as authorised in the legislation.[281] It is also an offence for either or both the licence holder and a person covered by a licence to breach a licence condition.[282] In all cases the offender must know that the organism is a GMO. Accordingly, people inadvertently dealing with GMOs, without knowing that it is a GMO, would not commit an offence.

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[275] Aust, OGTR, *GMO Record* (http://www.ogtr.gov.au/gmorec/recordinfo.htm accessed 16/2/04).
[276] Aust, OGTR, *Risk Assessment and Risk Management Plan for Commercial Release of Bayer GM Canola into the Environment: Application No DIR 021/2002* (1 April 2003), p 3.
[277] J Lee, 'Developments in Biotechnology Law – Gene Technology Act 2000' (Dec 2001/Jan 2002) 11 *Australasian Biotechnology* 27, 27.
[278] J Lee, 'Developments in Biotechnology Law – Gene Technology Act 2000' (Dec 2001/Jan 2002) 11 *Australasian Biotechnology* 27, 27.
[279] *GT Act* s 185(2A).
[280] To provide some protection from those groups opposing GT, it is a criminal offence to interfere with premises or things with intention to prevent or hinder authorised GMO dealings. *GT Act* s 192A.
[281] *GT Act* ss 32-38.
[282] *GT Act* ss 34 and 35. Cf in the US where one significant criticism of the regulation of GMO releases there is that the regulatory system does not bind growers, but only licence holders or registrants. See, for eg, R Bratspies, 'The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops' (2002) 10 *New York University Environmental Law Journal* 297, 353-4.

Two levels of offences are created – strict liability offences and offences requiring knowledge or recklessness.[283] Lower penalties are imposed on the strict liability offences (or technical breaches).[284] The heaviest penalties are imposed on unlawful dealings that cause, or are likely to cause, significant damage to the health and safety of people or to the environment.[285] There is no reference to property damage or economic loss in the relevant section. It is submitted that therefore, as with insurance requirements discussed in section 2.8.6, the GTR's narrow understanding of environment means such penalties should not be available where only harm to others' economic interests occurs.

Penalties for individuals convicted of unauthorised dealings with GMOs include fines ranging from $5,500 to $220,000 and up to five years imprisonment.[286] The Act makes no provision for compensation to any person injured by an authorised release. Conversely though, it provides no immunity to any person releasing GMOs with the GTR's authority. Further, it seems that the legislation was not intended to affect the common law avenues for redress available to people suffering harm because of actions taken by the GTR or those using GT.[287]

2.9.4 *Monitoring and Enforcement*

For the regulatory scheme to be effective the GTR must be able to monitor compliance with the legislation and enforce that compliance. The GTR is given wide powers in this regard.[288] For example, the GTR may require regular reporting, auditing, routine inspections or a combination of these.

Licences or other approvals can be cancelled or suspended.[289] Suspected or actual breaches can be reported directly to the Commonwealth Parliament.[290] The GTR may also pursue a prosecution under the legislation through the Director of Public Prosecutions. The GTR or any other person aggrieved may also seek an injunction[291] from the Federal

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[283] OGTR Handbook, p 41.
[284] OGTR Handbook, p 41.
[285] *GT Act* s 38.
[286] The possible fines are greater where the offender is a body corporate. See *Crimes Act 1914* (Cth) s 4B.
[287] Aust, IOGTR and the Cth-State Consultative Group on Gene Technology, Discussion Paper, *Proposed national regulatory system for genetically modified organisms. How should it work?* (Draft for discussion) (October 1999), p 34. There is no section in the *GT Act* expressly preserving common law rights.
[288] *GT Act* s 10 and Part 11. Inspectors with significant monitoring and enforcement powers can also be appointed.
[289] *GT Act* Part 5 Div 7. This may necessitate the recall of the GMO or the cessation of any dealings with it.
[290] *GT Act* Part 9 Div 5.
[291] Including an interim injunction. *GT Act* s 147(5).

Court to restrain an offence or threatened offence against the legislation.[292] 'Person aggrieved' is not defined in the *GT Act*. Accordingly general case law on the term is relevant. This generally requires that the person suffer a grievance as a result of the decision beyond that of an ordinary member of the public.[293] Their interest must be one involving more than mere emotional or intellectual concern.[294]

Enforcement powers also include the power to direct licence holders or persons covered by licences to take any reasonable steps to comply with the Act.[295] This includes, for example, remediation and clean-up of neighbouring properties where contamination occurs because of the breach of legislation. However, unlike destruction orders under the State legislation described in Chapter 3, the GTR cannot order contaminated neighbours to destroy or allow the destruction of their crops. Further, directions to commercialisers must be reasonably necessary to protect the health and safety of people or the environment. Once again, uncertainty as to the interpretation of 'environment' creates additional uncertainty with respect to the obligations of commercialisers here. If the GTR's interpretation that environment and the risks to it that she is to address do not include socio-economic impacts is correct, such directions could not lawfully be made simply because another farmer's property or organisms have been or are threatened to be contaminated by a GMO. There would have to be a risk to the 'environment' as understood by the GTR.

2.9.5 *Right of Review*

(a) Rights of commercialisers

Some GTR decisions are 'reviewable decisions'.[296] Those who may seek review are called 'eligible persons'.[297] Reviewable decisions include many of the decisions of concern to commercialisers.[298] Most importantly, licence applicants or holders, as the case may be,

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[292] *GT Act* s 147(1).
[293] OGTR Handbook, p 155. The *GT Act* expressly extends the meaning of 'person aggrieved' for these purposes to include a State or Territory. *GT Act* s 183A(2). See also s 183A(1).
[294] *Australian Conservation Foundation Inc v Cth* (1980) 146 CLR 493 at 530-1, 539-40 and 548; *Onus v Alcoa of Australia Ltd* (1981) 149 CLR 27 at 35-7, 41-2, 53 and 74; *Shop Distributive and Allied Employees Association v Minister for Industrial Affairs of SA* (1995) 183 CLR 552 at 558.
[295] *GT Act* s 146.
[296] *GT Act* s 179. When a reviewable decision is made by the GTR, written notice must be provided to the relevant person containing the terms of the decision, reasons for decision and a statement setting out the person's rights of review. *GT Act* s 180.
[297] *GT Act* s 179.
[298] The applicant for or holder of a certification or accreditation, as the case may be, can seek the review of decisions regarding certification of facilities (decisions made under *GT Act* ss 84, 86-88) or accreditation of

can seek review of GTR decisions to refuse to issue a licence,[299] to impose a licence condition,[300] to suspend or cancel a licence,[301] or to vary a licence.[302] Further, a commercialiser who has made an application for information provided to the GTR to be declared CCI[303] can seek the review of a decision to refuse to make such a declaration[304] or to revoke such a declaration.[305]

Where a reviewable decision has been made by the GTR's delegate, an internal review of the decision may be sought.[306] In such cases, the GTR must review the decision personally[307] and may substitute her decision if appropriate.[308] If the original reviewable decision was made by the GTR, or there has been an internal review, the person seeking review may seek review by the Administrative Appeals Tribunal ('AAT') under the *Administrative Appeals Tribunal Act 1975* (Cth).[309] Such a review is on the merits of the case.[310]

Where an eligible person wants a question of law in relation to the making of a decision reviewed, they must apply to the Federal Court. Such application is made under the *Administrative Decisions (Judicial Review) Act 1977* (Cth) ('*ADJR Act*').[311] Standing is required to seek such a review. Standing requires that the person be a 'person aggrieved' by the decision for the purposes of the *ADJR Act*.[312] A commercialiser could establish such interest in most decisions concerning them under the *GT Act*.

Decisions made by the GTR in the performance of a function or exercise of a power conferred by a corresponding State law are reviewable State decisions for the purposes of

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an organisation (decisions made under *GT Act* ss 92, 94-96). No review process is provided for with respect to decisions by the GTR regarding applications to transfer licences from licence holders to other people.

[299] Decision made under *GT Act* s 55.

[300] Decision made under *GT Act* s 55.

[301] Decision made under *GT Act* s 68.

[302] Decision made under *GT Act* s 71.

[303] Pursuant to *GT Act* s 184.

[304] Decision made under *GT Act* s 185.

[305] Decision made under *GT Act* s 186.

[306] *GT Act* s 181(1). This must be done in writing (*GT Act* s 181(1)) and within 30 days of the decision coming to the notice of the applicant (*GT Act* s 181(2)). This period can be extended (*GT Act* s 181(2)).

[307] *GT Act* s 181(3).

[308] *GT Act* s 181(4).

[309] *GT Act* s 183.

[310] There has been one appeal to the AAT under the *GT Act*. The appeal was discontinued. M Tranter, 'A question of confidence: an appraisal of the operation of the Gene Technology Act 2000' (2003) 20 *Environmental and Planning Law Journal* 245, 256.

[311] *ADJR Act 1977* (Cth) s 5(1).

[312] *ADJR Act 1977* (Cth) ss 3(4) and 5(1).

the Commonwealth *GT Act*.[313] In that case, commercialisers may apply to the AAT for review of the decision.[314] Commercialisers have no right of review with respect to actions by the GTMC.

(b) Rights of third parties

Commercialisers may be concerned as to whether the public can challenge or seek review of GTR decisions under the Act. Members of the public, including the commercialiser's neighbours or GM opponents, cannot apply to the AAT for merit review of GTR decisions.[315] Where members of the public seek review on a question of law with respect to a GTR decision by the Federal Court they must establish, as noted above in relation to commercialisers' rights of review, that they are a 'person aggrieved' for the purposes of the *ADJR Act*.[316] In most cases, members of the public would not have standing to challenge decisions under the *GT Act*. However, residents and landowners, such as organic farmers, whose land adjoins or is nearby the property on which a GMO is to be released, may have sufficient special interest in the relevant GTR decision to seek review.[317] In some cases, environmental groups may also have standing.[318] There is uncertainty though because standing is left to judicial tests rather than a legislative definition.[319]

Members of the public can, of course, also provide information to the GTR at any time. Such information could lead the GTR to use her discretionary power and take action under the Act. In such a case, the commercialiser must be notified of the proposed action and be

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[313] This is provided that the State law provides for review by the AAT and that the decision has been declared by the Regulations to be a reviewable State decision. *GT Act* s 19(2).
[314] *GT Act* s 19(1). Gene Technology Regulations 2001 (Cth) reg 38 provides for additional rights of review not relevant to commercialisers. They concern membership and procedures of the committees established by the *GT Act*.
[315] See *GT Act* s 183.
[316] *ADJR Act 1977* (Cth) ss 3(4) and 5(1). See also *Australian Institute of Marine and Power Engineers v Secretary, Department of Transport* (1986) 13 FCR 124 at 131-3; *Big Country Developments Pty Ltd v Australian Community Pharmacy Authority* (1995) 60 FCR 85 at 92; *Right to Life Association (NSW) Inc v Secretary, Department of Human Services and Health* (1995) 56 FCR 50 at 64-5 and 84; *Transurban City Link Ltd v Allan* (1999) 95 FCR 553 at 565.
[317] *Cautionary Tale* Report, [5.72] citing submission No 77 p 130 from the IOGTR. See *Day v Pinglen Pty Ltd* (1981) 148 CLR 289 at 299-300; *Spitzer v Nicholls Properties Ltd* (Unreported, Tasmanian Supreme Court, Zeeman J, September 1990); *Sims v Planning Appeal Tribunal* (1992) 57 SASR 325 at 341.
[318] The IOGTR considered that organisations that have as part of their constitution or terms of reference, a reference to GT are likely to have standing according to *Cautionary Tale* Report, [5.72] citing IOGTR submission No 77, p 130. See also *Tasmanian Conservation Trust Inc v Minister for Resources* (1995) 127 ALR 580; *North Coast Environment Council Inc v Minister for Resources* (1994) 127 ALR 617. See also M Tranter, 'A question of confidence: an appraisal of the operation of the Gene Technology Act 2000' (2003) 20 *Environmental and Planning Law Journal* 245, 255.
[319] M Tranter, 'A question of confidence: an appraisal of the operation of the Gene Technology Act 2000' (2003) 20 *Environmental and Planning Law Journal* 245, 255.

given the opportunity to make a submission.[320] Information may also lead the GTR to revoke a declaration that information is CCI.[321] In that case, the revocation does not take effect until all review rights under the Act have been exhausted.[322]

2.10 FOOD REGULATION

As discussed in Part 2.1, sector based end product regulatory schemes continue to operate alongside the GT scheme. The GT scheme has meant some changes though to the procedures under such schemes where the end product is GM.[323] Existing federal regulators must now seek the GTR's advice on biosafety issues before making decisions on GM products.[324] That advice must be taken into account although it does not have to be followed. The GTR is also to be informed of the ultimate decision made in each case. Those decisions are then entered on the Record of GMOs and GM Product Dealings. A description of the end product regulatory scheme relevant to two of the case studies, food regulation, is given in this Part. This scheme is relevant to discussions in Chapters 5 and 6.

2.10.1 *Introduction*

Arguably the most controversial use of GMOs is their use in food. In Australia, the preparation and sale of food has traditionally been, and still is, regulated by the States under a uniform scheme. A national Food Standards Code sets out quality, or composition, and labelling requirements. State legislation, such as the *Food Act 1984* (Vic), then adopts the Code into each jurisdiction's law.[325] Until May 1999 there was no monitoring of any new food products before introduction to the market regardless of how it was produced.[326] No distinction was made by food regulations regarding whether the product was produced using GT or not.[327] That regime was changed by the introduction of *Standard 1.5.2 – Food*

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[320] *GT Act* s 72 (with respect to licence suspensions, cancellations or variations); s 89 (with respect to certification); s 97 (with respect to accreditation). There is an exception with respect to changes to licences where the GTR considers that there is an imminent risk of death, serious illness, serious injury or serious damage to the environment. See *GT Act* s 72(6) (with respect to licence suspensions, cancellations or variations); s 89(6) (with respect to certification); s 97(6) (with respect to accreditation).

[321] Pursuant to *GT Act* s 186.

[322] *GT Act* s 186(2).

[323] Such changes were largely made pursuant to the *Gene Technology (Consequential Amendments) Act 2000* (Cth).

[324] See, for eg, *Food Standards Australia New Zealand Act 1991* (Cth) ss 14(1) and 3(1) (definition of 'appropriate government agency').

[325] *Food Act 1992* (ACT); *Food Act 1989* (NSW); *Food Act 1986* (NT); *Food Act 1981-84* (Qld); *Food Act 1985* (SA); *Public Health Act 1962* (Tas); *Food Act 1984* (Vic); *Health Act 1911* (WA).

[326] Cf food additives which were and still are assessed prior to their initial release.

[327] For the legal ramifications of the previous lack of distinction, see K Ludlow, 'Waiter, There's a Genetically Modified Organism in my Soup – Genetically Modified Food and Australian Food Regulation' (1999/2000) 4 *Bio-Science Law Review* 154.

Produced Using Gene Technology into the Australian New Zealand Food Standards Code.[328] Prior to initial commercial release, the national food regulator, the Food Standards Australia New Zealand ('FSANZ'),[329] must now assess GM food. There are also specific regulations concerning labelling of such food.

The Standard applies to all 'food produced using gene technology'. Such food is defined as:

> food which has been derived or developed from an organism which has been modified by gene technology.[330]

'Gene technology' is defined as 'recombinant DNA techniques that alter the heritable genetic material of living cells or organisms'.[331] The definition is less sophisticated than that of the same term in the *GT Act*. Nevertheless, most GMOs and their harvested products sold as food fall within the ambit of the Standard. An editorial note in the Standard provides that the definition of 'food produced using gene technology' does not include food derived from animals or other organisms which have been fed food produced using GT, unless the animals or organisms are themselves products of GT. Presumably it would also not include food from organisms that have been administered GM agents, such as GM veterinary products, via other non-genetic routes.

The Standard has two Divisions. These are:

- Division 1 which concerns the sale and use of foods covered by the Standard; and
- Division 2 which provides for the labelling requirements for such foods.[332]

2.10.2 *Safety*

It is unlawful to sell or use as an ingredient or component of any food, foods produced using GT unless they have been specifically approved.[333] Approval requires mandatory

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[328] The Standard was known as *Standard A18 – Food Produced Using Gene Technology* before the introduction of the new Code. The Standard came into operation on 13 May 1999 but was subsequently amended.
[329] Previously known as the Australia New Zealand Food Authority ('ANZFA').
[330] Australia New Zealand Food Standards Code Standard 1.5.2 cl 1.
[331] Australia New Zealand Food Standards Code Standard 1.5.2 cl 1.
[332] Division 1 does not apply to food additives and processing aids produced using GT. (Australia New Zealand Food Standards Code Standard 1.5.2 cl 2.) These are regulated under other standards in the Code. The same pre-market assessment and approval processes are required for these products under those other standards. The labelling requirements in Division 2, however, do apply to food additives and processing aids together with other GM food.

pre-market safety assessment by the food authority and approval by the Australia and New Zealand Food Regulation Ministerial Council.[334]

Once assessed and approved, the food is listed as being permitted for sale and use.[335] Entry on the list permits the sale and use of the food and products derived from it. So, for example, food components derived from GM canola, such as oil, may be used in foods such as breads, pastries and snack foods if the GM canola from which it is derived has been assessed and approved as safe. The various breads, pastries and snack foods containing the GM canola do not need to be individually assessed.[336]

A producer of a GM food may apply to the food regulator to have that food listed as safe.[337] The food must also comply with any listed special conditions on the sale of the food, such as special labelling.[338] For example, the GM food must have been determined to be at least as safe as its traditional counterpart to get approval for sale. However, if it contains a factor known to cause an allergic reaction in some part of the population, it may need to be labelled appropriately. Such a requirement would be listed and would need to appear on all such food. The GM involved may also raise significant ethical, cultural or religious concerns regarding the origin of the genetic material used in the GM. In that case the Standard provides that additional labelling or other information requirements in relation to the food concerned may be specified.[339]

2.10.3 *Labelling*

The labelling requirements for GM food are set out in Division 2 of Standard 1.5.2.[340] For the purposes of Division 2, 'genetically modified food' is defined as 'food that is, or

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[333] Australia New Zealand Food Standards Code Standard 1.5.2 cl 2.

[334] Because the Standard was introduced after some GM foods had already been introduced to the Australian market, transitional arrangements were put in place to permit them to remain in the marketplace while the foods underwent safety assessment. This was done by an amendment to Standard A18 agreed to by ANZFA on 30 March 1999. See Australia New Zealand Food Standards Code Standard 1.5.2 cl 3(2). It was reported that twenty GM foods, originating from GM soybean, canola, corn, potato, sugarbeet and cotton were approved in this way. G Strong, 'Hard to Swallow', *The Age* (Melbourne), 19 June 1999, News Extra pp 1-2; M Curtis, 'If GM food is safe why did manufacturers not tell us we were eating it?', *Sunday Herald Sun* (Melbourne), 14 November 1999, Magazine pp 12 and 15.

[335] In Column 1 of the Table to clause 2, Australia New Zealand Food Standards Code Standard 1.5.2.

[336] ANZFA, Submission to the New Zealand Royal Commission on Genetic Modification, Part B, [15].

[337] Pursuant to *Food Standards Australia New Zealand Act 1991* (Cth) s 12(1).

[338] Australia New Zealand Food Standards Code Standard 1.5.2 cl 2. Such requirements would be listed in Column 1 of the Table to clause 2.

[339] Australia New Zealand Food Standards Code Standard 1.5.2 cl 7(e). Such requirements would be listed in Column 2 of the Table to clause 2.

[340] Cf provisions re labelling of GM food in Truth in Food Labelling Bill 2003 (Cth).

contains as an ingredient, including a processing aid, a food produced using gene technology which:

(a) contains novel DNA and/or novel protein; or

(b) has altered characteristics;'[341]

'Novel DNA and/or novel protein' is defined to mean DNA or a protein which, as a result of the use of GT, is different in chemical sequence or structure from DNA or protein present in counterpart food produced without GT.[342]

A food produced using GT has 'altered characteristics' if:[343]

- the GM has resulted in one or more significant changes in composition or nutritional parameters of the food, outside the normal range of values for existing non-GM counterpart food;
- there are significant differences in levels of anti-nutritional factors or natural toxicants in the food compared to its existing non-GM counterpart;
- the food contains a new factor known to cause an allergic response in particular sections of the population; or
- the intended use of the GM food is different to the existing non-GM counterpart food.

From 7 December 2001[344] the label on all GM food packages must include the statement 'genetically modified' in conjunction with the name of that food, ingredient or processing aid.[345] For example, the label could say 'canola oil – genetically modified'. For GM ingredients and processing aids, the required statement may be in the product's table of ingredients.[346] For those GM foods which are not sold in packaging, such as fruit and

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[341] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1).
[342] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1).
[343] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1) (definition of 'altered characteristics') and cl 7(a)–(d).
[344] Although the Standard was introduced in May 1999, the labelling provisions did not take effect until 7 December 2001.
[345] Australia New Zealand Food Standards Code Standard 1.5.2 cl 5.
[346] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(2).

vegetables, the required information must be displayed on or in connection with the display of the food.[347]

Where a food is not GM, no statement as to its genetic status is required by the Standard.[348] If a producer chooses to label such a product, for example, as being 'GM free', they must be able to verify the truth of that statement or risk penalties under the Australian consumer protection laws.[349] This may require the method used to verify that status be disclosed on the label.[350]

Exemptions from the labelling requirements in Standard 1.5.2 apply to:

- highly refined food without altered characteristics where the effect of the refining process is to remove the novel DNA and/or novel protein.[351] For example, wine made with modified yeast where the yeast is not present in the final product;
- processing aids and food additives except those where novel DNA and/or novel protein from them is present in the final food;[352]
- flavours which are present in a concentration less than or equal to 0.1 percent in the final food;[353] and
- food intended for immediate consumption which is prepared and sold from premises and vehicles, such as take away food, food in restaurants or airline food.[354]

Food, ingredients and processing aids are also allowed to contain up to one percent of *unintended* presence of GM product without requiring labelling.[355] Where GM product is intentionally present, the food cannot be labelled as GM free or not be labelled in this regard even if the GM product makes up less than one percent of the product.

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[347] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(3).
[348] Australia New Zealand Food Standards Code Standard 1.5.2 cl 6.
[349] Australian National Foods is reported to be the first company in Aust to use a GM free label. It labelled its So Natural soy milk as 'free from genetically engineered soy beans'. M Coffey, 'Industry Splits on What to Tell', *Herald Sun* (Melbourne), 10 March 1999, pp 10-1.
[350] For testing methods for the presence of GMOs see Aust, Dept of Agriculture, Fisheries and Forestry – Australia, *Segregating Gene Technology Products – Requirements, Costs and Benefits of Identity Preservation, Segregation and Certification* by Leading Dog Consulting and Peter Flottmann and Associates, Scoping study (May 2001), pp 21-3; S Smyth and P W B Phillips, *Identity-preserving production and marketing systems in the global agri-food market: Implications for Canada* (August 2001), pp 12-4.
[351] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1)(c).
[352] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1)(d).
[353] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1)(e).
[354] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(4).
[355] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1)(f).

However, even where a GM food is exempt from labelling requirements, it still must be approved for sale and use under Division 1 of Standard 1.5.2 unless it is a food additive or processing aid.[356]

2.11 CONCLUSION

Two matters of particular importance to commercialisers selecting GMOs for commercialisation arise from the introduction of the GT regulatory scheme. First, how the scheme affects them. Secondly, whether commercialisers are better off under the new regime. These are considered below and a summary of the application of the legislation to each of the case studies is given.

2.11.1 *Effect of the Scheme*

Commercialisers must comply with the GT regulatory scheme (or in the case of the pig, would have to if the project took place today). The case studies are all GMOs for the purposes of the *GT Act* whether any particular organism held by the commercialiser is a parent organism or progeny. The products of the case studies could also theoretically be regulated by the GTR. However, neither the Regulations nor the relevant licences currently provide for this.[357] Nevertheless, because such products cannot be produced without the organisms, even if the commercialiser is interested only in the GMO's products the operation of the legislation cannot be avoided.

The Act regulates 'dealings' with GMOs. All activities necessary for successful field trialling and selection of the case studies are dealings regulated under the legislation. Authorisation under the legislation is therefore required for those activities to proceed. Authorisation occurs when the dealing is exempt, a NLRD, listed on the GMO Register or licensed by the GTR. To be an exempt dealing or a NLRD there must be no intentional release to the environment. Field trialling will generally require such release. It is therefore unlikely that the relevant dealings with the case studies will be in these categories.

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[356] The labelling requirements have recently been reviewed and approved. See FSANZ, *Report on the Review of Labelling of Genetically Modified Foods* (December 2003) which was approved by the FSANZ Board on 9 December 2003. See also Australia and New Zealand Food Regulation Ministerial Council, *Joint Communique* (28 May 2004).

[357] Aust, OGTR, *Commercial release of InVigor canola* (Brassica napus) *for use with Australian cropping system DIR 021/2002 Bayer CropScience Pty Ltd. Licence conditions and reasons for the conditions* (undated) and Aust, OGTR, *Conditions of Licence – DIR 030/2002 Florigene Ltd – Colour modified carnation* (undated, circa June 2003) (http://www.ogtr.gov.au/ir/dir030.htm) (copy on file with author).

The third form of authorisation is dealings on the GMO Register. Intentional release to the environment during field trials is possible under this type of authorisation. However, no organism has yet been listed on the GMO Register although the GM carnation commercialiser intends to seek listing in the future.[358] For commercialisers' purposes, such inclusion is advantageous because it is a simpler form of authorisation than licensing. There is no need to seek and maintain a licence. Nor is it necessary for the licence holder or other persons covered by the licence to comply with licence conditions although conditions may be entered on the GMO Register that must be met. However, by having a dealing included on the GMO Register the commercialiser loses an important advantage conferred by a licence. Where use of a GMO is authorised by licence rather than through being listed on the GMO Register, use by anyone not covered by the licence is an offence under the *GT Act*. This may be a deterrent to competitors of the commercialiser seeking to use the commercialiser's product.[359] It is a deterrent additional to enforcement of the commercialiser's IP rights. Where a GMO is listed on the GMO Register though, the organism can for the purposes of the legislation be dealt with by anyone. The commercialiser in such cases would have to rely on their IP rights, if any, in the organism to prevent competitors using the organism.

A licence for dealings with a GMO is the most relevant form of authorisation for this study. The less rigorous licence procedure involved where there is no intention to release a GMO into the environment may be applicable to some field trials.[360] However, release into the environment was required in the trialling of the carnation and canola case studies. The commercialisers of both these organisms therefore followed the DIR licence procedures. Limitations imposed by relevant end product regulators must also be complied with by commercialisers.

Legal responsibility for enforcing the regulatory scheme lies with the GTR. Although members of the public may complain to the GTR they cannot usually enforce the legal

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[358] Aust, OGTR, *Application for Licence for Intentional Release of GMOs into the Environment: Application No DIR 030/2002. Summary Information* (December 2002), p 2.

[359] Assuming the licence does not authorise a group that includes competitors. See, for eg, the licence for the GM canola which covers all persons in Aust. Aust, OGTR, *Commercial release of InVigor canola* (Brassica napus) *for use in the Australian cropping system DIR 021/2002 Bayer CropScience Pty Ltd. Licence conditions and reasons for the conditions* (undated).

[360] Field trials will usually require the release of the GMO and/or its products into the environment. It is possible though that there will be no intentional release of the GMO into the environment. For eg, GM pigs could theoretically be raised entirely in a secure facility approved, or certified, by the GTR. In that case, provided the products of such organisms have not themselves been declared GMOs for the purposes of the legislation, a DNIR licence would be relevant.

obligations of commercialisers pursuant to the *GT Act*. The *GT Act* does not impose liability on commercialisers for damage caused as a result of an authorised, or even unauthorised, GMO release.[361] There is also no statutory right of action or compensation fund[362] to compensate those affected by a breach or otherwise of the legislation.[363] However, the Act also does not provide immunity to those who comply with the legislation but nevertheless cause harm to others. The *GT Act* specifically provides that licence conditions may require commercialisers to hold adequate insurance against any loss, damage or injury that may be caused to human health, property or the environment by the licensed dealing.[364] It is an offence for a licensed commercialiser to breach a licence condition.[365] Such a condition though means only that the commercialiser is more likely to be able to pay any amount for which they are liable.[366] It does not create such liability.[367]

Finally, the *GT Act* also provides for the protection of CCI. The usefulness of such protection to commercialisers depends upon the information concerned and the enforcement by the GTR of the relevant penalty provisions. More importantly, it depends upon how the GTR interprets the term 'public interest' in the legislation. Commercialisers will need to bear this in mind when considering what IP protection to pursue.

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[361] Although the commercialiser may be liable to repay the Cth the costs of steps taken by the GTR to, for eg, remediate land damaged following a breach of the Act. *GT Act* ss 146(5) and 158(4).

[362] The Federal Court may, in its discretion, award damages to an aggrieved person seeking an injunction under the *GT Act*. See *GT Act* s 147(6) which expressly reserves the Federal Court's powers, including the power to make orders as required and *Federal Court Rules* O25 r 1.

[363] It is unlikely that third parties could successfully bring an action against a commercialiser for breach of statutory duty where the commercialiser has failed to comply with the *GT Act*. The provisions of the *GT Act* are arguably not designed to benefit an ascertainable class of persons and provide for fines and other criminal sanctions as penalties. These factors strongly indicate Parliament did not intend to provide compensation by way of breach of statutory duty.

[364] *GT Act* s 62(3).

[365] *GT Act* ss 34 and 35.

[366] Assuming insurance is available.

[367] If a commercialiser is found liable in respect of an authorised release, the commercialiser may seek contribution or indemnity from the GTR. Contribution or indemnity would only be available if the GTR is liable in negligence to the plaintiff. On this see D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 159-61. With respect to liability of government authorities generally see S Kneebone, *Tort liability of public authorities* (LBC Information Services, North Ryde, NSW, 1998). With respect to suggestions for government response to assisting those hurt by GMO releases see, for eg, New Zealand, Law Commission, *Liability for Loss Resulting From the Development, Supply, or Use of Genetically Modified Organisms* Study Paper 14 (Wellington, 2002). See also J M Merry, 'The Bioengineering Revolution: Genesis of a Compromise Solution' (1988) 20 *Pacific Law Journal* 163, 188-94.

2.11.2 *Summary of Application to Case Studies*

(a) Carnation

Approval to field test and then to deal with the GM carnation as a general commercial release was originally given by GMAC.[368] That approval was deemed to be a licence under the *GT Act* upon that Act coming into force.[369] However, as with all deemed licences, the licence had to be reviewed by the GTR within a certain time.[370] This has occurred and a licence for the continued commercial propagation, growth and distribution of the GM carnation has been granted.[371] The licence allows for the general sale and use of both carnation plants and cut flowers in Australia.[372] No end product regulatory scheme applies. However, the commercialiser may have to comply with the State restrictions discussed in the next Chapter.

(b) Canola

The commercialiser of GM canola has also been granted a licence for commercial release. With GMAC and then the GTR's authority[373] Bayer conducted limited and controlled field trial releases of the canola in Australia.[374] The commercialiser then applied in July 2002 for a DIR licence for the commercial release of GM canola in all canola growing areas of Australia. On 17 June 2003 the GTR announced that the licence decision was being delayed so that new information raised in public submissions could be received and considered. As noted in section 2.8.5 a licence was granted in July 2003.[375] As discussed in Chapter 3, despite the GTR's licence it is still illegal to release GM canola in most

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[368] Aust, GMAC, *GR2 – A violet carnation*.
[369] Pursuant to *GT Act* s 190.
[370] *GT Act* s 190.
[371] Aust, OGTR, *Notification of decision to issue a licence on carnation application DIR 030/2002 – 17 June 2003*.
[372] The usual conditions have been imposed on the release. Aust, OGTR, *Conditions of Licence – DIR 030/2002 Florigene Ltd – Colour modified carnation* (undated, circa June 2003) (http://www.ogtr.gov.au/ir/dir030.htm) (copy on file with author).
[373] Aust, OGTR, *Risk Assessment and Risk Management Plan and Licence for Intentional Release of GMOs into the Environment: Application No DIR 010/2001 Summary Information* (undated, circa July 2002), p3.
[374] Not in the ACT and NT. Aust, OGTR, *Risk Assessment and Risk Management Plan and Licence for Intentional Release of GMOs into the Environment: Application No. DIR 010/2001 Summary Information*, p3.
[375] Aust, OGTR, *Decision on Issuing a Licence for Application DIR 021/2002 for Commercial Release of Bayer InVigor GM Canola* (25 July 2003). The use of glufosinate ammonium herbicide on the GM canola was also approved by the relevant end product regulator on the same day. Aust, OGTR, Media Release, *Rigorous Assessment Confirms GM InVigor Canola Safe as Non-GM Canola* (25 July 2003), p2.

States. Food regulations are also relevant to the commercialisation of GM canola. The oil derived from the canola has been approved for use as human food by FSANZ.[376]

(c) Pig

The GM pig project ceased before the introduction of the *GT Act*. If that project was to recommence now a licence under the Act would be required. That licence would probably need to be a DIR licence. It is possible that the pigs could be trialled[377] without an intentional release of the pigs into the environment. In that case a DNIR licence could be sought. If products of the pig were to be sold as human food, FSANZ approval would be required.

2.11.3 *Is Scheme an Improvement?*

The second matter of particular interest to commercialisers is whether they are better off under the new scheme. As already noted, all the case studies were developed prior to the introduction of the scheme. The GM carnation and canola have gone on to be regulated by the new legislation whereas commercialisation of the pig ceased before its introduction.

(a) New obligations

The *GT Act* introduces new legal obligations when selecting GMOs for commercialisation where previously, strictly speaking, there were none.[378] At first glance this creates new hurdles for commercialisers. The more rigorous the requirements of the scheme the more disadvantageous it seems for commercialisers competing with those using conventional organisms. As noted by Korwek, regulatory hurdles can result in long delays in delivery of products and drive up consumer costs.[379] Regulatory costs include those costs directly imposed by the scheme together with the costs incurred by commercialisers in complying with the scheme. Currently no fees or charges are imposed directly by the new scheme. Nevertheless, such costs may be imposed in the future.

Lack of regulation, though, can also harm commercialisation prospects. This is demonstrated by the experiences of those involved in the development of the GM pig. It is

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[376] Aust, OGTR, *Risk Assessment and Risk Management Plan DIR 021/2002. Commercial release of genetically modified (InVigor hybrid) canola. Executive summary* (undated, circa July 2003). See also ANZFA, Final Assessment Report on Application A372 (2001).
[377] And even commercialised.
[378] The previous scheme being a voluntary one.
[379] E L Korwek, 'FDA Regulation of Biotechnology as a New Method of Manufacture' (1982) 37 *Food Drug Cosmetic Law Journal* 289, 289-90.

submitted that the new scheme gives regulatory certainty in terms of time frames and assessment processes. It also provides a clearer pathway for seeking and gaining approval necessary to commercialise GMOs and their products. Authorisation under the *GT Act* could also, although incorrectly, be seen by the public as a form of official sanction of the quality and value of the GMO or its products.[380] Further, such authorisation provides some protection against the use by competitors of the GMO or product.

(b) Duplication

The Commonwealth Government intended that the new scheme avoid unnecessary duplication with existing regulators and create better coordination of the activities of all regulators involved in the approval of GMOs and their products.[381] Commercialisers will though, in many cases, still need approval from more than one regulator before commercialisation begins. For example, GM canola required FSANZ and GTR approval.[382] The introduction of the State restrictions discussed in the next Chapter means that State agencies will also need to be approached where exemptions or permits are being sought.

From a commercialiser's perspective, a central agency may have been preferable. A number of diverse agencies would then not have to be approached for approval. Multiple regulatory schemes also mean multiple sets of costs[383] for commercialisers and may increase the time taken to gain final approval for market. However, a central agency would not have been realistic, particularly as each agency's expertise would then have to be duplicated within the OGTR. Instead, as the Federal Government has pointed out, the existing system is advantageous because it recognises the roles of each existing regulator and the desirability of assessing GM products along with their non-GM counterparts under the relevant regulatory framework, with the GTR providing advice on the safety aspects associated with the GM of the product.[384] The current system is also said to ensure that

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[380] N Atkinson and B Sherman, 'Intellectual Property and Environmental Protection' [1991] *European Intellectual Property Review* 165, 166.

[381] Aust, IOGTR and the Cth-State Consultative Group on Gene Technology, Discussion Paper, *Proposed national regulatory system for genetically modified organisms. How should it work?* (Draft for discussion) (October 1999), p 16; Aust, IOGTR, *Consultation Draft Gene Technology Bill 2000* (16 December 1999), cl 4.

[382] Approval by the Australian Pesticides and Veterinary Medicines Authority under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) was also required for the full benefit of the GM to be utilised through the use of a particular herbicide to which the GM canola is resistant.

[383] There is a cost in time taken to comply with the *GT Act* even if there is no fee imposed under the scheme.

[384] Aust, IOGTR, *Questions and Answers on the Commercial Release of Roundup Ready and Roundup Ready/ Ingard Cotton*, Information Bulletin No 6 (September 2000), p 17.

like products are treated in a similar way (reducing market distortions) while also ensuring that any risks posed by GT are considered.[385] The Government also claims that the system ensures that the GTR acts as a centralised area of expertise on genetic safety and makes advice available to other regulators of GM products. This is said to reduce costs to the Government by eliminating the need for each regulatory agency to establish its own centre of expertise on GT.[386]

Which view is correct can really only be judged by hands on use of the system, something outside the scope of this study. However, the implementation of a scheme specifically for GMOs and the States' reactions to GMO releases may suggest to the public that GT and its products are inherently unsafe and require regulatory oversight. The same observation may be made in particular with respect to the changes to food regulation to deal with GM food. The existence of specific end product regulation singles out the technology and may reinforce the public's fear of it. The labelling requirements of Standard 1.5.2, in particular, may be detrimental to commercialisation in both increasing costs and causing negative attitudes in consumers. Conversely though, it may be that the greater transparency and accountability provided by the GT and end product regulatory schemes provides reassurance to the public.

(c) National scheme

That the scheme is a uniform national one was also an advantage. However, that advantage is being lost through the responses of the States to, in particular, the proposed release of GM canola. The introduction of varying State legislative requirements means there are now non-uniform requirements for field trials for at least some GMOs throughout Australia. Such requirements significantly restrict the actions of some commercialisers. Further, as noted by one biotechnology industry body, restrictions on GM cultivation in some parts of Australia may reduce all research and development in GMOs throughout Australia.[387]

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[385] Aust, IOGTR, *Questions and Answers on the Commercial Release of Roundup Ready and Roundup Ready/ Ingard Cotton*, Information Bulletin No 6 (September 2000), p 17.
[386] Aust, IOGTR, *Questions and Answers on the Commercial Release of Roundup Ready and Roundup Ready/ Ingard Cotton*, Information Bulletin No 6 (September 2000), p 18.
[387] AusBiotech Ltd, *Submission to the South Australian Genetically Modified Crops Management Bill 2003* (12 December 2003).

(d) GTR risk assessment

Significant uncertainty for commercialisers arises with respect to and because of the risks considered by the GTR in making licensing decisions. The GTR considers that social and economic implications of GMO releases are not relevant considerations. From a commercialiser's perspective this may seem advantageous. It means the GTR's assessment is essentially a scientific one and considers risks to only a narrow range of interests. However, it is submitted that the GTR's approach is disadvantageous to commercialisers for four main reasons. First, some value judgments still need to be made even in the current form of assessment. How such judgments are made is uncertain. Secondly, it has been submitted that the GTR's approach is incorrect. The risk of GM contamination and its consequences can and should, it has been argued, be considered by the GTR when preparing RA&RMPs. RA&RMPs are then required to be considered by the GTR when DIR licensing decisions are made. It has also been submitted that a broader range of matters fall within the term 'environment' than the GTR currently allows. In particular, it has been submitted that non-GM farming is part of the environment. Therefore risks to such parts of the environment could lawfully justify refusal of a licence by the GTR. The uncertainty regarding the correctness of the GTR's approach leaves her decisions vulnerable to attack via judicial review. It also creates additional uncertainty regarding commercialiser's obligations. For example, if the GTR's interpretation is correct, commercialisers cannot be lawfully directed to take steps to prevent GM contamination where the only result of that contamination will be harm to another's method of agriculture or agricultural organisms. Further, commercialisers cannot be required to obtain insurance in respect of liability for harm to economic interests of others, not consequential on property damage.

Thirdly, that the GTR does not consider the social and economic consequences of GM contamination may have ramifications under common law and environmental legislation. It may not, in light of those ramifications, be in commercialisers' best interests for the GTR to take such a narrow approach to risk assessment. This issue is pursued in Chapters 5 and 6.

Finally, as discussed above, that exclusion has weakened the national regulatory scheme. It has set the scene for the majority of States to impose moratoriums and new legal obligations on commercialisers, meaning there are now non-uniform requirements for field

trials for at least some GMOs throughout Australia. It is those State requirements that the next Chapter takes up.

(e) Summary

Subject to the GT regulatory scheme operating as proposed with respect to coordination with other regulators and reasonable fees and charges being imposed, it is submitted that the introduction of the scheme is an improvement for commercialisers on the previous voluntary scheme. Whether in fact one or more regulators are involved is not critical provided there is limited overlap and duplication. The scheme seems to address some of the public's concerns about GMOs by assessing risks to human health and safety and the environment whilst at the same time providing a relatively straightforward approval process. Ultimately though its usefulness for some commercialisers, such as those of GM canola, has been removed by the State imposed moratoriums and designated areas. These restrictions are considered in the following Chapter.

CHAPTER 3

STATE REGULATION

3.1 INTRODUCTION

Despite the national scheme described in Chapter 2, there has been continued public and governmental concern about GMO releases.[1] In particular, the proposed commercial release of GM canola in 2003 led many States to consider imposing moratoria on GMO releases.[2] Pursuant to very recent legislation all States other than Queensland and the NT have now prohibited certain releases of GMOs.[3] That State legislation is the subject of this Chapter.

Part 3.2 briefly describes the States' concerns and the GTMC's actions in response to those concerns. This provides the background for the legislative changes made or proposed by the States. These are described in Part 3.3. Analysis and conclusions are suggested in Part 3.4 where it will be submitted that the legislation creates considerable uncertainty and significant limitations for commercialisers. Two tables summarising the consequences of the legislation are then provided. The first, Table 3.1, summarises the most significant aspects of each State's legislative response to GMO releases. The second table, Table 3.2, summarises the legality of field trials of the case studies under State legislation.

3.2 DESIGNATED AREAS POLICY PRINCIPLE

The agreement by all States to participate in the national GT regulatory scheme means that risks assessed by the GTR under the *GT Act* cannot be grounds for the States refusing to allow GMO releases in their jurisdictions. Accordingly States cannot refuse GMO releases

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

[2] See, for eg with respect to Victoria, Vic, *Parliamentary Debates*, Legislative Assembly, 9 April 2003, p 963 (Savage, Member for Mildura).

[3] See Gene Technology (GM Crop Moratorium) Bill 2004 ('ACT GM Bill'); *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) ('*NSW GM Act*'); *Genetically Modified Crops Management Act 2004* (SA) ('*SA GM Act*'); *Plant Quarantine Act 1997* (Tas) ('*Tas Quarantine Act*'); *Control of Genetically Modified Crops Act 2004* (Vic) ('*Vic GM Act*'); *Genetically Modified Crops Free Areas Act 2003* (WA) ('*WA GM Act*'). See also Genetically Modified Organisms Control Bill 2004 (Tas) ('Tas GM Bill'). The ACT GM Bill was enacted after the completion date of this study and commenced on 10 July 2004. References to it in this study are to the legislation in its Bill form with footnotes noting significant relevant differences in its final enacted form.

on the basis of risks to human health and safety and the environment.[4] However, some States still have concerns about, inter alia, the socio-economic impacts of GMO releases.[5]

State legislation prohibiting GMO releases ('State moratorium legislation') was largely enacted after the making of the *Gene Technology (Recognition of Designated Areas) Principle 2003* ('Designated Areas Policy Principle') on 31 July 2003.[6] That Principle was made by the GTMC pursuant to the *GT Act*.[7] The GTMC oversees the operation of the national scheme described in Chapter 2.[8] It does not have a role in considering or assessing individual applications to deal with GMOs.[9] Instead it provides broad policy guidance to the GTR.[10] That guidance can be in a variety of forms including that of policy principles.[11] Policy principles are mandatory guidelines for the GTR.[12] The GTR cannot issue a licence if to do so would be inconsistent with a policy principle.[13] The GTMC has issued one policy principle so far.

Whilst the Principle does not change the risks assessed by the GTR and does not give legislative power to the States that they previously did not have, it was thought necessary to ensure that any State moratorium legislation could not be successfully challenged on

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[4] During negotiations leading to the GT regulatory scheme, Tasmania had wanted to reserve the power to withdraw from the national scheme in order to prevent GMO releases within its boundaries and to establish itself as a GM-free area. The *GT Act*, in the end, did not include an opt-out clause.

[5] For eg, ACT and SA have called for the GTR to add other considerations to risk assessments, including 'the economic and social impact of applications', when making licensing decisions. ACT, Legislative Assembly, Standing Committee on Health, *Inquiry into the Gene Technology Bill 2002. Report No 2* (December 2002), Recommendation 5. See also SA, House of Assembly Select Committee on Genetically Modified Organisms, *Final Report* (tabled 17 July 2003), Recommendation 16.

[6] The Principle took effect from 5 September 2003. See Designated Areas Policy Principle 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 Aust, Senate Committee on Community Affairs, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report on the Gene Technology Bill 2000* (November 2000) Tabled 1/11/00 PP No 263/00 ('*Cautionary Tale* Report'), [6.33]-[6.88]. See also Aust, Gene Technology Standing Committee, Introductory Paper, *Policy Principle to Recognise GM/Non-GM Designated Areas* (16/4/03). See further Aust, Gene Technology Standing Committee, draft policy principle, 'Gene Technology (Recognition of Designated Areas) Principle 2003'; draft Explanatory Memorandum and draft Regulatory Impact Statement.

[7] *GT Act* s 21(1).

[8] The GTMC comprises one Minister from the Cth and each State. Each jurisdiction decides which Minister will represent them – eg, health, environment or agriculture Minister. Aust, OGTR, *Handbook on the Regulation of Gene Technology in Australia* (2001) ('OGTR Handbook'), p 23.

[9] *GT Act* s 30.

[10] It also considers changes to the national legislative framework as required and advises on the appointment and dismissal of the GTR and the chairpersons of the advisory committees. Aust, OGTR, *Questions and Answers on the Gene Technology Act 2000* Information Sheet, p 6. See also OGTR Handbook, p 23.

[11] *GT Act* ss 21 and 22. The GTMC can also issue policy guidelines (*GT Act* s 23. See also s 56 which requires the GTR to have regard to such guidelines in making licensing decisions) and codes of practice (*GT Act* s 24(1)). Policy guidelines are guidance notes and advisory only. OGTR Handbook, p 15. Codes of practice guide applicants in their work with GMOs and a requirement to comply with them may be imposed as a licence condition. OGTR Handbook, p 21.

[12] *GT Act* ss 21 and 22.

[13] *GT Act* s 57(1) and Gene Technology Regulations 2001 (Cth) Sch 3 cl 2.1.

constitutional grounds. 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'.[14] It says:

> An 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.[15]

The Principle is relevant only to DIR licence applications.[16] Although the Regulatory Impact Statement states that the Policy Principle applies only to licences for the commercial release of GMOs, it seems from the rest of the Statement that this includes field trial releases.[17] The Principle is not intended to otherwise affect the GTR's discretion in licensing decisions or role of assessing and managing risks to the health and safety of people or the environment.[18] It is also not intended that the State laws, if any, be duplicated in any licence conditions imposed by the GTR.[19]

The Policy Principle refers only to GM or non-GM *crops*. The section of the *GT Act* empowering the GTMC to make such principles limits the GTMC's power in that way.[20] 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.'[21] Accordingly, both GM plants and animals can be affected by the Principle's introduction. The Principle and the empowering section also refer to 'marketing purposes'. The Regulatory Impact Statement states that this 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.[22]

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[14] Designated Areas Policy Principle s 4.
[15] Designated Areas Policy Principle s 5.
[16] Gene Technology Standing Committee, Regulatory Impact Statement on *Gene Technology (Recognition of Designated Areas) Principle 2003* ('DAPP Regulatory Impact Statement') s 1.1.
[17] DAPP Regulatory Impact Statement s 6.
[18] Designated Areas Policy Principle s 7.
[19] DAPP Regulatory Impact Statement s 1.1.
[20] *GT Act* s 21(1)(aa).
[21] DAPP Regulatory Impact Statement s 1.1.
[22] DAPP Regulatory Impact Statement s 2.

3.3 STATE MORATORIA

The Designated Areas Policy Principle was not intended to compel any State to make laws designating an area for the purpose of identity preservation.[23] Each jurisdiction must decide whether such action is desirable in light of commercial, rather than safety or environmental, risks.[24] As noted above, all States but Queensland[25] and NT[26] have declared moratoria on the commercial release of certain GMOs. In SA, WA and Tasmania,[27] the entire jurisdiction has been designated a 'GM-free' area. In the ACT, NSW and Victoria, the State is designated as one where the cultivation of certain GMOs is prohibited. Exemptions or permits allowing release despite the moratoria are provided for in each State.[28]

This Part describes the State moratorium legislation of each State, other than Queensland and NT, in sections 3.3.1 to 3.3.6. An analysis of the legislation is made in Part 3.4.

3.3.1 *ACT*

The ACT Government announced on 17 June 2003 that it would introduce a three year moratorium on the commercial release of GMOs.[29] On 11 December 2003 the Government tabled a draft Bill, the Gene Technology (GM Crop Moratorium) Bill 2004.[30]

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[23] Designated Areas Policy Principle s 6. It is outside the scope of this study to consider whether or not a State should introduce such areas. However, the DAPP Regulatory Impact Statement s 5.1 notes issues that may arise from designating such areas include 'compensation issues, administration costs and compliance with National Competition Policy or World Trade Organization (WTO) agreements'. See also s 5.2 of the Statement.

[24] With respect to some of the matters that any such legislation would need to address see DAPP Regulatory Impact Statement s 5.2.

[25] 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. Qld, Dept of Innovation and Information Economy, *Code of Ethical Practice for Biotechnology in Queensland* (1 September 2001).

[26] The NT Government's pre-election position on GMOs was to oppose any commercial development but support ongoing experimentation and testing. NT, *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.

[27] The proposed Tas GM Bill also provides that all of Tasmania can be declared GM-free.

[28] ACT GM Bill cl 8; *NSW GM Act* s 8; *SA GM Act* s 6; *Tas Quarantine Act* s 38; Tas GM Bill Part 3 Div 1; *Vic GM Act* s 6; *WA GM Act* s 6.

[29] D Jones, 'Three Year Ban on Genetically Modified Food' (2003) 3 *National Environmental Law Review* 23, 23. This was in response to the ACT, Legislative Assembly, Standing Committee on Health, *Inquiry into the Gene Technology Bill 2002. Report No 2* (December 2002), Recommendation 3.32.

[30] A private members bill, the GMO (Environment Protection) Bill 2003 (ACT), prohibiting the release of *all GMOs* into the environment was tabled in the ACT Legislative Assembly on 26 November 2003. 'GMO' was defined as in the *GT Act*. The Bill was negatived on 1 July 2004, after the completion date of this thesis.

The purpose of the Bill is to designate the ACT as an area where certain GMOs may not be cultivated.[31]

The Minister may make moratorium orders prohibiting the cultivation[32] of stated GM food plants[33] in the ACT.[34] Food plants are plants grown primarily for, or as an ingredient of, food for human consumption.[35] This does not include plants grown as livestock feed, even if the livestock are to be used as human food. Exemptions can be granted by the Minister.[36] The Bill does not require the Minister to consult prior to making a moratorium order or exemption.[37] The Act, if enacted, is to expire on 17 June 2006.[38]

It will be an offence to cultivate GM food plants in contravention of a moratorium order if the person is reckless about whether the plant is a GM food plant *and* whether the cultivation is in contravention of an order.[39] Anyone, whether inadvertently contaminated or otherwise, can be directed to, inter alia, destroy a plant the cultivation of which contravenes the legislation.[40] Additionally, future use of the contaminated land can be restricted.[41] Compensation from the Government is provided for in only limited circumstances not relevant to this study.[42]

3.3.2 *NSW*

During the 2003 NSW State election, the Labor government included a policy for a three year moratorium on the introduction of new GM food crops in NSW.[43] That policy

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[31] ACT GM Bill cl 6.
[32] Cultivate includes 'plant, tend, nurture or harvest the plant'. ACT GM Bill Dictionary 'cultivate'.
[33] A GM food plant is a food plant modified by GT (defined in essentially the same terms as in the *GT Act*) or progeny of such a plant that have inherited the modification. ACT GM Bill Dictionary 'GM food plant'. See also 'gene technology' and 'food plant'.
[34] ACT GM Bill cl 7(1).
[35] ACT GM Bill Dictionary 'food plant'.
[36] ACT GM Bill cl 8.
[37] The Act, as enacted, now requires the Minister to consult with the newly created ACT Advisory Council on Gene Technology before giving an exemption. *Gene Technology (GM Crop Moratorium) Act 2004* (ACT) ('*ACT GM Act*') s 8(2). See s 11 with respect to the Advisory Council.
[38] ACT GM Bill cl 38. Cf the *ACT GM Act* s 39(1) which provides that the Act is to expire no earlier than 17 June 2006, on a date to be fixed.
[39] ACT GM Bill cl 9. Pursuant to the *Criminal Code 2002* (ACT) s 20(4) recklessness includes intention, knowledge or recklessness. See also ACT GM Bill cl 5. See further cls 13(1) and 14 (now *ACT GM Act* ss 14(1) and 15).
[40] ACT GM Bill cl 11(2) (now *ACT GM Act* s 12(2)).
[41] ACT GM Bill cl 11(3) (now *ACT GM Act* s 12(3)).
[42] ACT GM Bill cls 28(4) and 31 (now *ACT GM Act* s 29(4) and 32). See also ACT GM Bill cl 34 (now *ACT GM Act* s 35).
[43] P Young, 'States, Feds divided on GM Crops' (7 March 2003) *Australian Biotechnology News* (http://www.biotechnews.com.au/index.php?id=120808320&taxid=6) (copy on file with author).

became law pursuant to the *Gene Technology (GM Crop Moratorium) Act 2003* (NSW).[44] The Act and its purpose are generally the same as the ACT GM Bill and its purpose although there are some differences. As in the ACT, the relevant Minister can publish moratorium orders prohibiting the cultivation[45] of specified GM food plants.[46] GM food plants are defined in the same way as in ACT.[47] A moratorium order with respect to the GM canola case study was published on 25 July 2003.[48] There is no minimum or maximum time limit for such an order although the Act expires in 2006.[49]

It is an offence to cultivate GM food plants contrary to the moratorium knowing or being reckless as to whether the plant is a GM food plant.[50] Unlike in the ACT, there is no requirement for such intent with respect to whether or not there is any contravention of a moratorium order. The Minister can grant exemptions.[51] Dealings with GM canola not involving intentional release into the environment[52] and certain research trials[53] have been exempted from the moratorium. Unlike pursuant to the ACT GM Bill, a new body, the NSW Agricultural Advisory Council on Gene Technology, must be consulted before an exemption is made.[54]

There is no provision for compensation to any third person affected by a breach of the legislation. The Act expressly provides that no compensation is payable by the Government to a person whose crop is destroyed or otherwise affected pursuant to Government action[55] after being contaminated.[56] This includes where future cultivation of the contaminated land is prohibited.[57] The owner or person with control or custody of the plants is liable for the costs of destruction.[58]

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[44] The Act commenced 25 June 2003 although the Act applies to plants planted before that date. *NSW GM Act* Sch 1 cl 2. However, no offence occurs with respect to acts/omissions before the declaration of the moratorium order.
[45] Cultivate includes 'plant, tend, nurture or harvest the plant'. *NSW GM Act* s 4(1) (definition of 'cultivate').
[46] *NSW GM Act* s 6. Alternatively the cultivation of a class of GM food plants can be prohibited. See also *Gene Technology (New South Wales) Act 2003* (NSW) s 6(1).
[47] See *NSW GM Act* s 4(1) (definitions of 'GM food plant' and 'food plant') and s 5.
[48] *NSW Government Gazette*, No 119 25 July 2003, p 7513. See also *NSW Government Gazette*, No 198 24 December 2003, p 11686 Moratorium Order Number 2 with respect to a second GM canola.
[49] *NSW GM Act* s 43.
[50] *NSW GM Act* s 7. See also ss 20 and 21. Possible penalties include imprisonment for two years, a fine or both. For corporations, see also s 37. With respect to proof of defence see s 36.
[51] *NSW GM Act* s 8.
[52] *NSW Government Gazette*, No 119 25 July 2003 Exemption Order Number 1, p 7516.
[53] *NSW Government Gazette*, No 198 24 December 2003 Exemption Order Number 2, pp 11684-5.
[54] *NSW GM Act* s 8(2). See *NSW GM Act* s 13 with respect to the Council.
[55] Pursuant to *NSW GM Act* s 14.
[56] *NSW GM Act* s 33(1).
[57] Pursuant to *NSW GM Act* s 14(4).
[58] *NSW GM Act* s 16.

3.3.3 *SA*

The *Genetically Modified Crops Management Act 2004* (SA) commenced on 29 April 2004.[59] It provides for the designation of areas of the State as GM or GM-free for all or particular crops to preserve the identity of food crops.[60] The whole State has been designated as GM free.[61] The Act applies only to GM food crops.[62] 'Food crops' are crops intended for human or livestock consumption.[63] Animals are not included in the term 'crop'.

Under the Act, cultivating[64] a GM food crop in a designated area[65] is an offence.[66] Exemptions can be granted for limited and contained cultivation or, if the person has a DIR licence from the GTR, small scale cultivation for experimental purposes.[67] Exemptions for commercial releases can also be granted if the cultivation is to occur in a system designed to ensure segregation of the GM crop from other crops.[68]

There is no requirement that the cultivation be done knowingly or recklessly as to whether the crop is GM. However, the Act provides for a defence for those innocently contaminated by a GMO. Such people are protected from any action in a SA court or under SA law on account of the fact that the material is present on their land or that the person has dealt with the material.[69] The defence requires the owner or occupier of the

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[59] For earlier legislative attempts in SA see Genetically Modified Material (Temporary Prohibition) Bill 2000 (SA); Gene Technology (Temporary Prohibition) Bill No 23 of 2002; Gene Technology (Temporary Prohibition) Bill No 60 of 2002.

[60] *SA GM Act* s 5(1). The designation is made by the Governor on the recommendation of the relevant Minister. See further s 5(2) and (3).

[61] Genetically Modified Crops Management (Designation of Areas) Regulations 2004 (SA) reg 3. See also *The South Australian Government Gazette* 22 April 2004, p 1092.

[62] *SA GM Act* s 5.

[63] *SA GM Act* s 3(1) (definition of 'food crop'). A GM food crop is essentially one that is a GMO under the *Gene Technology Act 2001* (SA) (which uses similar definitions to those in the Cth *GT Act*) or its progeny that have inherited GM traits. See s 3(1) (definitions of 'genetically modified food crop', 'genetically modified organism' and 'gene technology'). See also definitions of 'livestock' and 'plant'.

[64] 'Cultivate' is defined as including '(a) to breed, germinate, propagate, grow, raise, culture, harvest or collect plants, or plant material, for, or as part of, that crop; (b) to spread, disseminate, deal with or dispose of ant plant or plant material that has formed part of that crop; (c) to undertake any other activity brought within the ambit of this definition by the regulations' but does not include use of crop products as animal feed in prescribed circumstances or any other activity excluded by the regulations. *SA GM Act* s 3(1) (definition of 'cultivate'). There are, as yet, no relevant regulations.

[65] Or cultivating a GM food crop of the wrong class, as the case may be. See *SA GM Act* s 5(1)(b) and (c).

[66] *SA GM Act* s 5(12). Punishable by fine. Section 5(12). For bodies corporate see also s 22.

[67] *SA GM Act* s 6(2)(i) and (ii). An exemption has been made for some releases of GM canola. See *The South Australian Government Gazette*, 13 May 2004, pp 1249-56 Genetically Modified Crops Management Act 2004 Exemption Notice and *The South Australian Government Gazette*, 29 April 2004, pp 1123-30 Genetically Modified Crops Management Act 2004 Exemption Notice.

[68] *SA GM Act* s 6(2)(iii).

[69] *SA GM Act* s 27(2).

contaminated land not to have 'deliberately dealt with a crop knowing that genetically modified plant material was present in order to gain a commercial benefit'.[70] The court must also be satisfied that it is not in the interests of justice that another person's rights with respect to the material should be recognised or protected.[71] This defence will protect inadvertently contaminated farmers from conviction for offences under the *Gene Technology Act 2001* (SA), other SA environmental legislation or from liability in tort as discussed in Chapter 5.

GM crops cultivated in contravention of the Act, whether an offence or not, can be destroyed.[72] Even those inadvertently contaminated may have their crops destroyed. In such cases though, compensation is payable by the Crown.[73] Contraveners of the Act can be required to reimburse the Government for destruction costs.[74] There is no requirement that the person have been convicted in such cases. Furthermore, *convicted* offenders can be ordered, inter alia, to compensate others for loss or damage caused by any contravention of the legislation or pass on any financial benefit from the offence to the Government.[75] Unlike in ACT and NSW though, there is no power to restrict the future use of land. The Act is to be reviewed by 29 April 2007.[76]

A Bill dealing with GMOs has also been introduced into the SA Parliament. That Bill is the Gene Technology (Responsibility for the Spread of Genetically Modified Plant Material) Bill 2003.[77] Pursuant to it those with a proprietary interest in a GM plant will be liable in tort to owners or occupiers of land who suffer loss or damage because the GMO has spread to it.[78] It is not necessary that the defendant have been negligent.[79] 'Proprietary interest' is not defined but presumably includes those with patent rights in the plant or who own and release the plant. There is one defence. It requires the defendant to prove, amongst other things, that they had produced[80] 'comprehensive instructions of the highest

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[70] *SA GM Act* s 27(3).
[71] *SA GM Act* s 27(3).
[72] *SA GM Act* s 18(1).
[73] *SA GM Act* s 18(5).
[74] *SA GM Act* s 18(4).
[75] *SA GM Act* s 24(1).
[76] *SA GM Act* s 29(1).
[77] As at 12 May 2004 the Bill is in Committee in the Legislative Council.
[78] Gene Technology (Responsibility for the Spread of Genetically Modified Plant Material) Bill 2003 (SA) cl 3.
[79] Gene Technology (Responsibility for the Spread of Genetically Modified Plant Material) Bill 2003 (SA) cl 3(2).
[80] Or ensured the production of.

standard relating to the measures' to prevent the spread of the material.[81] The defence is available only if the defendant proves that they took all reasonable steps to ensure the instructions were always issued with the supply of the plant material but the instructions had not been complied with to a material degree.[82] There is no explanation of how a court is to determine whether the instructions are of the 'highest standard' or what factors are relevant in making that determination. It is not clear therefore whether meeting the requirements under the *GT Act* and/or standards set by the industry concerned would be sufficient.

3.3.4 *Tasmania*

Tasmania had acted to limit GMO releases in that jurisdiction before the introduction of the Policy Principle.[83] The possession[84] of certain GM plants and plant materials has been banned in Tasmania since 22 July 2000[85] to protect Tasmania's marketing image.[86] Under current arrangements, all GMOs[87] which are plants or plant products of prescribed species are declared pests under the *Plant Quarantine Act 1997* (Tas).[88] All of Tasmania[89] has been declared a protected area.[90] Such GMOs are then prohibited from being moved into

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[81] Gene Technology (Responsibility for the Spread of Genetically Modified Plant Material) Bill 2003 (SA) cl 3(3).
[82] Gene Technology (Responsibility for the Spread of Genetically Modified Plant Material) Bill 2003 (SA) cl 3(3).
[83] There was doubt whether the early Tasmanian action was constitutionally valid. It is now largely a moot point given the passing of the Designated Areas Policy Principle. See M Tranter, 'A question of confidence: an appraisal of the operation of the Gene Technology Act 2000' (2003) 20 *Environmental and Planning Law Journal* 245, 257.
[84] Not defined in the legislation.
[85] Tasmanian Government Notice, Plant Quarantine, *Plant Quarantine Act 1997 Section 10, Tasmanian Government Gazette*, 26 July 2000, p 1164. The original notice appeared in the public notices section of State newspapers on 22 July 2000. That declaration was revoked on 10 April 2002. See Tasmanian Government Notice, Plant Quarantine, *Plant Quarantine Act 1997 Section 8, Tasmanian Government Gazette*, 10 April 2002, p 430.
[86] Tasmania, Dept of Primary Industries, Water and Environment, *Gene Technology Policy Review – Position Paper; A Balanced Approach* (2003) (http://www.dpiwe.tas.gov.au/inter.nsf/WebPages/CPAS-5K6VRK?open accessed 27/1/04).
[87] Defined as the term is defined under the *GT Act*. See Tasmanian Government Notice, Plant Quarantine, *Plant Quarantine Act 1997 Revocation and Declaration of Protected Area, Tasmanian Government Gazette*, 29 January 2003, p 109.
[88] Pursuant to *Tas Quarantine Act* s 8. See also Tasmanian Government Notice, Plant Quarantine, *Plant Quarantine Act 1997 Revocation and Declaration of Protected Area, Tasmanian Government Gazette*, 29 January 2003, p 109.
[89] Except certain Crown land.
[90] *Tas Quarantine Act* s 35. See Tasmanian Government Notice, Plant Quarantine, *Plant Quarantine Act 1997 Revocation and Declaration of Protected Area, Tasmanian Government Gazette*, 29 January 2003, p 109.

the State for intentional release into the open environment.[91] Banned plants include GM canola and GM carnations.[92]

Contravention of the prohibition is an offence.[93] The legislation provides for a defence if the 'offender' proves that the offence was not the result of any failure to take all reasonable action and care to avoid committing the offence.[94] The prescribed GM plants can be destroyed under the Act, whether the owner has been inadvertently contaminated or not.[95] The owner/occupier is then liable for the costs of destruction.[96] No compensation from the Government is available[97] nor is there provision for compensation from any 'offender'. Permits are provided for under the legislation.[98] The ban is to be reviewed by 30 June 2008.[99] There is also an extra-legislative moratorium on the commercial release of GM animals in Tasmania and the Government is opposed to the use of GM livestock feed.[100]

On 7 April 2004 a new Bill was introduced to the Tasmanian House of Assembly.[101] That Bill, the Genetically Modified Organisms Control Bill 2004, applies to both GM plants and animals.[102] Under the Bill the whole or part of Tasmania may be declared an area free of GMOs if it 'would aid in preserving the identity of non-genetically modified crops and animals for marketing purposes'.[103] A substantial fine is imposed on those who deal with[104] GMOs in a GMO-free area without a permit under the Bill[105] *and* a licence under

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[91] *Tas Quarantine Act* s 36. See Tasmanian Government Notice, Plant Quarantine, *Plant Quarantine Act 1997 Revocation and Declaration of Protected Area*, *Tasmanian Government Gazette*, 29 January 2003, p 109.

[92] Tasmanian Government Notice, Plant Quarantine, *Plant Quarantine Act 1997 Revocation and Declaration of Protected Area*, *Tasmanian Government Gazette*, 29 January 2003, p 109; Tasmanian Government Notice, Plant Quarantine, *Plant Quarantine Act 1997Amendment of Declaration of a Protected Area*, *Tasmanian Government Gazette*, 11 June 2003, p 858.

[93] *Tas Quarantine Act* s 39. Punishable by fine. Section 39. For corporations, see s 87.

[94] *Tas Quarantine Act* s 86.

[95] *Tas Quarantine Act* s 54.

[96] *Tas Quarantine Act* s 78.

[97] *Tas Quarantine Act* s 82.

[98] *Tas Quarantine Act* s 38.

[99] This is a policy position and not provided for in the legislation. See Tasmania, *Parliamentary Debates*, House of Assembly, 21 April 2004, (Kons, Minister for Primary Industries and Water).

[100] Tas, Dept of Primary Industries, Water and Environment, *Gene Technology Policy Review – Position Paper; A Balanced Approach* (2003) (http://www.dpiwe.tas.gov.au/inter.nsf/WebPages/CPAS-5K6VRK?open accessed 27/1/04), pp 4-5, 12.

[101] As at 12 May 2004, the Bill is still to be considered by the Legislative Assembly.

[102] Tas GM Bill cl 3 (definitions of 'genetically modified organism' and 'GMO'). 'Genetically modified organism' is defined as in the *GT Act 2001* (Tas), which uses definitions in similar terms to those in the Cth *GT Act*. 'Plants' and 'animals' are not defined.

[103] Tas GM Bill cl 5(1).

[104] 'Deal with' is defined in similar terms to the definition in the *GT Act*. See Tas GM Bill cl 3 (definition of 'deal with').

[105] With respect to permits see Tas GM Bill Part 3 Div 1.

the GT regulatory scheme.[106] When deciding whether to grant a permit, the likely impact on market access for non-GMOs must be considered.[107] There is no provision regarding when an impact will be adverse and, presumably, justify refusal of a permit.

The Bill does not require intention for there to be an offence. However, there is some provision for those who inadvertently deal with GMOs. Such people can be ordered to destroy the GMO.[108] They can then seek compensation under the legislation for loss or damage suffered as a result of the destruction.[109] Where the Government destroys the GMO, the person reasonably believed to have introduced the GMO to the land or to have dealt with it or with possession, control or charge of it can be required to pay the reasonable costs of the destruction.[110] Where a permit holder contravenes the legislation,[111] directions to rectify matters giving rise to the contravention can also be made.[112] This could allow directions that compensation be paid (or repaid) by the permit holder to the contaminated party.

3.3.5 *Victoria*

In 2000 Victoria investigated 'the potential to label products sourced in particular areas of Victoria as "GEFZ" products – that is, they come from Genetic Engineering Free Zones'.[113] It concluded that statutory, regional GM-free zones would not be established.[114] The Victorian Government nevertheless announced on 8 May 2003 that there would be a twelve month moratorium on the commercial production of GM canola in Victoria.[115] The Government entered into an extra-legislative agreement with the companies wanting to release GM canola to that effect.[116] An independent reviewer was appointed in November

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[106] Tas GM Bill cl 7. With respect to body corporates, see also cl 31.
[107] Tas GM Bill cl 9(2)(b). The Secretary of the Department for Primary Industries and Water will make the decision. See cl 9(1). See also cl 3 (definition of 'Secretary').
[108] Tas GM Bill cl 26(b).
[109] See amendment moved by Mr Booth, Tasmania, *Parliamentary Debates*, House of Assembly, 22 April 2004, (Booth, Member for Bass). See also cl 28.
[110] Tas GM Bill cl 27(6).
[111] Or in other yet to be prescribed circumstances. Tas GM Bill cl 19(2).
[112] Tas GM Bill cl 19(4) and (5).
[113] Vic, Dept of Natural Resources and Environment, *Genetic engineering-free zones* Consultation Paper (March 2001), p 3.
[114] Vic, Dept of Natural Resources and Environment, *Genetic Engineering-free Zones. Report of the Victorian Government Consultation* (December 2001), p 11. Nevertheless, effective S&IP systems were found to be needed where there are market opportunities for differentiated agrifood products (p 11).
[115] Vic, *Report of the Independent Reviewer to the Government of Victoria. Review of Market Impacts of Genetically Modified Canola and Industry Preparedness* by P J Lloyd (undated, circa 2004) ('Lloyd Report').
[116] C McGrath, 'A system under strain: The Regulation of Gene Technology' (2003) 2 *National Environmental Law Review* 32, 36.

2003 to advise the Victorian Government on the marketing impacts of the commercial release of GM canola.[117] The reviewer's report recommended, inter alia, a limited release of GM canola for a trial period beginning in 2004.[118] Despite this, on 25 March 2004 the moratorium on commercial releases of GM canola was extended until at least 2008.[119]

On 31 March 2004, the Control of Genetically Modified Crops Bill 2004 was introduced into the Victorian Legislative Assembly. The Act commenced on 12 May 2004.[120] Pursuant to the legislation, the Minister may make orders designating all or part of Victoria as GM-free for all or certain crops or, conversely, order that GM crops may be grown in that area.[121]

GM crops are regulated under the legislation. These are crops that consist of or include GM plants.[122] 'Plant' includes all plants, whether food plants or otherwise.[123] It also includes seed or other parts of the plant. Accordingly plants and their parts to be used as animal feed are included. The cultivation[124] of GM canola, although licensed by the GTR, is prohibited until 29 February 2008.[125] The Minister can grant exemptions allowing cultivation of specified classes of GM crops on a limited scale for the purposes of research or development.[126] There is no explanation of research or development. Exemptions can also be granted to allow dealings with GM crops, their material or specified classes of GM crops.[127] Cultivation pursuant to a DNIR licence from the GTR is also exempt.[128]

It is an offence to cultivate GM crops in contravention of an order[129] if the person knows or is reckless as to whether the crop is a GM crop.[130] As in SA the Minister can determine

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[117] Minister Bob Cameron, Victorian Minister for Agriculture, *Media Release: Victoria Appoints Independent GM Canola Reviewer* (26 November 2003).
[118] Lloyd Report, Recommendation 1, p ix.
[119] D Buttler, 'GM canola out until 2008' *Herald Sun* (Melbourne), 26 March 2004, p 13.
[120] *Vic GM Act* s 2.
[121] *Vic GM Act* s 4(1).
[122] *Vic GM Act* s 3 (definition of 'GM crop'). See also 'genetically modified organism' which is defined in the same way as in the Victorian and therefore Commonwealth *GT Act*.
[123] *Vic GM Act* s 3 (definition of 'plant').
[124] Cultivate is given an extended meaning and includes to breed, germinate, propagate, grow, raise, culture, harvest or collect plants or plant material and any activity prescribed by regulations. *Vic GM Act* s 3 (definition of 'cultivate').
[125] *Vic GM Act* s 28 and Sch.
[126] *Vic GM Act* s 6(1)(a).
[127] *Vic GM Act* s 6(1)(b).
[128] *Vic GM Act* s 6(3).
[129] Or to otherwise contravene an order.
[130] *Vic GM Act* s 17(1). The legislation also restricts dealings with GM crop related material. See s 17(1) and s 3 (definition of 'GM crop related material'). Penalty is a fine. Section 17(2). For bodies corporate, see also s 21.

threshold amounts for the presence of a GMO in crops.[131] GMO amounts less than the threshold are then to be disregarded for the purposes of the Act.[132] As in SA there is no explanation of how such thresholds will be set. Crops cultivated in contravention of the Act can be destroyed.[133] However, this requires an order by the Magistrates Court.[134] There is no provision for compensation. There is though a defence of due diligence.[135] This requires proof that all reasonable precautions were taken and due diligence was exercised to prevent the offence.

The Act creates a further offence of particular relevance to commercialisers. Providing a GMO to another person where the provider[136] knows or had reasonable cause to know that the other person intended either to contravene an order or to pass the GMO to someone else to do so, is an offence.[137]

3.3.6 *WA*

The WA Cabinet has passed legislation to reinforce its' policy of a five year moratorium on commercial plantings of GM food crops.[138] That legislation, the *Genetically Modified Crops Free Areas Act 2003,* gives the responsible Minister power to issue orders designating areas free of all or specified GM crops.[139] The legislation applies only to GM plants.[140] 'Plants' is not defined and therefore could include food and non food plants. On 22 March 2004 the Premier announced that all of the State would be declared a GM-free area[141] to 'protect the State's "clean and green" status'.[142]

Under the legislation it is an offence to 'cultivate'[143] GM crops in a designated area.[144] However, there must be an intentional release to the environment.[145] Further, the

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[131] *Vic GM Act* s 7(1); *SA GM Act* s 4(1).
[132] *Vic GM Act* s 7(3); *SA GM Act* s 4(2).
[133] *Vic GM Act* s 15(1).
[134] *Vic GM Act* s 15(1).
[135] *Vic GM Act* s 24.
[136] Referred to in the Act as the 'gene technology provider'. They must have made, developed, produced or manufactured the GMO. See *Vic GM Act* s 18(1).
[137] *Vic GM Act* s 18(1).
[138] DAPP Regulatory Impact Statement s 5. With respect to earlier steps in WA see Genetically Modified Material (Temporary Prohibition) Bill 1999.
[139] *WA GM Act* s 4(1). A GMO is an organism modified by GT (defined as in the *GT Act*) or its progeny that have inherited the GM traits. *WA GM Act* s 3 (definition of 'genetically modified organism').
[140] See *WA GM Act* s 3 (definition of 'genetically modified crop'). See also 'cultivate' which refers only to crops.
[141] Pursuant to *WA GM Act* s 4(2).
[142] WA Premier's Dept, Media Release *Western Australia to be "GM-free"* (22 March 2004).
[143] 'Cultivate' includes 'breed, propagate, grow, raise or culture plants, or parts of plants, for that crop'. *WA GM Act* s 3 (definition of 'cultivate').
[144] *WA GM Act* s 5. Penalty is a fine.

'offender' must know or be reckless as to whether the crop is a GM crop.[146] Finally, the moratorium does not apply to field trials licensed under the *GT Act*[147] or where an exemption has been granted.[148] A 'field trial' is small scale cultivation of the crop for the purpose of assessing the viability and environmental risks of the crop and not for commercial purposes.[149] The meaning of commercial purposes is not explained.

If a person is convicted under the legislation and another person has suffered loss or damage because of the offence, the offender can be ordered to compensate that other person.[150] As in all other States, crops inadvertently contaminated by a GMO can be destroyed.[151] Compensation is available to the owners of such crops.[152] This is subject to it being just.[153] Further, the person seeking compensation must not have been successfully prosecuted under the Act nor be the subject of a current prosecution.[154] Offenders responsible for the contamination may be ordered to repay the Government the costs of such destruction or compensation.[155] The Act is to be reviewed after five years.[156]

3.4 COMMENT AND CONCLUSION

Socio-economic concerns and the GTR's failure to consider them perhaps led to the introduction of the Designated Areas Policy Principle. Whether concerns about GMO releases, particularly the economic effect of GMO releases on trade in non-GMOs, are legitimate is debateable[157] but it seems that most States want more time to consider them.[158] The legislation gives them that time. However, despite being in response to concerns about effects of GMO releases other than risks to human health, safety and the

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[145] *WA GM Act* s 5(3).
[146] *WA GM Act* s 5(1)(d).
[147] *WA GM Act* s 5(2).
[148] *WA GM Act* s 5(4). See also s 6.
[149] *WA GM Act* s 3 (definition of 'field trial')
[150] *WA GM Act* s 10(3).
[151] *WA GM Act* s 8.
[152] *WA GM Act* s 9(1).
[153] *WA GM Act* s 9(2).
[154] *WA GM Act* s 9(3).
[155] *WA GM Act* s 10(2).
[156] *WA GM Act* s 19(1).
[157] See section 1.4.2 in Chapter 1 on the predicted economic effects on trade of GMO releases. Whether the concerns are justified is outside the scope of this study.
[158] See, for eg, NSW, *Parliamentary Debates*, Legislative Assembly, 30 May 2003, (Newell, Member for Tweed) and NSW, *Parliamentary Debates*, Legislative Assembly, 17 June 2003, (Campbell, Member for Keira and Minister for Regional Development, Illawarra and Small Business).

environment,[159] the legislation does little to clarify what those effects are or how their acceptability or otherwise is to be judged.[160]

Certainly some economic consequences of GMO releases will be considered by Ministers making decisions under the legislation. However, it is not clear whether only negative economic impacts are relevant or whether the economic benefits of GMOs will also be relevant. Social objections, such as concern that farmers' rights to farm as they choose may be lost upon the release of GMOs, may or may not be relevant. It is suggested that this depends upon how broadly 'market' is interpreted by the relevant Minister and how that objection is linked to economic and trade issues. For example, it could be argued that the views of the public, being possible consumers, are relevant to marketing.

Even if relevant, how economic impacts and social objections will be determined and assessed is not clear. Only the SA legislation explicitly requires consideration of the likely impact of GMO cultivation on markets in making moratorium orders.[161] The SA legislation also provides that the Minister must, inter alia, take into account 'market requirements' when deciding whether to grant exemptions.[162] The Tasmanian Bill explicitly requires consideration of the impact of GMOs on non-GM agriculture when making decisions regarding permits.[163] As discussed below, other jurisdictions have limitations with respect to the scale and purpose of releases for which exemptions are sought. However, the SA legislation is alone in requiring consultation before a moratorium order is made.[164] In NSW and SA consultation is required but only before making an exemption.[165] Further, the review of decisions to make moratorium orders or

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[159] See ACT GM Bill cl 6; *NSW GM Act* s 3; *SA GM Act* Preamble; Tas GM Bill Preamble; *Vic GM Act* s 1; *WA GM Act* Preamble. The *Tas Quarantine Act* does not deal with this.

[160] Parliamentary debates and explanatory memoranda also provide little, if any, assistance. For the limited assistance, see SA, *Parliamentary Debates*, House of Assembly, 17 July 2003, (Hanna, Member for Mitchell); Tas, *Parliamentary Debates*, House of Assembly, 22 April 2004, (Kons, Minister for Primary Industries and Water); Vic, *Parliamentary Debates*, House of Assembly, 1 April 2004, (Cameron, Minister for Agriculture).

[161] *SA GM Act* s 5(5)(c).

[162] *SA GM Act* s 6(2)(b).

[163] Tas GM Bill cl 9(2)(b).

[164] There must be consultation with the public (see *SA GM Act* s 5(3)) and an Advisory Committee (see *SA GM Act* s 5(8)). See *SA GM Act* Part 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. *Vic GM Act* s 10.

[165] In NSW, there must be consultation with an Advisory Council created under the Act. See *NSW GM Act* s 8(2). With respect to the Advisory Council see s 13. In SA consultation with an Advisory Committee is required. See *SA GM Act* s 6(3). The *ACT GM Act*, in contrast to the Bill, also provides that an Advisory Council is to be consulted with respect to exemptions. See *ACT GM Act* s 8(2). See also s 11 with respect to the Council.

grant exemptions/permits is expressly prohibited in the ACT and NSW[166] and not provided for in the moratorium legislation of the other States.[167]

It is disappointing that the States did not take the opportunity to clarify these matters. Without such clarification there is no definite framework against which commercialisers can confidently judge whether a declaration or exemption will be made or revoked. The lack of clarity regarding the consequences relevant to decisions under the State moratorium legislation and what steps will be taken to assess those consequences also has, as discussed in Chapters 5 and 6, repercussions when attempting to predict commercialisers' liability in tort and pursuant to environmental legislation.

It is clear though, that the State moratorium legislation directly affects whether and how field trialling can proceed. The differences between jurisdictions means that commercialisers must consider which State is the most appropriate for them. All GMO commercialisers will need to comply with at least some State imposed limitations. Commercialisers of GM pigs would need be concerned in such regard only in Tasmania.[168] Field trialling of GM carnations, as a non-food plant not included within any moratorium order thus far, is restricted in WA and Tasmania. Field trialling of GM canola, however, is or will be restricted in all States but Queensland and the NT. That GMOs will not respect State boundaries means differences in approach between the States is a further complication for commercialisers.

How restrictive in practice the moratoria are depends upon the ease with which exemptions/permits are granted. In WA, the moratorium does not apply to GTR licensed field trials.[169] 'Field trial' is not defined in the *GT Act*. However, the WA legislation limits 'field trials' to trials that are not for commercial purposes.[170] Further, the cultivation must be on a small scale and for the purpose of assessing the viability and environmental risks of the crop.[171] Similarly in SA and Victoria where the circumstances in which exemptions can be granted are more restricted by the legislative provisions than in the other jurisdictions,[172] there is a requirement of, amongst other things, cultivation on a

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[166] ACT GM Bill cls 10 and 39; *NSW GM Act* ss 11 and 18.
[167] Other than under the Tas GM Bill cl 30(a) where a person aggrieved by a decision, inter alia, to refuse to grant a permit can have the decision reviewed.
[168] Assuming the Tas GM Bill is enacted.
[169] *WA GM Act* s 5(2).
[170] *WA GM Act* s 3 (definition of 'field trial').
[171] *WA GM Act* s 3 (definition of 'field trial').
[172] Cf *SA GM Act* s 6(2) and *Vic GM Act* s 6(1) with ACT GM Bill cl 8(1); *NSW GM Act* s 8(1) and (6); *Tas Quarantine Act* s 38(1) and (2); Tas GM Bill cl 9(2); *WA GM Act* s 6(1). In NSW (*NSW GM Act* s 8(2)), SA

limited scale for the purposes of, in SA, experiment or, in Victoria, research or development.[173] In no jurisdiction is there any clarification of these restrictions. In SA however, trials undertaken for the dual purposes of experimentation and seed production have been exempted.[174] SA's exemption provisions also allow cultivation on a larger scale and for other purposes provided the GMO and its material are segregated from other crops and material.[175] Even in those jurisdictions where there are no express legislative limitations on exemptions, such as NSW, large scale trials have been refused exemption.[176]

The State moratorium legislation exposes commercialisers to new offences if GMO releases occur in designated areas without exemption/permit. Failure to comply with State restrictions can, depending upon the jurisdiction, result in fines, imprisonment or both. It may also be relevant to commercialisers' common law or statutory liability. This is taken up in Chapters 5 and 6. However, of interest to commercialisers, none of the State moratorium legislation provides for the issuing of injunctions where there is a breach or threatened breach of the legislation on the application of a member of the public. Further, only the NSW legislation provides for the Minister to seek an injunction in such circumstances.[177]

The offences created by, and defences provided in, the legislation differ between States. For example, in SA and Tasmania, neither intention nor recklessness is required to contravene the legislation.[178] In ACT the intention or recklessness must be not only as to the GM status of the organism but also as to whether there is a contravention of the moratorium.[179] Intention or recklessness as to whether the organism is a GMO is required in NSW, Victoria and WA[180] with the WA legislation also requiring an intentional release to the environment.[181]

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in some cases (*SA GM Act* s 6(3)) and pursuant to the *ACT GM Act* s 8(2) though, advisory bodies must be consulted prior to the giving of exemptions.

[173] *SA GM Act* s 6(2)(a)(i); *Vic GM Act* s 6(1)(a).

[174] *The South Australian Government Gazette*, 1 July 2004, p 2344 Genetically Modified Crops Management Act 2004 Exemption re GTR licence DIR 032/2002.

[175] *SA GM Act* s 6(2)(a)(iii).

[176] NSW refused exemption for trials on 3,500 hectares in May 2004. NSW, *Parliamentary Debates*, Legislative Assembly, 7 May 2004, p 8654 (Draper, Member for Tamworth).

[177] See *NSW GM Act* s 32.

[178] *SA GM Act* s 5(12); *Tas Quarantine Act* s 39; Tas GM Bill cl 7. Defences are provided in those two jurisdictions. See *SA GM Act* s 27; *Tas Quarantine Act* s 86. There is no defence, though, provided under the Tas GM Bill.

[179] ACT GM Bill cl 9.

[180] *NSW GM Act* s 7; *Vic GM Act* s 17(1); *WA GM Act* s 5(1)(d).

[181] *WA GM Act* s 5(3). The term 'intentional release to the environment' is not defined.

The legislation also differs in its application because of the differing GMOs to which it applies. For example, the moratorium applies to only prescribed GM plants under the current Tasmanian Act,[182] all GMOs under the proposed Tasmanian Bill[183] and all GM plants in Victoria[184] and WA.[185] In SA the legislation applies only to GM plants intended for human or animal consumption[186] and in ACT and NSW[187] only GM plants for human consumption. Pursuant to all legislation other than the Tasmanian GM Bill and that in WA, parts and/or products of the plant are included in the term plant. Disappointingly for commercialisers, all States but SA and Victoria, failed to take the opportunity to clarify thresholds with respect to GMO presence. The lack of a clear threshold as to when GMO presence in a crop can be disregarded creates considerable uncertainty for commercialisers in determining when the legislation applies. Additionally these failings will, as discussed in Chapter 5, have important repercussions in tort proceedings following GM contamination and only add to the confusion facing GMO commercialisers.

Importantly, in SA, WA and Tasmania[188] the legislation also creates a new statutory liability to compensate those harmed by the cultivation of GM crops.[189] This is not provided for in the *GT Act*. The State legislation also goes further than the *GT Act* because in all States it provides for the destruction of a third party's organisms contaminated by GMOs.[190] In Victoria, though, this can only be done with the order of the court.[191] In ACT and NSW contaminated third parties can also be restricted in the future use of their land.[192] In NSW, Victoria and Tasmania (under its current regime) and for all relevant purposes, ACT, no governmental compensation is available under the legislation to such persons for these losses.[193] This creates another form of harm for which third parties may seek compensation from commercialisers in tort or under environmental legislation. Additionally, in NSW and under the Tasmanian GM Bill the owner or person with custody

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[182] *Tas Quarantine Act* s 36.
[183] Tas GM Bill cl 13 (definitions of 'genetically modified organism' and 'GMO').
[184] *Vic GM Act* s 3 (definition of 'GM crop').
[185] *WA GM Act* s 3 (definition of 'genetically modified crop').
[186] *SA GM Act* s 3(1) (definition of 'food crop').
[187] ACT GM Bill Dictionary 'food plant'; *NSW GM Act* ss 4(1) (definition of 'food plant') and 5.
[188] Assuming the Tas GM Bill is enacted.
[189] *SA GM Act* s 24(1); *WA GM Act* s 10(3); Tas GM Bill cl 19(4) and (5).
[190] ACT GM Bill cls 11(2) and 12 (now *ACT GM Act* ss 12(2) and 13); *NSW GM Act* s 14(2) and (3); *SA GM Act* s 18(1) and (2); *Tas Quarantine Act* s 54; Tas GM Bill cls 26 and 27; *Vic GM Act* s 15(1); *WA GM Act* s 8(1) and (2).
[191] *Vic GM Act* s 15.
[192] ACT GM Bill cl 11(3) (now *ACT GM Act* s 12(3)); *NSW GM Act* s 14(4).
[193] *NSW GM Act* s 33(1); *Tas Quarantine Act* s 82; ACT GM Bill cls 28(4) and 31 (now *ACT GM Act* ss 29(4) and 32). *Vic GM Act* has no relevant provision for compensation.

or control of the contaminated plants is liable for the costs of destruction.[194] Commercialisers can also be made responsible for such costs in SA and WA.[195]

That the position in some or all States may change with or without a change in Government further adds to the legal challenges of those trying to commercialise GMOs in Australia. In Victoria, for example, it seems that a change of Government would see a change of approach.[196] In SA though, a change of Government is unlikely to result in a lifting of the moratorium.[197] What will happen on the expiry of the various legislation is also difficult to predict.

Finally, none of the legislation protects commercialisers who comply with the legislation from tort or statutory liability. Interestingly, although the penalties for offences under the State moratorium legislation are serious,[198] an offence under that legislation is not clearly relevant to whether a licence applicant is a suitable person under the *GT Act*. As discussed in Chapter 2, only convictions under legislation for the protection of the environment or the health and safety of people are described as 'relevant' to the *GT Act* licence procedure.[199] The purpose of the State legislation is to preserve the identity of GMOs and/or non-GMOs for marketing purposes, rather than protect people or the environment.[200] The exception to this is Tasmania where the current relevant Act is one for the protection of the environment. However, if the Tasmanian Bill is enacted, this will not be the case.[201] It should be noted though that the *GT Act* does not limit consideration of applicants' suitability to 'relevant convictions'. Even convictions not defined as relevant can be considered.[202]

For the challenges described above to be worth meeting, commercialisers must first be satisfied as to their IP rights in the GMO. IP rights in GMOs are the subject of the next Chapter.

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[194] *NSW GM Act* s 16(2); Tas GM Bill cl 27(1) (definition of 'responsible person') and 27(6).
[195] *SA GM Act* s 18(4); *WA GM Act* s 10(1).
[196] See, for eg, comments by the Leader of The Nationals in Victoria, Vic, *Parliamentary Debates*, Legislative Assembly, 22 April 2004, pp 773-5 (Ryan, Leader of The Nationals) and Dr Napthine, Vic, *Parliamentary Debates*, Legislative Assembly, 20 April 2004, pp 605-10 (Napthine, Member for South-West Coast).
[197] See, for eg, SA, *Parliamentary Debates*, House of Assembly, 29 March 2004 (Williams, Member for MacKillop).
[198] Being a substantial fine in SA, Tasmania, Victoria and WA and fine, imprisonment or both in ACT and NSW. See ACT GM Bill cl 9; *NSW GM Act* s 7; *SA GM Act* s 5(12); *Tas Quarantine Act* s 39; Tas GM Bill cl 7; *Vic GM Act* s 17(2); *WA GM Act* s 5(1).
[199] See *GT Act* s 58(3).
[200] See ACT GM Bill cl 6; *NSW GM Act* s 3; *SA GM Act* Preamble; *Vic GM Act* s 1; *WA GM Act* Preamble.
[201] Tas GM Bill Preamble and see cl 5(1).
[202] See *GT Act* s 58(1).

TABLE 3.1: SUMMARY OF PERTINENT PROVISIONS OF STATE MORATORIUM LEGISLATION

	ACT	NSW	SA	TAS	VIC	WA
LEGISLATION	Gene Technology (GM Crop Moratorium) Bill 2004 (The Bill was enacted and the Act commenced after the completion date of this study)	*Gene Technology (GM Crop Moratorium) Act 2003*	*Genetically Modified Crops Management Act 2004* (also Gene Technology (Responsibility for the Spread of Genetically Modified Plant Material) Bill 2003 - not included in Table)	Current: *Plant Quarantine Act 1997* Proposed: Genetically Modified Organisms Control Bill 2004	*Control of Genetically Modified Crops Act 2004*	*Genetically Modified Crops Free Areas Act 2003*
GM TYPE THAT CAN BE REGULATED	GM food plants[a]	GM food plants[b]	GM food crops[c]	Current: Prescribed GM plants and their products and parts Proposed: All GMOs under *GT Act*	GM crops[d]	GM crops[e]

[a] GM plants and their parts grown primarily for, or as an ingredient of, food for human consumption. Does not include plants grown as animal feed.
[b] As for a.

	ACT	**NSW**	**SA**	**TAS**	**VIC**	**WA**
OFFENCE	Cultivating GMO in ACT knowing or being reckless as to whether it is a GMO and whether it contravenes a moratorium order, without exemption	Cultivating GMO in NSW knowing or being reckless as to whether it is a GMO, without exemption	Cultivating GMO in SA, without exemption	Current: Moving GMO into Tas for intentional release into open environment Proposed: Dealing with GMO in GMO-free area without permit *and* GTR licence	Cultivating GMO in Vic knowing or reckless as to whether it is a GM crop, without exemption	Intentionally releasing into environment and cultivating GM crops in WA, knowing or reckless as to whether it is a GM crop, without exemption Does not apply to GTR licensed 'field trials'
PENALTY	Maxm fine of $20,000 (individuals) and $100,000 (corpr'ns), imprisonment for up to 2 years or both	Maxm fine of $55,000 (individuals) and $137,500 (corporations), imprisonment for up to 2 years or both	Maxm fine of $200,000	Current: Maxm fine of $10,000 (individuals) and $50,000 (corporations) Proposed: Maxm fine of $200,000 (individuals) and $1,000,000 (corporations)	Maxm fine of $24,000 (individuals) and $120,000 (corporations)	Maxm fine of $200,000

[c] GM plants and their parts intended for human or animal consumption.
[d] All GM plants and their parts.
[e] All GM plants.

	ACT	NSW	SA	TAS	VIC	WA
INADVERTENT OFFENDERS	Intention required	Intention required	Intention not required Defence – no action in SA against inadvertently contaminated farmers (subject to certain conditions being met)	Current: Intention not required Defence - if taken all reasonable action and care to avoid offence	Intention required Defence – due diligence	Intention required
	Crop can be destroyed and future use of land can be restricted	Crop can be destroyed and future use of land can be restricted	Crop can be destroyed	Crop can be destroyed	Crop can be destroyed on order of Court	Crop can be destroyed
	Limited compensation available from Govt	Act provides that no compensation is available in such circumstances	Compensation available from Govt and com'rcialiser can be ordered to repay Govt Convicted offenders can be ordered to compensate persons harmed by offence	Act provides that no compensation is available	Act makes no provision for compensation in such circumstances	Compensation available from Govt and commercialiser can be ordered to repay Govt Convicted offenders can be ordered to compensate persons harmed by offence

	ACT	NSW	SA	TAS	VIC	WA
				Proposed: Intention not required GMOs can be destroyed Compensation available from Govt May be that permit holders can be ordered to pay/repay compensation		
ABILITY TO SET 'GM' THRESHOLD	No	No	Yes	No	Yes	No
REVIEW/ EXPIRY	Bill provides expires 17 June 2006 (The enacted legislation provides expiry is to be no earlier than 17 June 2006)	Expires 3 March 2006	Review by 29 April 2007	Current: Govt policy to review by 30 June 2008 Proposed: No provision for review/expiry	Order with respect to GM canola expires 29 February 2008	Review after 24 December 2008

TABLE 3.2: EFFECT OF STATE MORATORIA ON FIELD TRIALS OF CASE STUDIES

STATE	GM CANOLA	GM CARNATION	GM PIG
ACT	Prohibited without exemption	Non human food plant therefore legislation inapplicable	Not applicable
NSW	Prohibited without exemption	Non human food plant therefore legislation inapplicable	Not applicable
NT	No moratorium	No moratorium	No moratorium
QLD	No moratorium	No moratorium	No moratorium
SA NOTE: a second Bill makes those with a proprietary interest in GM plants liable to owners/occupiers of land who suffer loss or damage because of GMO spread	Prohibited without exemption	Non human food and non animal feed plant therefore legislation inapplicable	Not applicable

STATE	GM CANOLA	GM CARNATION	GM PIG
TAS	Current: Prohibited without permit Proposed: Prohibited without permit	Current: Prohibited without permit Proposed: Prohibited without permit	Current: Not applicable Proposed: Prohibited without permit
VIC	Prohibited without exemption DNIR licensed releases automatically exempted	Applicable but not covered by current order	Not applicable
WA	Prohibited without exemption Moratorium does not apply to GTR licensed field trials (which must not be for commercial purposes)	Prohibited without exemption Moratorium does not apply to GTR licensed field trials (which must not be for commercial purposes)	Not applicable

CHAPTER 4

INTELLECTUAL PROPERTY PROTECTION FOR GMOS AND THEIR PRODUCTS

4.1 INTRODUCTION

When the Delicious apple tree was being developed, it was grown in an iron cage to prevent shoots being stolen by competitors.[1] The concern for commercialisers is whether IP protection is available to them so that they will not need to take such measures when field trialling their new organisms.

This Chapter discusses the uncertainties that arise when Australian IP regimes are used to protect GMOs and their products. Many of those uncertainties arise because of the unique characteristics of GMOs. For example, that they are living and, unlike other inventions, can self-reproduce will cause particular uncertainties in the application of IP laws created for inanimate objects. Additional uncertainty exists regarding the relevance of socio-economic concerns to the availability of IP protection and its scope.

IP protection of the gene sequence or techniques and processes involved in creating the GMO or product is more commonplace than protection of the organism or product itself. There is considerable literature concerning the protection of the former subject matter[2] but not the protection of organisms and their products. Furthermore, with respect to patent

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[1] J Rossman, 'Plant Patents' (1931) 13 *Journal of the Patent Office Society* 7, 9. At that time patents for this type of plant were not available in the US.

[2] See, for eg, I Kayton, 'Copyright in Living Genetically Engineered Works' (1981-82) 50 *George Washington University Law Review* 191; S A Bent et al, *Intellectual Property Rights in Biotechnology Worldwide* (Stockton Press, New York, 1987); G M Hoffman and G M Karny, 'Can Justice Keep Pace with Science?' [1988] *European Intellectual Property Review* 355; D L Burk, 'Copyrightability of Recombinant DNA Sequences' (1989) 29 *Jurimetrics Journal* 469; S Hird and M Peeters, 'UK Protection for Recombinant DNA - Exploring the Options' [1991] *European Intellectual Property Review* 334; R S Eisenberg, 'Genes, Patents, and Product Development' (1992) 257 *Science* 903; G W G Karnell, 'Protection of Results of Genetic Research by Copyright or Design Rights?' [1995] *European Intellectual Property Review* 355; A Speck, 'Genetic Copyright' [1995] *European Intellectual Property Review* 171; H Laddie et al, 1 *The Modern Law of Copyright and Designs* (2nd ed, Butterworths, London, 1995), Ch 21; R S Eisenberg, 'Intellectual property issues in genomics' (1996) 14 *Trends in BioTechnology* 302; J Stanley and D C Ince, 'Copyright Law in Biotechnology: A View from the Formalist Camp' [1997] *European Intellectual Property Review* 142; D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69; C Lawson, 'Patenting Genetic Materials: Old Rules May Be Restricting the Exploitation of a New Technology' (1999) 6 *Journal of Law and Medicine* 373; R Eisenberg 'Re-examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49 *Emory Law Journal* 783; D Nicol and J Nielson, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347; Australian Law Reform Commission, *Gene Patenting and Human Health* Discussion Paper 68 (February 2004) ('ALRC Discussion Paper 68'). See also *Kirin-Amgen Inc v Board of Regents of University of Washington* (1995) 33 IPR 557.

protection, a patent for an organism or material characterised by having some particular trait (a product patent) is significantly different from a patent with respect to a process used to create a particular organism or material (a process patent). Product patents give stronger protection, protecting the product regardless of how it was manufactured. In contrast, a process patent only gives a patentee a monopoly in the product produced by a particular process.[3] This gives the patentee of a biotechnology process invention no effective protection at all:[4] once the gene sequence is disclosed it is relatively simple to deduce numerous other ways to make the same product resulting from the patented process without incurring the same research and development costs as the patentee. This study considers only product patents.

In practical terms if, for example, patent protection is obtained for the organism it may be unnecessary to seek to protect the products of the organism separately. Nevertheless, if IP protection of the organism, such as the pig or carnation, itself is not possible (for example, because of policy), protection for products of the organism will be attractive. One of the most significant products of organisms is progeny, such as piglets and new plants. However, it is unlikely a commercialiser would seek IP rights with respect to GMO progeny without seeking those rights in respect of the parent (or founder) organism. Independent protection of the progeny is probably then unnecessary. Protection of progeny separately from the founder organism will therefore not be considered. Instead protection of the parent and its other products will be considered.

A variety of IP rights are available in Australia. This study considers only those particularly relevant to the selection and development stage of commercialisation. Marketing and trade issues with respect to the GMO or product are not the subject of this study.[5] Accordingly, although it is possible that, for example, trade mark protection may be available to commercialisers, such protection will not be considered.[6] Further, with respect to copyright protection of GMOs or their products, artistic intent by the

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[3] G Wei Sze Shun, 'Mus Musculus and Homo Sapiens: Murine Metaphysics and the Canadian Supreme Court' [2003] *Singapore Journal of Legal Studies* 38. Wei Sze Shun notes that process claims may be more susceptible to invention around or other means of avoidance in biotechnology patents (in text accompanying fn 118).

[4] I Purvis, 'Patents and genetic engineering - does a new problem need a new solution?' [1987] *European Intellectual Property Review* 347.

[5] Although they may arise incidentally at the selection and development stage. The effect of GMO releases on trade in other organisms is relevant but that does not raise IP issues.

[6] That topic has previously been considered by the author. See K Ludlow, 'Genetically Modified Organisms and Trade Mark Protection' (1999) 10 *Australian Intellectual Property Journal* 23.

commercialiser will probably be necessary.[7] This is unlikely to be present during commercial selection and development and is not pursued here.

Arguably it is only the plant breeder's rights ('PBR') regime that has no significant unique problems in its application to GMOs or their products.[8] New varieties of plants created using GM can clearly be protected pursuant to the *Plant Breeder's Rights Act 1994* (Cth).[9] There is no equivalent scheme in Australia for animals.[10] The relevance of the regime to commercialisers is considered in the next Part of the Chapter.

Patent protection is available pursuant to the *Patents Act 1990* (Cth) ('*Patents Act*'). There are various prerequisites the creator of an invention must meet to qualify for patent protection and particular difficulties may arise in the case of GMOs and their products. Part 4.3 considers those difficulties.[11] The scope of patent protection is also examined.

Protection as confidential information, for which there is no particular legislative regime,[12] is often seen as a commercial alternative to patenting and PBR.[13] It must also be relied upon until patent protection has been secured. The protection of GMOs and their products as confidential information may pose unique problems because of their ability to move and replicate without human assistance. Furthermore, in many instances a modification can be copied without the underlying technology being understood or replicated. The

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[7] See K Ludlow, 'My Pig is a Work of Art: Copyright Protection for Genetically Modified Organisms in Australia' (1999) 4 *Media & Arts Law Review* 141; S Coke, 'Copyright and Gene Technology' (2002) 10 *Journal of Law and Medicine* 97. See also *The Grain Pool of Western Australia v The Commonwealth* (2000) 202 CLR 479 at [132] (Kirby J).

[8] Aust, as a member state of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') negotiated during the Uruguay Round of Talks under the General Agreement on Tariffs and Trade (GATT) must recognise and ensure an IP right to breeders of new plant varieties. That protection can be by patents or a *sui generis* system or both. As a member state of the International Union for the Protection of New Varieties of Plants, 1991 (UPOV), Aust has adopted the UPOV model for its *sui generis* system. That system is created in the *Plant Breeder's Rights Act 1994* (Cth). Aust also, as discussed in Part 4.3, offers patent protection to plants.

[9] Not all 'plants' are protectable this way. The definition of 'plant' in *Plant Breeder's Rights Act 1994* (Cth) s 3 does not include bacteria, bacteroids, mycoplasmas, viruses, viroids and bacteriophages. In addition, s 42(1) provides that Regulations may provide that certain taxons (groups) are not registrable.

[10] It has been suggested from time to time that a similar scheme be established with respect to animals. For eg, see N Lesser, 'Animal Variety Protection: A Proposal for a US Model Law' (1993) 75 *Journal of the Patent and Trademark Office Society* 398 (with respect to US); N Peace and A Christie, 'Intellectual Property Protection for the Products of Animal Breeding' [1996] *European Intellectual Property Review* 213.

[11] Only standard patent protection is considered in this study.

[12] Cf the position in US where a number of States have legislation dealing specifically with the protection of trade secrets.

[13] S Irvine, 'The Patenting of Transgenic Animals - Will it Matter at the End of the Day?' (1990) *Current Developments in Intellectual Property and Trade Practices* 6. As to the advantages and disadvantages of confidential information compared to patent protection see R Jarvis, 'Trade Secrets As a Means of Protecting New Life-forms' (1991) 14 *Intellectual Property Forum* 14.

implications of these traits for protection as confidential information is considered in Part 4.4.

The final part of the Chapter, Part 4.5, draws together the conclusions reached in this Chapter.

4.2 PLANT BREEDER'S RIGHTS

4.2.1 *Legal Requirements for PBR Protection*

PBR protection for GM plants is clearly available although its value may be limited for the reasons discussed in section 4.2.3.[14] Protection pursuant to a PBR requires the new plant variety[15] to be a registrable plant variety.[16] It must also have a breeder[17] and be distinct from known varieties, uniform, stable and not have been exploited or only recently been exploited.[18] There are additional requirements, such as with respect to the application itself and deposit of propagating material and supply of specimen plants, but these are unlikely to cause unique difficulties for GM plants.[19] There are no limitations on the basis of socio-economic impacts. However, such grounds could theoretically be the basis for GM plants being prescribed by regulation as not being 'plants' for these purposes.[20]

4.2.2 *Application to GM Plants*

GM plant groupings can be plant varieties for the purposes of the legislation.[21] Provided the GM plant is not a variety of plant in a prescribed taxon,[22] it is a registrable plant variety. As to the requirement that there be a breeder, it seems GM is considered breeding for the purposes of the Act.[23]

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[14] With respect to the constitutional validity of the legislation, see *The Grain Pool of Western Australia v The Commonwealth* (2000) 202 CLR 479.

[15] A plant variety is a plant grouping within a single botanical taxon of the lowest known rank that can be defined by the expression of characteristics resulting from the genotype of each individual within the plant grouping, distinguishable from other groupings by the expression of at least one of those characteristics and can be considered as a functional unit because of its suitability for being propagated unchanged. *Plant Breeder's Rights Act 1994* (Cth) s 3(1) (definition of 'plant variety').

[16] *Plant Breeder's Rights Act 1994* (Cth) s 44(1)(b)(ii).

[17] *Plant Breeder's Rights Act 1994* (Cth) s 43(1)(a).

[18] *Plant Breeder's Rights Act 1994* (Cth) s 43(1)(b)-(e).

[19] See J McKeough et al, *Intellectual Property in Australia* (3rd ed, LexisNexis Butterworths, Sydney, 2004), [15.8] for a summary of these requirements.

[20] *Plant Breeder's Rights Act 1994* (Cth) s 42(1).

[21] *Plant Breeder's Rights Act 1994* (Cth) s 6.

[22] *Plant Breeder's Rights Act 1994* (Cth) s 42.

[23] *Plant Breeder's Rights Act 1994* (Cth) s 5(1), which defines breeding, does not refer to GM. However, breeding a plant variety has been interpreted by commentators as including humanly induced genetic mutation or other human intervention. See R B Jarvis, 'Plant Patent, Plant Variety Right - or Both?' (1993) 4

Distinctiveness can be due to GM.[24] It requires only a minor variation in one or more measurable characteristics of commonly known varieties.[25] The variation does not have to be an improvement over existing varieties. Morphological characteristics, such as the blue colour of GM carnations, and physiological characteristics, such as the herbicide tolerance of GM canola, would be measurable characteristics.[26] However, it seems that for a genotypic difference to be relied upon to establish distinctiveness, it must be expressed by the plant.[27]

It is possible that a natural equivalent of some GM plants may already exist. It is not clear when the mere existence of a variety will be a matter of common knowledge for the purposes of determining distinctiveness.[28] Common knowledge includes varieties the subject of Australian and overseas PBR applications[29] but presumably does not include natural equivalents unless they have become sufficiently known and publicly available through, for example, cultivation, marketing or precise description in a publication.[30]

Uniformity requires that individual specimens of the variety be sufficiently homogenous.[31] Stability requires that the variety maintain its characteristics throughout a sequence of multiplications.[32] Neither of these requirements present unique difficulties for GM plants.

The final requirement, that of no previous exploitation, is satisfied if the PBR application is made within one year of sales by, or with the consent of, the breeder of the propagating or harvested material of the variety in Australia.[33] Therefore, unlike patent protection, even if

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Australian Intellectual Property Journal 211, 223 (with respect to the *Plant Variety Rights Act 1987* (Cth) (repealed)).

[24] *Plant Breeder's Rights Act 1994* (Cth) s 6.

[25] *Plant Breeder's Rights Act 1994* (Cth) s 43(2) and International Convention for the Protection of New Varieties of Plants, 1991 Article 7. See also J W Dwyer et al, 1 *Lahore. Patents, Trade Marks & Related Rights* (Reed International Books Australia Pty Ltd, Sydney, 2001, looseleaf), [29,155].

[26] See *Maris Druid - Spring Barley* [1968] FSR 559 (UK Plant Variety Office); *L. Daehnfeldt Ltd v The Controller of Plant Varieties* [1976] FSR 94 (UK Plant Varieties and Seeds Tribunal) (both with respect to the *Plant Varieties and Seeds Act 1964* (UK)).

[27] *Plant Breeder's Rights Act 1994* (Cth) s 3(b) and (c).

[28] *Plant Breeder's Rights Act 1994* (Cth) s 43(2).

[29] *Plant Breeder's Rights Act 1994* (Cth) s 43(8).

[30] See J W Dwyer et al, 1 *Lahore. Patents, Trade Marks & Related Rights* (Reed International Books Australia Pty Ltd, Sydney, 2001, looseleaf), [29,150] n 1.

[31] *Plant Breeder's Rights Act 1994* (Cth) s 43(3).

[32] *Plant Breeder's Rights Act 1994* (Cth) s 43(4).

[33] *Plant Breeder's Rights Act 1994* (Cth) s 43(6)(a). In the case of trees or vines exploited overseas, the application must be within six years of sales (*Plant Breeder's Rights Act 1994* (Cth) s 43(6)(b)(i)). In the case of all other plants, four years of sales (*Plant Breeder's Rights Act 1994* (Cth) s 43(6)(b)(ii)). For a discussion of the meaning of 'sale' with respect to the *Plant Variety Rights Act 1987* (Cth) (repealed) see *Sun World International Inc (formerly Sun World Inc) v Registrar, Plant Breeder's Rights (formerly Registrar, Plant Variety Rights)* (1998) 42 IPR 321; *Sun World Inc v Registrar, Plant Variety Rights* (1997) 39 IPR 161 (Fed Ct). See also *Re Elizabeth of Glamis-Rose* (1966) FSR 265.

a variety was developed (or by analogy, discovered) earlier and described in literature, provided it was not made available commercially it can still be protected by PBR.[34] Further, if commercialisation occurred without the breeder's consent PBR protection remains available.[35]

4.2.3 *Scope of Protection*

The holder of a PBR in a plant variety is given, amongst other things, exclusive rights to produce or reproduce propagating material of the variety and to sell or offer such material for sale.[36] The rights are an absolute monopoly because they can be exercised against anyone, including someone who independently creates the same variety. Such rights may, in limited ways, also protect the products of the protected variety.[37] Breeders' rights also extend to varieties which are 'essentially derived' from a protected variety.[38] The Federal Court may grant an injunction and either damages or an account of profits where infringement occurs.[39] It is also a criminal offence to intentionally or recklessly infringe a breeder's primary rights.[40] A court, faced by an 'innocent' infringer though, where the person did not know and had no reasonable grounds to suspect the PBR existed, may refuse to award damages or an account.[41]

The exclusive rights are limited in two important respects.[42] First, s 16 provides for a 'breeder's exemption'. Pursuant to this exemption, third parties may in certain circumstances use the protected variety without restriction. Those circumstances are where the use is for the production of new varieties, experimental purposes or if the use is private and for non-commercial purposes. Secondly, there is a 'farmer's privilege' provided for in s 17. Pursuant to this exemption, farmers may harvest propagating material of a protected variety as seeds for later planting.[43] The harvested propagating material must come from

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[34] *Sun World Inc v Registrar, Plant Variety Rights* (1997) 39 IPR 161 at 170 (Fed Ct). See also A Christie, 'Novelty Requirement in Plant Breeders' Rights Law' (1988) 19 *International Review of Industrial & Copyright Law* 646.
[35] *Plant Breeder's Rights Act 1994* (Cth) s 43(5). See also A Christie, 'Novelty Requirement in Plant Breeders' Rights Law' (1988) 19 *International Review of Industrial & Copyright Law* 646.
[36] *Plant Breeder's Rights Act 1994* (Cth) s 11. See also ss 11, 14 and 15. As to the duration of a PBR see s 22.
[37] *Plant Breeder's Rights Act 1994* (Cth) s 12.
[38] *Plant Breeder's Rights Act 1994* (Cth) ss 4 (definition of 'essentially derived varieties') and 12.
[39] *Plants Breeder's Rights Act 1994* (Cth) s 56(3).
[40] *Plant Breeder's Rights Act 1994* (Cth) s 74.
[41] *Plant Breeder's Rights Act 1994* (Cth) s 57(1).
[42] Additional limitations are provided for in *Plants Breeder's Rights Act 1994* (Cth) ss 18, 19 and 23. These raise no unique problems with respect to GM plants.
[43] Some taxons of plants may be excluded by Regulation. No such Regulations have been made so far. See also new technology that enables commercialisers to alter seed so that it will provide one crop only. 'Control

propagating material 'legitimately obtained'.[44] This requires that the farmer either have purchased the original material or harvested the propagating material from such material.[45] It is uncertain whether plants arising following GM contamination would be legitimately obtained. It is suggested that farmers who harvest from GM plants in such circumstances would not fall within the exemption. However, as noted above, a court may refuse to award a remedy in such circumstances. An injunction, being a discretionary remedy, may also be refused in such circumstances.

4.2.4 *Conclusion with respect to Case Studies*

PBR is obviously inapplicable to the GM pig. GM plants on the other hand do not present any unique difficulties in satisfying the requirements for PBR protection. Canola and the carnation could obtain PBR protection provided they are uniform and stable. However, PBR protection must be sought before the existence of organisms with the same characteristics has become common knowledge. This is required even if the other organism has a different genotype which results in the same phenotype as that of the commercialiser's plant. The existence of an equivalent plant in nature which has not been commercialised or precisely described will not, it seems, deprive the organism of distinctiveness and therefore protection. Finally, the commercialiser must be careful not to exploit the organism (or at least do so only within the grace period for sales in Australia or overseas) before the application for protection is made.

Nevertheless, the limitations on the rights of PBR holders described above mean that only narrow protection is obtained. The most significant part of a GM plant, the GM, will not be adequately protected by PBR. Further, others may make some use of the GM plant despite the protection. Accordingly both PBR and patent protection would often be sought in respect of the same plant.

4.3 PATENT PROTECTION

4.3.1 *Legal Requirements for Patentability*

To be patentable GMOs and the materials produced by them must meet a number of legal requirements. Most of these are provided for in s 18 of the *Patents Act*.

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of Gene Expression' US Patent Number 5,723,765 3 March 1998 cited in Note, 'Plant Breeders Rights' (1998) 9 *Australian Intellectual Property Journal* 105.

[44] *Plants Breeder's Rights Act 1994* (Cth) s 17(1)(a).

[45] *Plants Breeder's Rights Act 1994* (Cth) s 17(1)(a).

Section 18(1) provides:

18. (1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly[46] used in the patent area[47] before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.[48]

Each of the above requirements as to the subject matter of the patent must be satisfied. In addition, there are requirements concerning the patent application itself that must be met.[49] Of particular importance with respect to GMOs is the need for the invention to be useful, fully described and not obtained by false suggestion.

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[46] See *Patents Act 1990* (Cth) s 9.

[47] See *Patents Act 1990* (Cth) Sch 1 (definition of 'patent area').

[48] Section 18(2) excludes human beings and biological processes for their generation from patentability. This subsection is not relevant except as an illustration of the approach the Australian Parliament has taken towards defining patentable inventions. That is, a general definition is given with only limited subject matter excluded from patentability. Other excluded subject matter is nuclear technology (Chap 15) and patent applications which affect the defence of Aust (Chap 17 Pt 4) which are expressly excluded from patentability in certain circumstances. Bills proposing the inclusion of a further exception to patentable inventions, proposed by Senator Coulter in 1990 (which would have excluded GMOs and their progeny, amongst other things) and Senator Stott Despoja in 1996 and 2001 (which would exclude naturally occurring genes or gene sequences or descriptions of the base sequence of a naturally occurring gene or a naturally occurring gene sequence) have been rejected by the Senate. Cth, *Parliamentary Debates*, Senate, 20 September 1990, 2653-4 (J Coulter); Cth, *Parliamentary Debates*, Senate, 27 June 1996, 2332-5 (N Stott Despoja); Cth, *Parliamentary Debates*, Senate, 27 September 2001, 28193-7 (N Stott Despoja). The Stott Despoja amendments were re-tabled in 2002 but there has been no further Parliamentary consideration of them. ALRC Discussion Paper 68, [7.21].

[49] See, in particular, *Patents Act 1990* (Cth) s 40 and changes in the applicant's duty of disclosure in s 45(3).

Section 18 goes on to provide for the prerequisites for a second type of patent, innovation patents.[50] GMOs could not be protected this way and such patents are not considered in this study.[51]

Objections on the basis that the requirements for patentability have not been met can be raised at different stages in the patent's life. Generally, objections can first be raised at the examination stage when the patent application and specification are considered by the Patent Office. Objections can be made on the basis that the invention or specification does not satisfy the criteria in s 18(1)(a) and (b) or comply with s 40 or other prescribed matters, including the grounds specified in s 50 with respect to refusal of patent applications in certain circumstances.[52] In considering novelty and inventive step during examination, regard is not had to information publicly available through the doing of an act.[53] Instead regard is had only to information available through documentary disclosure.[54]

A patent application can also be opposed by any person (and this may involve reconsideration of the specification) upon publication of the complete specification but before grant.[55] The grounds of opposition include that the invention does not comply with s 18(1)(a) or (b).[56] Unlike at the examination stage, in considering an opposition, regard may be had to prior non-documentary anticipation.[57] A complete specification may also be re-examined, even after grant where the Commissioner chooses to do so or is asked to do so by the patentee, any other person or a court in which validity of the patent is disputed.[58] However, only novelty and inventive step are considered on re-examination and, as in

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[50] *Patents Act 1990* (Cth) s 18(1A). See also s 18(3) and (3).

[51] *Patents Act 1990* (Cth) s 18(3). Some products of GMOs could be protected by innovation patents. The Advisory Council on Intellectual Property is currently reviewing the exception in s 18(3). Advisory Council on Intellectual Property, *Innovation Patent – Exclusion of Plant and Animal Subject Matter* Issues Paper (2002).

[52] *Patents Act 1990* (Cth) s 45(1); Patents Regulations 1991 (Cth) reg 3.18(2). Different issues arise with respect to modified examination. See *Patents Act 1990* (Cth) ss 47 and 48.

[53] *Patents Act 1990* (Cth) s 45(1)(c) and (1A).

[54] The Commissioner of Patents must be 'satisfied' that the requirements of novelty and inventive step have been met and 'consider' that there is no lawful ground of objection. *Patents Act 1990* (Cth) s 49(1).

[55] *Patents Act 1990* (Cth) s 59(b). For a discussion of the opposition process under the *Patents Act 1990* (Cth) see T J Collins, 'Patents Act 1990: Opposition to Grant of a Standard Patent' (1993) 4 *Australian Intellectual Property Journal* 147.

[56] The other grounds are: that the nominated person is not entitled to a grant of patent for the invention and that the relevant specification does not comply with subsection 40(2) or (3) or is not a patentable invention under s 18(2). *Patents Act 1990* (Cth) s 59(a), (c) and (d).

[57] S Ricketson and M Richardson, *Intellectual Property. Cases, Materials and Commentary* (2nd ed, Butterworths, Sydney, 1998), [14.7.14]. Section 59, unlike the provisions with respect to examination, does not expressly exclude such acts from consideration.

[58] *Patents Act 1990* (Cth) s 97(1), (2) and (3). See P Spann, 'Re-examination in Australia: 10 years on' (2002) 13 *Australian Intellectual Property Journal* 97 with respect to re-examination generally.

examination, the Commissioner is not to have regard to information made publicly available only through the doing of an act.[59]

Finally, any person may seek the revocation of a patent at any time after grant.[60] Grounds of revocation include that the invention is not a patentable invention because it does not comply with s 18(1)(a) or 18(1)(b),[61] that the patent was obtained by false suggestion and that the specification does not comply with subsection 40(2) or (3).[62]

The following four sections discuss whether GMOs and their products can satisfy the prerequisites identified above. The sixth section, section 4.3.6, concerns the scope of protection which will be available if patent protection is possible. Conclusions with respect to the patent protection of the three case studies are suggested in section 4.3.7.

4.3.2 *GMOs and their Products as Patentable Subject Matter*

To be an invention, and also to be patentable subject matter, a GMO and/or its products must be a manner of manufacture. They must also not be excluded by any exception to patentable subject matter. The next two subsections examine what is required to be an invention and a manner of manufacture.[63] Those requirements are then applied to GMOs and their products. Finally, whether such matter would nevertheless be excluded from patentable subject matter pursuant to an exception to patentable subject matter is addressed. Two exceptions are relevant. The first is provided for in s 50(1) of the *Patents Act*. The second is the 'general inconvenience' exception which arises from the reference to the *Statute of Monopolies 1623* (Eng)[64] in s 18 of the *Patents Act*. Both are considered below.

(a) Invention

The term 'invention', as used in the first part of s 18(1), is defined as 'any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the

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[59] *Patents Act 1990* (Cth) s 98(1) and (2).
[60] *Patents Act 1990* (Cth) s 138(1). See also ss 121, 134 and 137(3).
[61] Additionally, it will not be a patentable invention for these purposes if the invention falls within s 18(2). This is not relevant to this study.
[62] *Patents Act 1990* (Cth) s 138(3).
[63] The ALRC has proposed that the Advisory Council on Intellectual Property be requested to review the continued presence of the manner of manufacture test as the threshold requirement for patentable subject matter. See ALRC Discussion Paper 68, Proposal 6-2.
[64] 21 Jac I c3.

Statute of Monopolies, and includes an alleged invention'.[65] Paragraph (a) of s 18(1) also specifies that the subject matter should be a manner of manufacture but does not use the phrase 'manner of new manufacture' as the definition of invention does.

The majority of the High Court[66] in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd*[67] ('*Philips*') has interpreted the use of the word 'invention' in the opening words of s 18(1) as introducing a general threshold requirement of 'newness'.[68] Therefore, although an invention may be novel and otherwise patentable, if the court finds that a specification claims an invention which is not 'new' (as distinct from novel) then it will not be patentable.[69] For example, if the alleged invention is nothing more than a process involving a new use of the known properties of an old substance, the invention will not be new and patent protection will be denied.

Such newness is decided, it seems, only by considering the face of the specification.[70] This matter was not clear, however, because of certain obiter comments by the majority of the High Court in *Philips*. Such comments suggested that the inquiry may go beyond the face of the specification.[71] In a later decision of the High Court, *Advanced Building Systems Pty Ltd v Ramset Fasteners (Australia) Pty Ltd*[72] ('*Ramset*') the majority[73] confined the inquiry to the specification. This did not settle the uncertainty with respect to the ambit of the inquiry, though, because that case concerned the 1952 *Patents Act*.[74] *Philips* concerned

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[65] *Patents Act 1990* (Cth) Sch 1.
[66] Brennan, Deane and Toohey JJ; Dawson and McHugh JJ dissenting.
[67] (1995) 183 CLR 655. See also *Advanced Building Systems Pty Ltd v Ramset Fasteners (Australia) Pty Ltd* (1998) 194 CLR 171 with respect to the *Patents Act 1952* (Cth) (repealed). For discussion of these cases, see J Cherry, 'Standard of Inventiveness for Australian Patents. NV Philips Gloeilampenfabrieken and Another v Mirabella International Pty Ltd' [1996] *European Intellectual Property Review* 365; D J Brennan and A F Christie, 'Patent Claims for Analogous Use and the Threshold Requirement of Inventiveness' (1997) 25 *Federal Law Review* 237; G Pryor, 'Manner of New Manufacture Post Philips and Ramset', Address to the 12th Annual IPSANZ Conference, Auckland, NZ, 28-30 August 1998; M Padbury, 'Inventiveness Apart from Novelty and Inventive Step - The High Court's Decisions on Manner of Manufacture in Philips and Ramset' (1998) 9 *Australian Intellectual Property Journal* 161.
[68] (1995) 183 CLR 655 at 659 and 664.
[69] See J W Dwyer et al, 1 *Lahore. Patents, Trade Marks & Related Rights* (Reed International Books Australia Pty Ltd, Sydney, 2001, looseleaf), [12,040] and J Cherry, 'Standard of Inventiveness for Australian Patents: NV Philips Gloeilampenfabrieken and Another v Mirabella International Pty Ltd' [1996] *European Intellectual Property Review* 365. The full Federal Court in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553 at [45] said it was difficult to envisage circumstances where this may happen.
[70] *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 183 CLR 655 at 664; *Advanced Building Systems Pty Ltd v Ramset Fasteners (Australia) Pty Ltd* (1998) 194 CLR 171 at [38]-[40] (Brennan CJ, Gaudron, McHugh and Gummow JJ).
[71] (1995) 183 CLR 655 at 666-7.
[72] (1998) 194 CLR 171.
[73] Brennan CJ, Gaudron, McHugh and Gummow JJ; Kirby J dissenting.
[74] In particular, *Patents Act 1952* (Cth) s 100(1)(d) 'manner of new manufacture'. See M Padbury, 'Inventiveness apart from Novelty and Inventive Step - The High Court's Decisions on Manner of Manufacture in Philips and Ramset' (1998) 9 *Australian Intellectual Property Journal* 161, 173.

the 1990 Act. The full Federal Court considered the issue again in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*[75] ('*Bristol-Myers*'). The Court said *Philips* meant that newness was to be decided on the basis of information in the specification.[76] In any case, any requirement of 'newness' is unlikely to pose a unique difficulty for the patenting of GMOs or their products.

(b) Manner of manufacture

NRDC case

The High Court in its leading decision with respect to patents, *National Research and Development Corporation v Commissioner of Patents*[77] ('*NRDC*'), took a wide and policy orientated approach to the meaning of manner of manufacture.[78]

In *NRDC* the applicant determined the relationship between the enzyme make-up of particular plants and a certain type of known hormone herbicide. The differences in the enzymic make-up of certain plants and weeds meant that the herbicide would kill weeds growing in association with the plants but not the plants themselves.[79] The patentable invention was not that discovery itself but the description of the method of applying the herbicide to the crops to achieve weed-free or comparatively weed-free crop-bearing land.[80]

The invention under consideration in *NRDC* was a process. That process took advantage of naturally occurring genetic differences, using a known chemical. The Court did not consider the patentability of organisms which possess such differences. Nevertheless, in exploiting such genetic differences, the invention was similar to the purpose of many GMs. They enable the survival of certain organisms because of different genetic make-ups. In

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[75] (2000) 46 IPR 553. A decision under the *Patents Act 1990* (Cth) but with respect to petty, rather than standard, patents.

[76] (2000) 46 IPR 553 at [30]. However, the face of the specification could be interpreted in light of information in prior publications or other known matters referred to in the specification. See also *University of Georgia Research Foundation v Biochem Pharma Inc* (2000) 51 IPR 222 at 249-51 (Delegate).

[77] (1959) 102 CLR 252 (HC, Full Ct).

[78] S Ricketson, *The Law of Intellectual Property* (Law Book Co, Sydney, 1984), [48.13]. Prior to the decision in *NRDC* various tests had been proposed to determine whether there was a manner of manufacture. The most significant of these was the vendible product test used in respect of processes. See *Re GEC's Application* (1942) 60 RPC 1.

[79] From the submission of the appellant's counsel (254-5) and the Court's judgment (266) it seems that the enzyme which the weeds produced degraded the herbicide. The products of such degradation were presumably toxic and lead to the death of the weeds.

[80] The decision in *NRDC* concerned three patent claims in respect of a method. The three claims in dispute are reproduced at (1959) 102 CLR 252 at 261.

any case, the plants in *NRDC* would not have been patentable because they existed naturally and therefore, as discussed below, their identification would be only a discovery. The plants may also not have been novel. Despite this, the Court's comments with respect to the meaning of 'manner of manufacture' apply equally to inventions which are products as to inventions which are processes.

As Ricketson notes, the High Court made it clear that the term 'manner of manufacture' was not intended to be a fixed formula but 'one that would widen as new industrial and technical developments occurred'.[81] In determining what was included within the term 'manner of manufacture' the Court stressed the need to look at the object sought to be achieved by s 6 of the *Statute of Monopolies*.[82] The right question, according to the High Court, is: '[i]s this a proper subject of letters patent according to the principles which have been developed for the application of section 6 of the Statute of Monopolies?' and not whether a given product or process is a manner or kind of manufacture.[83]

The High Court went on to say that they would not describe the ambit of s 6 because the purpose of the section was to encourage national development and it would be unsound to fetter its meaning in light of that.[84] Consistently with that, the High Court said that to be a manner of manufacture it was sufficient for a process to offer some advantage which is material, in the sense that the process belongs to a useful art as distinct from a fine art - that its value to the country is in the field of economic endeavour.[85]

Application to GMOs and their products

GMOs and their products which possess some new trait would usually, if not always, be capable of commercial application.[86] They should therefore be a manner of manufacture unless there is some other reason why they are not the proper subject of a patent according to the principles developed for the application of s 6 of the *Statute of Monopolies*. The

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[81] S Ricketson, *The Law of Intellectual Property* (Law Book Co, Sydney, 1984), [48.8]. In relation to the meaning of 'manufacture', see *Boulton and Watt v Bull* (1795) 2 H Bl 463 at 493; 126 ER 651 at 666 (Eyre CJ); *Hornblower and Maberly v Boulton and Watt* (1799) 8 TR 95; 101 ER 1285; *Gibson and Campbell v Brand* (1842) 1 Web PC 627 at 633; *Application by Compagnies Reunies des Glaces* (1931) 48 RPC 185 at 188; *Standard Oil Development Company's Application* (1951) 68 RPC 114 at 115.

[82] (1959) 102 CLR 252 at 269.

[83] (1959) 102 CLR 252 at 269.

[84] (1959) 102 CLR 252 at 271.

[85] (1959) 102 CLR 252 at 275.

[86] This is likely to be the case even in the scenario of a GM being made purely for aesthetic reasons or to make an organism useful for research. For a discussion of 'use' for the purposes of European and US law, see M Llewelyn, 'Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States' [1994] *European Intellectual Property Review* 473.

main objections to GMOs or their products being considered a manner of manufacture on the basis of such principles are:

(i) organisms are animate rather than inanimate objects;
(ii) GMOs and their products are mere collocations of pre-existing integers;
(iii) in respect of some GMs, the outcome is negative in the sense that a pre-existing characteristic is eliminated;
(iv) such outcomes are discoveries rather than inventions because the same matter may already exist in nature; and
(v) given that any modification must be expressed by the organism, the outcome is not the result of human intervention or at least sufficient human intervention to be a manner of manufacture. Both the level and type of intervention are relevant to this point.

Each of these objections is considered below. There will inevitably be some overlap between the issues identified above, particularly issues (iv) and (v). Nevertheless, they have been adopted as a useful taxonomy for analysis and discussion purposes. It is submitted that none of them justify the exclusion of GMOs and their products from patentable subject matter.

(i) Living Matter

That GMOs are living should not, of itself, prevent them from falling within the term 'manner of manufacture'.[87] The United States ('US') Supreme Court has ruled that living things are appropriate subject matter for patents.[88] That the subject matter of a patent is animate is also not, of itself, grounds for non patentability pursuant to the European Patent Convention[89] ('EPC')[90] or in Canada.[91]

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[87] S Ricketson, *The Law of Intellectual Property* (Law Book Co, Sydney, 1984), [48.42]; N Peace and A Christie, 'Intellectual Property Protection for the Products of Animal Breeding' [1996] *European Intellectual Property Review* 213, 219.

[88] *Diamond v Chakrabarty* 447 US 303 (1980) (which concerned a bacterium genetically modified to enable it to degrade oil). See also *Ex Parte Hibberd* 227 USPQ 443 (1985) (where the US Board of Appeals and Interferences held that multicellular plants were patentable subject matter); *Ex Parte Allen* 2 USPQ 2d 1425 (1987) (where the US Board of Appeals and Interferences found that multicellular animals (oysters) were patentable subject matter); *J.E.M. Ag Supply v Pioneer Hi-Bred* 122 S Ct 593 (2001) (US Supreme Court confirming the legality of patents on plants).

[89] Convention on the Grant of European Patents 1973. See, with respect to the relevant provisions of the EPC, L Bently and B Sherman, *Intellectual Property Law* (Oxford University Press, New York, 2001), pp 394-400.

[90] See, for eg, T 49/83 (CIBA GEIGY/ Propagating material) OJ EPO 1984, 112 cited by G Paterson, *The European Patent System. The Law and Practice of the European Patent Convention* (Sweet & Maxwell, London, 1992), [7-45]; T 19/90 (HARVARD/ Onco-mouse) OJ EPO 1990, 476; (1991) 22 IIC 74; T 365/96

There is nothing in *NRDC* which is inconsistent with the patenting of living organisms.[92] However, the question has not yet received direct judicial consideration in Australia. It has been addressed though by the Patent Office in *Ranks Hovis McDougall Ltd's Application*.[93] That decision concerned a patent application in respect of specific variants of a new strain of the microorganism *Fusarium graminearum* which was useful to produce edible protein. The Assistant Commissioner rejected an objection to a claim to the new microorganism on the basis that, because the invention was something living, it was not a manner of manufacture. He said that objection was based on too restricted a view of the meaning of manner of manufacture in s 6 of the *Statute of Monopolies*.[94] The fact that the organisms were living was no barrier to their patentability.

The effect of this decision was reiterated in an official notice of the Patent Office published in 1980.[95] That notice states that the criteria to be met before an application concerned with living organisms will be accepted are precisely the same as for any other application and that 'no distinction is to be made solely on the basis that a claimed product or process is, or contains or uses, a living organism'.

The same Patent Office notice also says that higher life forms will not be treated any differently from lower forms, such as microorganisms. This approach also seems to be taken by the US Patent Office.[96] However, in Europe and Canada the type of life form

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(Plant Genetic Systems) OJ EPO 1995, 545 (Tech Board of App). See also *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Articles 2.1(a) (definition of 'biological material') and 3.1.

[91] *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)* [1987] 3 FC 8 at 12. This decision and the appeals from it are discussed in subsection 4.3.3(c) below. See also R W Marusyk, 'The Patentability of New Plant Life Forms in Canada' (1990) 16 *Canadian Business Law Journal* 333; J B Bai, 'Protecting Plant Varieties under TRIPS and NAFTA: Should Utility Patents be available for plants?' (1997) 32 *Texas International Law Journal* 139

[92] The High Court has since noted that the effect of the decision in *NRDC* 'is to confirm that there is no intrinsic impediment to the patentability of plant varieties'. *The Grain Pool of Western Australia v The Commonwealth* (2000) 202 CLR 479 at [46] (Gleeson CJ, Gaudron, McHugh, Gummow, Hayne and Callinan JJ).

[93] (1976) 46 AOJP 3915.

[94] (1976) 46 AOJP 3915 at 3918.

[95] 'Patent Applications Concerned with Living Organisms' (1980) 50 *Australian Official Journal of Patents, Trademarks and Patents* 1162. This was confirmed in Practice Note No 6, 1991, issued by the Patent Office in April 1991 with respect to the *Patents Act 1990* (Cth). See also guide by IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms* (undated) (http://www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf accessed 8/3/04).

[96] The US PTO promulgated a rule stating that non-naturally occurring, non-human multicellular organisms, including animals, were patentable subject matter on 7 April 1987 1077 Off Gaz Pat Office 24 (21 April 1987), cited by E J Hecht, 'Beyond *Animal Defense Fund v Quigg:* The Controversy Over Transgenic Animal Patents Continues' (1992) 41 *American University Law Review* 1023, 1023. Further, see *Animal Legal Defense Fund v Quigg* 932 F2d 920, 18 USPQ 2d 1677 (1991) (where a challenge to the authority of

may be significant. In Europe the type of life form concerned is relevant when considering whether the claimed invention is contrary to *ordre public* or morality and therefore not patentable under an exception to patentability.[97] In Canada, the Supreme Court in *President and Fellows of Harvard College v Canada (Commissioner of Patents)*,[98] has ruled that a distinction be made between lower and higher life forms when deciding whether an article was patentable subject matter.[99]

In Australia an exception to patentability on the basis of public policy, known as the 'generally inconvenient' exception, also exists. It is therefore possible that the type of life form which has been modified may be significant in Australia. This is discussed in subsection 4.3.2(c).

(ii) Mere Collocation

GMOs should also not be viewed as only a collocation of unrelated parts. Mere collocations of pre-existing integers are not manners of manufacture and are therefore not patentable.[100] Some GMOs may be considered to be a new combination of parts and therefore patentable subject matter; namely the organism to be modified and genetic material taken or ultimately derived from existing organisms. In any case, where a GMO or its material is to be commercialised, presumably that is because it has some advantage over existing products. That advantage exists because the 'integers' are interrelating with one another to produce a new and useful result.[101] The result, the GMO or its product, is

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the US PTO to announce animals were patentable subject matter was dismissed because of the challengers' lack of standing).

[97] Decision of Examining Division of the EPO *In re President and Fellows of Harvard College* (1993) 24 IIC 103.

[98] [2002] 4 SCR 45. Decision was by a bare majority of 5:4.

[99] *President and Fellows of Harvard College v Canada (Commissioner of Patents)* [2002] 4 SCR 45 at [120]. The Court expressly declined to locate the line between patentable lower life forms and unpatentable higher life forms (at [204]). The minority (Arbour, Iacobucci, Bastarache, and LeBel JJ) in *Schmeiser v Monsanto Canada Inc* 2004 SCC 34 at [108] said, in obiter, that the decision in *Harvard College* was that 'higher life forms, including plants, are not patentable'. The majority did not comment on this. Cf Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (Canadian Biotechnology Advisory Committee, Ottawa, 2002), Recommendation 2 which recommends that higher life forms should be patentable in Canada.

[100] See, for eg, *Ramset Fasteners (Australia) Pty Ltd v Advanced Building Systems Pty Ltd* (1996) 34 IPR 256 at 272 (Fed Ct, Full Ct); *Advanced Building Systems Pty Ltd v Ramset Fasteners (Australia) Pty Ltd* (1998) 194 CLR 171 at [12] (HC). See also *Clayton Furniture Ltd's Application* (1965) AOJP 2303 (Pat Off); *Young's Application* (1966) AOJP 1028 (Pat Off); *Unilever Ltd* (1976) 46 AOJP 531 (Pat Off).

[101] *British Celanese Ltd v Courtaulds Ltd* [1935] RPC 171 at 193. Cozens-Hardy MR said, in *Mercedes Daimler Motor Company Ld v F.I.A.T. Motor Car Company Ld* (1913) 30 RPC 369 at 381, '[i]t may be a real invention to combine Alpha, Beta and Gamma - three known elements never before combined for this purpose - provided a useful result is produced thereby'. See also *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253.

therefore not a mere collocation but is a combination.[102] The inventiveness lies in the decision to assemble the components to create the organism.[103]

(iii) Negative Improvement

Some GMs result in negative improvements in the sense that the organism or product produced no longer exhibits a characteristic previously exhibited by it.[104] This should not prevent the resulting organism being a manner of manufacture. In *NRDC* itself the outcome of the process under consideration was the removal of something (weeds) rather than the addition of something.[105] Nevertheless the High Court dismissed any objection to patentability on the basis that the improvement was negative, concluding that a new process for chemically ridding the land of unwanted growth was good subject matter for a patent.[106] There is no good reason why the same conclusion should not be made with respect to a product improved by the deletion of an unwanted characteristic.[107]

(iv) Discovery

A 'discovery' is ordinarily understood as meaning the act of discovery or something discovered.[108] This may include things that the layperson refers to as inventions. However, the law has defined the terms discovery and invention so that although all inventions involve a discovery, a discovery is not enough by itself for an invention. A discovery alone is therefore not patentable.[109]

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[102] Where a patentable gene sequence is included in the organism, the organism will be patentable because the inclusion of a patentable integer in a collocation of pre-existing parts results in the whole collocation being patentable. See *Palmer v Dunlop Perdriau Rubber Company Ltd* (1937) 59 CLR 30 at 67 and 71-5; *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228 at 248; *Nelson v Hillmark Industries Pty Ltd* (1991) AIPC ¶ 90-768 (Pat Off).

[103] See, for eg, *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588 at 611; *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253; *Elconnex Pty Ltd v Gerard Industries Pty Ltd* (1991) 32 FCR 491 at 510; *Fallshaw Holdings Pty Ltd v Flexello Castors & Wheels PLC* (1993) 26 IPR 565 (Fed Ct, Full Ct).

[104] In a sense no longer exhibiting a characteristic the organism or product previously possessed is a 'new characteristic' (or positive improvement) because the organism or product is now doing something new in the sense, it is true, that it does not do something it used to.

[105] (1959) 102 CLR 252 at 274.

[106] (1959) 102 CLR 252 at 275.

[107] See also, for eg, *Russell v Cowley* (1835) 1 C M & R 864; 149 ER 1331; *Cooper's Application* (1902) 19 RPC 53.

[108] *The Macquarie Dictionary* (2nd revision, The Macquarie Library Pty Ltd, NSW, 1987).

[109] *NRDC* (1959) 102 CLR 252. A number of reasons have been suggested as to why discoveries are not patentable. See, for eg, R S Crespi, *Patenting in the Biological Sciences: a practical guide for research scientists in biotechnology and the pharmaceutical and agrochemical industries* (John Wiley & Sons Ltd, Chichester, 1982), p 39; S Ricketson, *The Law of Intellectual Property* (Law Book Co, Sydney, 1984), [48.28]; and US, Office of Technology Assessment Congress of the United States, *New Developments in Biotechnology: Patenting Life* (Marcel Dekker, Inc, New York, 1990), p 39. Although not patentable, scientific discoveries are of course still valuable to society. Suggestions have therefore been made that

If the canola or carnation plant or the pig was to be discovered in the wild for the first time today, it would not be patentable because it would simply be a discovery of something already in existence.[110] In *Ranks Hovis McDougall Ltd's Application*,[111] referred to above, the Assistant Commissioner stated that if the microorganisms the subject of the application were only naturally occurring organisms there may have only been a discovery. Patent protection would then not be possible because '[n]o invention was involved in the mere discovery, or the mere identification, or the mere isolation by an unspecified method, of something that occurs in nature.'[112] Patent Office criteria, used when assessing applications with respect to higher non-human life forms, reflect this by providing that naturally occurring plants themselves are not patentable.[113] In reality it would, as pointed out by commentators, be unusual to want to patent a wild plant anyway.[114] The 'discoverer' would normally undertake a number of propagation and selection cycles followed by inbreeding to guarantee stability and propagation true to character. Such human intervention is considered by commentators to be sufficient to result in patentable subject matter. The same position exists in the US[115] and Europe[116].

The borderline between discoveries and inventions is not precise.[117] Buckley J, in *Reynolds v Herbert Smith & Co, Ltd*, explained the distinction between a discovery and an invention as follows:

> Discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen.

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scientists who make discoveries should have a legal right to demand remuneration. For eg, see C J Hamson, *Patent Rights for Scientific Discoveries* (The Bobbs-Merrill Company Publishers, Indianapolis, 1930).

[110] A newly discovered wild organism would also not be patentable because it would not be novel. See section 4.3.3 below.

[111] (1976) 46 AOJP 3915.

[112] (1976) 46 AOJP 3915 at 3918.

[113] R B Jarvis, 'Plant Patent, Plant Variety Right - or Both?' (1993) 4 *Australian Intellectual Property Journal* 211.

[114] S A Bent et al, *Intellectual Property Rights in Biotechnology Worldwide* (Stockton Press, New York, 1987), p 134.

[115] See, for eg, *Funk Brothers Seed Co v Kalo Innoculant Co* 333 US 127 at 130 (1948) where Justice Douglas, speaking for the majority of the US Supreme Court, concluded that '[p]atents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.' (Citation omitted). See also *Diamond v Chakrabarty* 447 US 303 (1980) at 303.

[116] European Patent Convention Article 52(2)(a) provides that a discovery is not patentable. See also R S Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71, 73-5 (re gene sequences).

[117] *NRDC* (1959) 102 CLR 252 at 264. The High Court in that case noted that the dividing line between the initial discovery and the patentable invention may be a difficult one, e[illegible] where the real ingenuity lies in the first step and the application is a fairly straightforward develo[illegible]en [illegible] that case.

> Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result.[118]

Some commentators are of the view that GMOs are only discoveries and therefore are not patentable because the original organism and gene sequences ultimately occurred in nature.[119] That is, the 'creator' will not be giving anything to the public in return for the patent if all the creator has done is 'pluck' a naturally occurring organism from nature and combine it with a sequence which also ultimately occurs in nature.

Overseas case law and Australian Patent Office decisions establish that desirable substances 'plucked' from nature cannot be patented. In *Genentech Inc.'s Patent*[120] the English Court of Appeal considered that the determination of the full amino acid and DNA sequences coding for a known human protein constituted only a discovery in the sense that by their efforts the patentee 'discovered' the full details of the structure of the protein and the DNA which coded for it.[121] Similarly in *Kiren-Amgen Inc v Board of Regents of University of Washington*[122] the Australian Deputy Commissioner of Patents considered that a claim to the naturally occurring DNA sequence encoding for a naturally occurring protein would only be in respect of a discovery.[123] However, a claim to an isolated and purified DNA sequence was considered patentable subject matter.[124] This is the same as the position in the US[125] and Europe[126] where a purified natural product can be patented if it is not found in purified form in nature.[127]

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[118] (1903) 20 RPC 123 at 126.

[119] F Vogel, 'Discussion. Session 1', in F Vogel and A Grunwald (eds), *Patenting of Human Genes and Living Organisms* (Springer-Verlag, Berlin, 1994), p 35, 37. See also R S Crespi, 'Biotechnology Patenting: The Wicked Animal Must Defend Itself' [1995] *European Intellectual Property Review* 431; McInerney, 'Biotechnology: Biogen v. Medeva in the House of Lords'[1998] *European Intellectual Property Review* 14 (who notes at p 14 that alteration of organism already present in nature challenges the traditional distinction between a mere discovery and an invention).

[120] [1989] RPC 147 (also known as *Genentech Inc v Wellcome Foundation Ltd*).

[121] [1989] RPC 147 at 204 and 208 (Purchas LJ), 237 (Lloyd LJ) and 264 (Mustill LJ). The decision was with respect to the 1977 English Act.

[122] (1995) 33 IPR 557.

[123] (1995) 33 IPR 557 at 569. Appeal to the Federal Court dismissed on other grounds. *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1998) 41 IPR 325.

[124] (1995) 33 IPR 557 at 569.

[125] *Merck & Co v Olin Mathieson Chemical Corporation* 253 F 2d 156 (1958); *Ex parte Bergstrom and Sjovall* 427 F 2d 1394 (1970); *In re Bergy* 563 F 2d 1031 (CCPA 1977); *Amgen Inc v Chugai Pharmaceutical Co Ltd* 13 USPQ 2d 1737 (1989).

[126] See Decision of European Patent Office Opposition Division (HOWARD FLOREY/ Relaxin) OJ EPO 1995, 388; (1996) 27 IIC 704. Upheld on appeal: Relaxin: HOWARD FLOREY INSTITUTE (Unreported, Boards of Appeal, European Patent Office, TO272/95, 23 October 2002) (cited in ALRC Discussion Paper 68), [6.49]. See also Guidelines for Examination in the EPO, C-IV, 2.3 'Discoveries' cited by R

When science is capable of creating its own genes rather than taking them from nature, or modelling synthetic constructs on it, the resulting organism or product will clearly be an invention.[128] However, today's modifications are limited by the genetic material already in existence - whether the modification involves moving existing or synthetically constructed gene sequences based on existing genes to other organisms, deleting existing genes or rendering certain parts of an organism's genetic material inoperable.

Nevertheless, GMOs and their products should be treated as more than mere discoveries of naturally occurring articles.[129] It is submitted that this is correct even if, as may be possible with some GMOs and their products, the organism or product exists or could exist in nature. This is because the objection to patenting a discovered organism on the basis that it is a discovery is not because of its subject matter per se. It is because of how the claimed invention was arrived at.[130] This is reflected by the *Patents Act 1990* (Cth) s 15(1)(a) which, subject to some irrelevant exceptions, provides that only the 'inventor' can be granted a patent.[131]

In determining whether the subject matter of a patent application was a manner of manufacture in *NRDC*, the High Court quoted with approval the following statement with respect to what the subject matter must be:

> Something of a corporeal and substantial nature, something that can be made by man from the matters subjected to his art and skill, or at the least some new mode of employing practically his art and skill...[132]

Teschmacher, 'The Patentability of Living Matter. The Practice of the European Patent Office, with a Comparative Look at the Situation in the United States and Japan' (1994) 63 *Nordiskt Immateriallt Rättsskydd* 46, 52. Further, see *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Article 3.2.

[127] See also ALRC Discussion Paper 68.

[128] Even if synthetically created, science is not yet capable of creating new genetic material to serve a particular desired purpose. All transgenes are made up of various fragments of DNA originally derived from other organisms. However, science is working towards expanding the genetic code by incorporating artificial bases into DNA which in turn code for non-physiological amino acids. See J Stanley and D C Ince, 'Copyright Law in Biotechnology: A View from the Formalist Camp' [1997] *European Intellectual Property Review* 142, 146 and the articles referred to therein.

[129] See, however, Mustill LJ in *Biogen Inc. v Medeva* [1995] FSR 4. See also his decision in *Genentech Inc.'s Patent* [1989] RPC 147.

[130] S A Bent et al, *Intellectual Property Rights in Biotechnology Worldwide* (Stockton Press, New York, 1987), p 131. See also M Rohrbaugh, 'The Patenting of Extinct Organisms: Revival of Lost Arts' (1997) 25 *AIPLA Quarterly Journal* 371, 383-4.

[131] See also *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Article 3.2.

[132] (1959) 102 CLR 252 at 270 quoting from *R v Wheeler* (1819) 2 B. Ald. 345 at 350; 106 ER 392 at 395. A similar statement was made by Sir Stafford Cripps S-G in *Application by Compagnies Reunies des Glaces*

Human intervention is required to create GMOs even though the modification is, to some extent, dictated by what is already in existence in nature.[133] The creation of a new plant or animal by GM is different from identifying for the first time an organism or other natural substance in the wild not previously known to exist. In the latter case, the newly identified organism or substance is created entirely by nature. In contrast a GMO is produced with the aid of science. Although science starts with pre-existing forces and requires the cooperation of natural forces, it provides the special conditions needed to obtain the organism.[134]

(v) Organism Expresses the Modification

GMOs express the modified characteristic. The resulting organism or material may therefore be considered the result of that which is inherent in the organism, that is, the result of a natural process, rather than the result of human intervention and not a manner of manufacture. There is case law in support of such an approach. For example, in *Re R.H.F.'s Application*,[135] Morton J approved a statement by an Examiner that 'fruit and other growing crops, although the assistance of man may be invoked for their planting and cultivation, do not result from a process which is a "manner of manufacture"'. The High Court in *NRDC* agreed with that statement.[136] The High Court went on to add that '[h]owever advantageously man may alter the conditions of growth, the fruit is still not produced by his action.'[137]

In Canada the lack of human intervention has been one basis on which GMOs have been found not patentable.[138] In *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)*[139]

(1931) 48 RPC 185 at 188 who stated: '...by manner of manufacture I understand a manner of adapting natural materials by the hands of man or by man-made devices or machinery'.

[133] Human input includes identifying, isolating and reproducing the gene sequence and carrying out the modification.

[134] Burger CJ in *Diamond v Chakrabarty* 447 US 303 (1980) at 309 used the newly discovered mineral, in dicta, as an eg of subject matter which is not patentable. The US Patent Office had decided that the GM bacterium under consideration was not a product of nature. The US Supreme Court did not consider this issue on appeal. Moufang concludes that, like all other fields, GM starts with pre-existing things and does not change the laws of nature and to exclude new plant varieties [and, by analogy, other organisms] from patent law for such reasons would be an unjustifiable discrimination. R Moufang, 'Protection for Plant Breeding and Plant Varieties. A Frontier of Patent Law' (1992) 61 *Nordiskt Immateriellt Rättsskydd* 330, 339. A similar point was made in *Merck & Co v Olin Mathieson Chemical Corporation* 253 F 2d 156 at 161-2 (1958) (US CA).

[135] (1944) 61 RPC 49.

[136] (1959) 102 CLR 252 at 278.

[137] (1959) 102 CLR 252 at 278.

[138] Patents on life forms more commonly are not issued in Canada for failure to comply with the disclosure requirements of s 36(1) of the Canadian Patents Act. M B Landau, 'Multicellular Vertebrate Mammals as

the Canadian Federal Court of Appeal refused a patent application claiming a new soybean variety developed from artificial cross-breeding but cultivated naturally.[140] The Court noted the appellant's submission that not only was an equivalent organism not previously found in nature but the chance of it being created by natural processes without human intervention was essentially impossible.[141] Nevertheless the Court held that the plant was not an invention.[142] On appeal, the Canadian Supreme Court decided the case solely on the basis that there was insufficient disclosure.[143] The issue of human intervention was raised although not finally decided. Lamer J of the Supreme Court, however, emphasised that the effects of inherent natural forces were not changed by the applicant and that the plant was growing according to the laws of nature. The plant was therefore only a discovery.[144]

A similar decision was reached in *President and Fellows of Harvard College v Canada (Commissioner of Patents)*,[145] where the GM 'Harvard oncomouse' was found not to be patentable.[146] Again the Canadian Federal Court noted that the organism being considered does not occur naturally.[147] The Court said that the creation of the oncomouse was 'a marriage between nature and human intervention'.[148] However, although the Court said that the inventor did not need to have direct control over all aspects of the natural processes leading to the creation of the end product, the Court required an element of control. It did not explain what level of control was required. On the facts before it though, human intervention was responsible only for the inclusion of the particular transgene and everything else was present independently of human intervention.[149] That was not

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"Patentable Subject Matter" Under 35 USC para 101: Promotion of Science and the Useful Arts or an Open Invitation for Abuse?' (1993) 97 *Dickinson Law Review* 203, 205 n 4.

[139] [1987] 3 FC 8. See R W Marusyk, 'The Patentability of New Life Forms in Canada' (1990) 16 *Canadian Business Law Journal* 333.

[140] Artificial cross-breeding is not GM. It is a traditional plant-breeding method whereby plants with desired characteristics are selected and then crossed by hydridisation.

[141] [1987] 3 FC 8 at 12.

[142] One reason given by the Court was that the plant could not be said to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means as required by the common meaning of the words 'manufacture' and 'composition of matter' in the Canadian legislation. [1987] 3 FC 8 at 13.

[143] [1989] 1 SCR 1623. That issue had also been dealt with by the Federal Court of Appeal.

[144] [1989] 1 SCR 1623 at 1634. But cf statements at 1637. The decision has been criticised. See, for eg, R Moufang, 'Protection for Plant Breeding and Plant Varieties. A Frontier of Patent Law' (1992) 61 *Nordiskt Immateriellt Rättsskydd* 330.

[145] [1998] 3 FC 510 (Federal Court, Trial Division).

[146] The patent claims related to a mouse genetically modified to contain a gene artificially introduced into the chromosomes of the mouse or its ancestors at the embryonic stage. The gene predisposes the mouse to developing malignant tumours.

[147] [1998] 3 FC 510 at [29].

[148] [1998] 3 FC 510 at [27].

[149] [1998] 3 FC 510 at [24].

considered sufficient for patentability. On final appeal,[150] the Canadian Supreme Court also held that the mouse was not patentable.[151] The majority[152] held that higher life forms such as the mouse were not 'manufactures' or 'compositions of matter' and therefore not inventions for the purposes of the legislation.[153] Once again the Court pointed out that part of the process of producing the oncomouse is reliant on 'elements which require no human intervention'.[154] The Court did not expand on how much of a part those elements were. The Court did go on to note though that the mouse could not be 'defined solely with reference to the genetic matter of which it is composed'[155] and that it possessed numerous unique qualities that transcended its particular genetic material.[156]

From the above decisions, it seems that the Canadian courts take a quantitative approach when determining whether there has been adequate human intervention for patentability. That is, in determining when a natural process moves to an invention, the courts focus on the level or extent rather than type, of human intervention. In contrast, the European Parliament seems to have taken a qualitative approach, concentrating on the type of intervention, when it recently gave 'crossing or selection'[157] as examples of processes for the production of plants and animals which are essentially biological and therefore not patentable pursuant to the EPC, Article 53(b).[158] Crossing or selection can require as much human intervention as other agricultural processes but have been classified as not patentable. Nevertheless a quantitative approach is still relevant to whether such processes are patentable because the distinction between biological and non-biological processes is answered having regard to 'the extent to which there is intervention by man in the process'.[159] However, it should be noted that unlike the position in Australia and Canada, biological processes are an exception to patentability pursuant to the EPC. That is, the

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[150] From the Canadian Federal Court of Appeal *President and Fellows of Harvard College v Canada (Commissioner of Patents)* [2000] 4 FC 528. The Court of Appeal had allowed the appeal in respect of the product claims. Linden and Rothestein JJ A; Isaac JA dissenting.

[151] *Canada (Commissioner of Patents) v President and Fellows of Harvard College* [2002] 4 SCR 45.

[152] L'Heureux-Dube, Gonthier, Iacobucci, Bastarache and LeBell JJ. McLachlin CJ, Major, Binnie and Arbour JJ dissenting.

[153] [2002] 4 SCR 45 at [120] and [155]. Possible policy concerns, such as ethical, religious or environmental considerations, were not considered, the Court indicating that these were matters for Parliament. See, for eg, [11], [14], [75], [120] and [153].

[154] [2002] 4 SCR 45 at [162].

[155] [2002] 4 SCR 45 at [163].

[156] [2002] 4 SCR 45 at [163].

[157] Crossing and selection are not GM for the purposes of this study. They are traditional techniques of plant breeding and do not involve the deliberate and direct modification of the DNA of organisms. See section 1.3.1 for further discussion of GM.

[158] *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Article 2(2).

[159] G Paterson, *The European Patent System. The Law and Practice of the European Patent Convention* (Sweet & Maxwell, London, 1992), [7-56].

EPC does not provide that such processes are not inventions, it provides that they are excepted from patentable subject matter. This means decisions with respect to the EPC on this point are of little relevance to Australia except to illustrate the meaning of a qualitative approach.

Whether the Australian courts will take a quantitative or qualitative approach in determining the human intervention required for manner of manufacture is considered in the first subsection below. The level and type of human intervention required are then examined. Some of the case law considered concerns the patentability of processes which use living organisms rather than patentability of the organisms themselves. Nevertheless the case law provides guidance as to the likely approach to the patenting of organisms. In subsection D, the law is applied to GMOs and their products to determine whether they involve sufficient intervention to be a manner of manufacture. It is submitted that the level and type of human intervention necessary to create a GMO and its products are sufficient for the outcomes to be patentable subject matter in Australia. The fact that the assistance of the organism's own biological processes is required to produce the outcome should not change that conclusion.

A Quantitative or Qualitative Approach

Prior to the decision in *NRDC*, agricultural and horticultural processes were generally considered by the Australian courts not to be patentable subject matter.[160] Established Patent Office practice, which was criticised by the High Court in *NRDC*, was also to deny that such processes were patentable. A qualitative approach was therefore taken. Accordingly, as is the case pursuant to the EPC, crossing or selection (and presumably the products of such techniques) would not have been patentable processes in Australia prior to *NRDC*.

However, in *NRDC* the High Court doubted the correctness of certain earlier decisions.[161] The High Court held that the fact that a process is relevant to an agricultural or horticultural enterprise did not mean of itself that it is not a patentable process.[162]

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[160] The High Court in *NRDC* considered that there were several reasons why such processes were not patentable. For a summary of these reasons see J McKeough et al, *Intellectual Property. Commentary and Materials* (3rd ed, Law Book Co, Sydney, 2002), pp 272-3.

[161] The High Court referred to *Standard Oil Development Company's Application* (1951) 68 RPC 114 (PAT); *Dow Chemical Co's Application* [1956] RPC 247 (Pat Off); and, regarding animals, *Canterbury Agricultural College's Application* [1958] RPC 85 (PAT). See also *Virginia-Carolina Chemical Corporation's Application* [1958] RPC 35 (PAT); *American Chemical Paint Co.'s Application* [1958] RPC 47 (PAT).

[162] (1959) 102 CLR 252 at 279.

Nevertheless, as for all other subject matter, there must be sufficient human intervention in order for there to be an invention for the purposes of the *Statute of Monopolies* and therefore patentable subject matter.[163] The approach of the Australian courts should therefore be seen to be a quantitative rather than a qualitative one.

This was recognised by Barrowclough CJ of the New Zealand Supreme Court in *Swift and Company v Commissioner of Patents* ('*Swift*').[164] Given animals as well as plants can be GM, *Swift* is relevant for a second reason. The case concerned an appeal against a decision of the New Zealand Assistant Commissioner of Patents refusing a patent application in respect of a method of tenderising meat. This involved injecting a proteolytic enzyme into the animal immediately before slaughter so that the animal's heart could pump the enzyme throughout the animal's body. After slaughtering, the enzyme would then decompose the meat to the desired tenderness. Prior to this invention, the enzyme was pumped through the animal's vascular system after death using a pumping apparatus.

The invention was therefore 'a biological or a physiological invention' rather than a process relevant to an agricultural or horticultural enterprise. Nevertheless Barrowclough CJ said that 'the conclusion reached by the High Court [in *NRDC*] is as applicable to biological inventions as it is to horticultural and agricultural enterprises'.[165] The 'invention' under consideration by him was not to be treated as not being patentable only because it was a biological invention.

Barrowclough CJ noted that following the decision in *NRDC*, the subject matter of a patent must be the result of an artificial state of affairs.[166] He concluded that the process before him was a manner of manufacture because, amongst other things, the process had as its ultimate end result 'the artificial effect of producing meat which is more tender than meat derivable from animals not subjected to that process'.[167]

In both *NRDC* and *Swift* an organism's own internal processes were an essential part of the success of the relevant invention. As noted above, the invention in *NRDC* was a method of adding a hormone herbicide to a field of crops and allowing the natural genetic differences between the crops and weeds to do the rest; in *Swift* the animal's own heart and vascular

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[163] This is consistent with the basic principle that discoveries are not inventions and therefore are not patentable.
[164] [1960] NZLR 775.
[165] [1960] NZLR 775 at 779.
[166] [1960] NZLR 775 at 779.
[167] [1960] NZLR 775 at 780.

system were used. Nevertheless in both cases the process was patentable. The view that an organism's own internal processes can contribute to the outcome is also supported by the statement by the High Court in *NRDC* that it was a mistake to conclude that only if tangible goods are made by hand or machine would there be manufacture.[168]

B. Level of Human Intervention Required

Neither the High Court in *NRDC* nor Barrowclough CJ in *Swift* dealt expressly with the level of human intervention necessary to result in a claimed invention, in those cases processes, being a manner of manufacture. The High Court did, as noted above, agree with Morton J in *Re R.H.F.'s Application*,[169] that fruit and other growing crops do not result from a process which is a manner of manufacture, although human assistance is invoked for their planting and cultivation. By extension, the resulting fruit and crops themselves would also not be patentable as not being manners of manufacture. In *Genentech Inc.'s Patent*,[170] Mustill LJ said that human intervention was required for there to be an 'invention' but that even a considerable amount of human intervention may not result in a patent. An indication of the level of human intervention required is given by the High Court's treatment of certain earlier cases in *NRDC*.

The Court referred to two earlier decisions without apparent disapproval.[171] Those cases were *Re Lenard's Application*[172] and *Re N.V. Philips' Gloeilampenfabrieken Application*.[173] In both cases the patent applications under consideration were rejected.

The High Court said of these decisions that 'both seem to depend on the view that the process in question was only one for altering the conditions of growth, so that the contemplated end result would not be a result of the process but would be "the inevitable result of that which is inherent in the plant"'.[174] The lack of disapproval by the High Court indicates that it agreed that there was insufficient human intervention in those cases for the 'inventions' concerned to be manners of manufacture. In short, altering conditions of growth was not considered sufficient human intervention.

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[168] (1959) 102 CLR 252 at 269.
[169] (1944) 61 RPC 49.
[170] (1989) 8 RPC 147 (with respect to the *Patents Act 1977* (UK)).
[171] (1959) 102 CLR 252 at 279.
[172] (1954) 71 RPC 190.
[173] (1954) 71 RPC 192.
[174] (1959) 102 CLR 252 at 279.

In *Re Lenard's Application*, an application for a patent for '[i]mproved methods for meeting or offsetting the advance of disease in clove trees' was rejected. The application was based on the discovery by the applicant that the disease Dieback and Sudden Death was caused by a fungus and that the drastic pruning of clove trees protected trees from dying from the disease.

The applicant submitted that the application disclosed a manner of manufacture because, amongst other things, the claimed process was wholly human-conducted since it involved pruning and spraying. Although it was the subsequent conduct of nature that enabled one to make the assertion that the value of the tree was enhanced (because the tree either recovered, if infected, or became resistant), nature itself took no part in the process sought to be protected. Therefore the applicant contended that although utility and inventiveness rested on nature's assistance, manner of manufacture did not rest on it. The Examiner rejected the application on the basis that the alleged invention did not disclose a manner of manufacture.

The applicant's appeal was dismissed. Lloyd-Jacob J concluded that a method of agricultural or horticultural treatment such as the one the subject of the application could not come within the *Patents Act 1949 (UK)*.[175] The reason for this conclusion was that the subject matter of the application was not a manner of manufacture.[176]

A similar result was reached in *Re N.V. Philips' Gloeilampenfabrieken Application*.[177] In that case, the applicant applied for a patent for 'improvements in and relating to methods of producing a new form of Poinsettia'.[178] The applicant produced plants which had more flowering heads than usual by subjecting the plants before flowering to a sequence of artificial conditions. The applicant submitted that the growing, by artificial means, in specially equipped greenhouses, of plants of a special form, which can only be produced by such artificial conditions employing considerable labour and plant, is in the truest sense a productive industry and one having a very close analogy to a factory process. Nevertheless the applicant agreed that the application raised the fundamental question of whether the method was a manner of manufacture within the *Statute of Monopolies*. The Examiner rejected the application on the basis that not only the methods of growing plants but also the plants themselves were not regarded as 'manners of manufacture'.

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[175] (1954) 71 RPC 190 at 192.
[176] (1954) 71 RPC 190 at 192.
[177] (1954) 71 RPC 192.
[178] Poinsettia is a tropical plant.

Once again, the applicant's appeal was dismissed by Lloyd-Jacob J. It was accepted that the circumstances surrounding the development of agricultural and horticultural products approach the conditions in industry. However, Lloyd-Jacob J said that a 'manner of new manufacture' must be 'disclosed as an essential ingredient of the invention itself, and cannot satisfactorily be found in the means by which the invention is exploited'.[179]

The invention under consideration was, according to Lloyd-Jacob J in a statement cited by the High Court in *NRDC*, one that 'resides in the modification of climatic conditions, the production of the end product being the *inevitable result of that which is inherent in the plant*' (emphasis added).[180] Lloyd-Jacob J went on to say:

> If that be right (and I can see no escape from it), can it be said that there is any feature either of manufacture or production in such modification? When, as I have endeavoured to indicate, one can isolate the alleged invention as a modification of the conditions under which natural phenomena will pursue their inevitable course, I feel constrained to come to the conclusion that it would be a misuse of language to hold that that discloses a manner of manufacture.[181]

A similar view has been taken by the Patent Office. In *Ranks Hovis McDougall Ltd's Application*[182] the Assistant Commissioner made a distinction between two different situations. The first was where the 'inventor' discovers a naturally occurring microorganism and changes its morphological characteristics by altering its conditions of growth. He thought these would not be patentable. The second was where the inventor produced a new microorganism with improved or altered useful properties by some human controlled microbiological process. These organisms he considered would be patentable following *NRDC*.[183]

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[179] (1954) 71 RPC 192 at 193-4.
[180] (1954) 71 RPC 192 at 194.
[181] (1954) 71 RPC 192 at 194. Similarly Lloyd-Jacob J said in a later decision '[i]f to secure [the end product of the alleged invention] the development of living animal or vegetable matter by the operation of natural laws is essential, the applicant cannot claim to have invented it nor the means of procuring it.' *Virginia-Carolina Chemical Corporation's Application* [1958] RPC 35 at 37. In *Dow Chemical Company's Application* [1956] RPC 247 (Pat Off) the Superintending Examiner, when referring to the claimed invention in the case before him and in *Standard Oil Development Company's Application* (1951) 68 RPC 114 (PAT), said '[i]n both cases, it is hoped that *nature will provide* an improved ultimate crop in the absence of competing weeds' (emphasis added). Once again the bar to patentability may have been insufficient human intervention.
[182] (1976) 46 AOJP 3915.
[183] (1976) 46 AOJP 3915 at 3918. See also *General Electric Co Ltd's Application* [1961] RPC 21 (PAT) where a process for artificially inducing mutations in microorganisms by a specific electrical treatment was held not to be an invention because no manufacturing application was disclosed or could be inferred from the specification.

C. Type of Human Intervention Required

The type of process involved should be irrelevant in determining whether there has been sufficient human intervention for the process and, by analogy, the products of the process, to be patentable. The High Court's attitude to the classification of a process as agricultural or horticultural is described above. Similarly, whether the process is characterised as a chemical, biological or microbiological one should not be determinative of patentability. The issue should instead be a quantitative one - whether the outcome is considered the result of the human intervention or the result only of that which is inherent in the organism.

In *NRDC* the High Court said that a distinction had to be drawn between two different classes of case.[184] The first was those where the process was one for altering conditions of growth so the end result was the inevitable result of that which was inherent in the plants. Examples of this group are the processes considered in *Re Lenard's Application*[185] and *Re N.V. Philips' Gloeilampenfabrieken Application*.[186] Such processes are not patentable. The second group was cases of methods employing microorganisms which may be patentable.[187]

The reason for the distinction was not, in light of the example given by the High Court which is discussed below, on the basis of whether the process was a biological one. The process in the case given as an example was considered to be a biological one rather than a chemical one but was still patentable. Nor, in light of the fact that the Court referred to the first class as those that inevitably produce a certain result, could it have been because of concerns over reproducibility as has recently concerned the Canadian courts.[188] It was because 'in the latter class of cases the process is analogous to a chemical process in that, given the micro-organisms and the appropriate conditions, the desired result inevitably follows *from the working of the process*' (emphasis added).[189] In light of the Court's other

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[184] (1959) 102 CLR 252 at 279.
[185] (1954) 71 RPC 190.
[186] (1954) 71 RPC 192.
[187] The High Court referred to *Commercial Solvents Corporation v Synthetic Products Company Ltd* (1926) 43 RPC 185; *Adhesives Pty Ltd v Aktieselskabet Dansk Gaerings-Industri* (1935) 55 CLR 523; *Virginia-Carolina Chemical Corporation's Application* [1958] RPC 35 and *Re Joseph Szuec's Application* [1956] RPC 25 as egs of this group.
[188] *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)* [1987] 3 FC 8 (Canadian Fed Ct of Appeal); [1989] 1 SCR 1623 (Canadian Sup Ct); *President and Fellows of Harvard College v Canada (Commissioner of Patents)* [1998] 3 FC 510; *Canada (Commissioner of Patents) v President and Fellows of Harvard College* [2002] 4 SCR 45 (Canadian Supreme Court).
[189] (1959) 102 CLR 252 at 279.

comments this seems to mean that the result was considered the result of the human intervention rather than the organism's inherent characteristics alone.

The High Court referred to *Re Joseph Szeuc's Application*[190] as an example of an invention which was patentable on the basis that the desired result inevitably followed from the working of the process. In *Re Joseph Szeuc's Application* the process was one for the production of edible mushroom tissue using a particular fungi in a nutrient solution and agitation and aeration of the mixture to produce tissue in pelletted form. The process was considered to be a biological one rather than a chemical one. However, the desired result was considered to be the inevitable consequence of the process and patentable.

Recognition that the type of process should be irrelevant is consistent with scientific knowledge. It is now recognised that any distinction on the basis of whether a process is referred to as biological or chemical is arbitrary. As Frankfurter J said in *Funk Bros. Seed Co. v Kalo Inoculant Co.*,[191] in a statement cited with approval by the High Court in *NRDC*, '[everything] that happens may be deemed "the work of nature", and any patentable composite exemplifies in its properties "the laws of nature."'[192]

All biological processes can now be described by reference to chemical or, more accurately, biochemical reactions.[193] With respect to GM, DNA is simply a chemical substance and any modification to it can be seen as a chemical process. Even if that is not the case, an important part of GM relies on physical or chemical means. For example, where mutagenic processes are involved physical or chemical mutagens will be used. In respect of transgenics, microinjection will involve physical intervention.[194]

The courts have long accepted that products produced by microorganisms, such as acetone and alcohol[195] and antibiotics,[196] are the inevitable result of microorganisms being placed in human determined conditions and are patentable. Arguably, two scientific factors have combined so far to prevent the same acceptance with respect to the products of higher organisms or even such organisms themselves. First, science was not capable of making

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[190] [1956] RPC 25.
[191] 333 US 127 (1948) at 134, 135.
[192] (1959) 102 CLR 252 at 264.
[193] '[I]n effect, biology is becoming chemistry.' Aust, Commonwealth Scientific and Industrial Research Organisation, *Priorities for Science and Technology Policy in Australia. Report to the Minister for Science and Technology* (Canberra, 1997), p 4.
[194] R Moufang, 'Protection for Plant Breeding and Plant Varieties. A Frontier of Patent Law' (1992) 61 *Nordiskt Immateriellt Rättsskydd* 330, 347.
[195] *Commercial Solvents Corporation v Synthetic Products Company Ltd* (1926) 43 RPC 185.
[196] *American Cyanamid Co v Berk Pharmaceuticals Ltd* [1973] FSR 487.

controlled modifications to higher organisms until recent times.[197] Secondly, until recently science was unable to show that the particular 'new' characteristic of the organism was the inevitable result of the modification and not simply natural processes.

Now that GM can be used in a controlled way on higher organisms and science can demonstrate that human intervention is responsible for particular outcomes, it should be possible to establish that the organism and products produced by the organism following GM are the result of human intervention.[198] To continue to differentiate between higher organisms and microorganisms would be to ignore the basic similarity of all life forms and their biochemistry.

D. Whether there is Sufficient Intervention in GMOs and their Products

1. GMOs

The human intervention required to produce founder GMOs is more significant than merely creating artificial conditions for growth. At its most basic, the starting organism and the gene sequence to be modified need to be selected and the actual modification must be carried out. As noted above, the fact that an organism's own internal processes are to some extent required to be involved in the process used to produce the outcome should not prevent the organism from being a manner of manufacture.[199] Unlike the position under the EPC, the type of intervention involved (that is, chemical, biological or microbiological) should not affect the patentability of the organism so long as the outcome is shown to be the result of the intervention.[200]

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[197] This gives rise to problems satisfying the disclosure requirements of patent law. For eg, one of the earliest decisions on the patenting of animals *Red Dove (Rote Taube)* [1969] GRUR 672; [1970] 1 IIC 136. See also *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)* [1989] 1 SCR 1623 which also discusses the problem of reproducibility. This is discussed in section 4.3.5. This could continue to be a problem for classically bred organisms. See, for eg, P T Clark, 'Animal Invention Protection' (1988-89) 16 *AIPLA Quarterly Journal* 442.

[198] Llewelyn has suggested that there is an increased blurring of the distinction between discoveries and human manufactures, apparently for protectionist purposes. M Llewelyn, 'Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States' [1994] *European Intellectual Property Review* 473.

[199] See *Swift & Co's Application* [1962] RPC 37 where the English Divisional Court said that reliance on the fact that the process used the heart and vascular system of a living animal as the material step in the process as a reason for non-patentability would be in direct conflict with *Swift* and *NRDC*. Following that case it was held in *US Rubber Company's Application* [1964] RPC 104 that a method of medically treating animals would be patentable. In another English case regarding whether living processes fall within manner of manufacture, the point was not considered. See *Commercial Solvents Corporation v Synthetic Products Company Ltd* (1926) 43 RPC 185.

[200] See European Patent Convention Article 53(b) where the distinction between 'essentially biological processes' and non-biological processes and between biology and microbiology remains important. With

2. Products of GMOs

The generally accepted view is that products produced by living organisms, at least those produced by microorganisms, are patentable.[201] For instance in *American Cyanamid Company (Danns) Patent*,[202] a patent in respect of, amongst other things, an antibiotic not known to exist in nature produced by a microorganism under certain artificial conditions was held to be valid. The House of Lords in that case, however, was not required to consider whether the antibiotic was an invention.[203] Similarly in *Re Joseph Szeuc's Application*,[204] although the decision of the Superintending Examiner concerned only the process claims, the specification as accepted included claims to the product produced by the process, edible mushroom tissue.

Nevertheless, it is possible to argue that the products of higher GMOs do not involve sufficient human intervention to be manners of manufacture.[205] The invention under consideration in *NRDC* was a process rather than a product. Although the part played by humans was not the material step in the process, humans were involved each time the process was performed.[206] They were required to prepare and spray the chemical onto the field. With respect to the products of GMOs, the inventive step (the modification) may be too distant for the products themselves to be patentable. Further, *American Cyanamid Company (Danns) Patent*[207] and *Re Joseph Szeuc's Application*[208] concerned a microorganism and a fungi respectively rather than higher organisms.

It is submitted that products produced by higher GMOs should be treated as capable of involving sufficient human intervention to be patentable subject matter. It is true that the product will be produced by the organism's natural processes. However, the High Court in

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respect to whether a particular process is biological or microbiological see T 356/93 (PLANT GENETIC SYSTEMS/ Glutamine synthetase inhibitors) OJ EPO 1995, 545; (1997) 28 IIC 75.

[201] See U Schatz, 'Patentability of Genetic Engineering Inventions in European Patent Office Practice' (1998) 29 *International Review of Industrial & Copyright Law* 2, 7 with respect to position under the EPC.

[202] [1971] RPC 425.

[203] [1971] RPC 425 at 437.

[204] [1956] RPC 25.

[205] For eg, Landau has noted in relation to progeny of non-naturally occurring life forms that they may be 'naturally occurring'. M B Landau, 'Multicellular Vertebrate Mammals as "Patentable Subject Matter" Under 35 USC para 101: Promotion of Science and the Useful Arts or an Open Invitation for Abuse?' (1993) 97 *Dickinson Law Review* 203, 208 n 14.

[206] In *Swift & Co's Application* [1962] RPC 37 the English Divisional Court noted that in neither *NRDC* or *Swift* was the human intervention the material step and yet in both cases the invention under consideration was patentable. With respect to *NRDC*, the Divisional Court said that 'the material step was within the weed itself which broke down the chemical into an acid which destroyed the weed.' [1962] RPC 37 at 43.

[207] [1971] RPC 425.

[208] [1956] RPC 25.

NRDC stated that an invention is patentable where no effort is required after the research stage and nature was permitted to work in its own way after that.[209] Further, the human intervention does not have to be the material step in the process or, by analogy, in the production of the outcome. Applied to products of GMOs it should not matter that the human intervention will have occurred only in relation to the organism rather than the production of the organism's products.

(c) Exceptions to patentable subject matter

To be patentable, GMOs and their products must not fall within an exception to patentable subject matter. There are two exceptions which may apply. The first is provided for in s 50(1) of the *Patents Act*. Pursuant to that section, the Commissioner of Patents has a discretion to refuse to accept a patent application or to grant a patent. The discretion arises where the use of the claimed invention would be contrary to law[210] or where certain types of food or medicine are claimed as an invention.[211] The second exception is the 'general inconvenience' exception. Pursuant to this exception, GMOs and their products may be excluded from patentable subject matter on the basis of public policy.

Section 50(1)

(i) Contrary to Law

Pursuant to s 50(1)(a) of the *Patents Act*, the Commissioner has a discretion to deny patent protection where the use of the claimed invention would be contrary to law. There has been little judicial consideration of the meaning of 'contrary to law' in Australia.[212] It has been suggested that if the use of the invention will be unlawful, whether under statute, other delegated legislation or at common law, then its use will be 'contrary to law'.[213] Being contrary to public policy is therefore unlikely to result in the denial of protection pursuant to this provision, although this is not certain.[214]

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[209] (1959) 102 CLR 252 at 263.
[210] *Patents Act 1990* (Cth) s 50(1)(a).
[211] *Patents Act 1990* (Cth) s 50(1)(b).
[212] See *Dow Chemical Co v Ishihara Sangyo Kaisha Ltd* (1985) 5 IPR 415 (NZ HC) (interlocutory decision) in relation to the New Zealand equivalent.
[213] IP Australia, *Manual of Practice and Procedure*, Vol 2 - National, (Cth of Australia, Canberra, 2002), [8.6.1] cited in J W Dwyer et al, 1 *Lahore. Patents, Trade Marks & Related Rights* (Reed International Books Australia Pty Ltd, Sydney, 2001, looseleaf), [12,150], n 4.
[214] Cf the provisions of the EPC, Article 53(a) and *Patents Act 1977* (UK) s 1(3) which raise the issues of 'ordre public' and whether the patent would 'be generally expected to encourage offensive, immoral or antisocial behaviour'. See generally on these provisions, L Bently and B Sherman, *Intellectual Property Law* (Oxford University Press, New York, 2001), pp 405-12.

Certain uses of the GMOs or their products may be unlawful in some or all Australian jurisdictions. For example, contravention of the *Gene Technology Act 2000* (Cth) ('*GT Act*'), certain provisions of the food regulatory scheme, both discussed in Chapter 2, or the State moratorium legislation discussed in Chapter 3, are criminal offences. Use of GMOs which contravene such legislation may then be 'contrary to law' and the discretion become relevant. Importantly, however, the Australian Patent Office Examiners' Manual says that the discretion should only be exercised against claims for which no lawful use is described.[215] Where the invention may be used both lawfully and unlawfully then regard is to be had to the main purpose of the invention.[216] GMOs will frequently have many uses. For example, they may be used to generate new organisms. But in many cases, the main purpose of the production of the organism or material is, for example, for sale as food. It is submitted that because use is authorised, and in most cases a licence would already have been obtained to allow at least the research and development to proceed, the exception in s 50(1)(a) is unlikely to apply.

(ii) Certain Food and Medicine

Many GM products are, or will be, used as food or medicine. For example, products of both the GM pig and canola are destined for the food market.

Food and medicine for humans or animals are prima facie patentable so long as they meet the relevant criteria for patentability. But this is subject to the discretion in s 50(1)(b). The relevant part of that section gives the Commissioner a discretion to refuse to accept a patent application or grant a patent where the food or medicine claimed as the invention consists of a mere mixture of known ingredients.[217]

Whether patent protection would be denied on the basis of s 50(1)(b) depends upon whether the invention being the outcome of GM is a 'mixture of known ingredients'.[218] 'Mixture' is interpreted broadly and can include mixtures of gases and liquids.[219] In the case of GM products, the mixture would be of genes at the genetic level and gene products

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[215] IP Australia, *Manual of Practice and Procedure*, Vol 2 – National, (Cth of Australia, Canberra, 2002), [8.6.4] cited in J W Dwyer et al, 1 *Lahore. Patents, Trade Marks & Related Rights* (Reed International Books Australia Pty Ltd, Sydney, 2001, looseleaf), [12,150], n 5.

[216] *Pessers and Moody v Haydon & Co* (1909) 26 RPC 58 (interlocutory decision). The issue is whether the invention was primarily devised to be used in a lawful or unlawful manner. S Ricketson, *The Law of Intellectual Property* (Law Book Co, Sydney, 1984), [48.22].

[217] *Patents Act 1990* (Cth) s 50(1)(b)(i) and (ii).

[218] It also requires that the claimed invention be food or medicine.

[219] S Ricketson, *The Law of Intellectual Property* (Law Book Co, Sydney, 1984), [48.23].

at the macro level. Pork and canola oil produced from GM pigs and canola may therefore constitute 'a mixture of known ingredients'.[220] Known ingredients, such as the original plant or pig and the relevant genetic material,[221] are used for the production of the resulting food.

Nevertheless, it is unlikely patent protection will be denied pursuant to this section. First, it seems unlikely that cellular components, such as genes and gene products, will qualify for consideration as 'ingredients'. Even if they do, the discretion is likely only to be relevant where the GM concerned involves the addition of genetic material. Where GM occurs through the deletion of genetic material or existing material being rendered inoperative, the product is unlikely to be a 'mixture'.[222]

Secondly, a patent is unlikely to be refused given the Patent Office's approach to the section. The Patent Office Manual says that 'mere mixture of known ingredients' means:

- ... a mixture exhibiting only the aggregate of the known properties of the ingredients. Not only must the properties be known, but the property which makes the ingredients useful for the purpose of the invention must also be known.

- If the result achieved by the invention is more than might be expected from a mere mixture (ie synergism), the invention is patentable.[223]

To be worth commercialising, a GMO or its products must produce an outcome offering some advantage over non-GM products. To achieve such superiority the 'mixture' of genes or gene products must have a synergistic effect. That is, the combined activity of the genetic material or gene products, as the case may be, produces a better result than the effect of each ingredient alone.

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[220] Cripps concludes that a finding that GM products are a mixture of known ingredients is a possibility with respect to the equivalent New Zealand provision. Y M Cripps, 'Genetic Engineering - A Problem for the Patent Office?' [1979] *New Zealand Law Journal* 232, 237.

[221] Such material may be 'known' both by its genetic sequence and by its gene products.

[222] It may not be irrelevant if s 50(1)(b) is interpreted as including the method used to produce the original GM because deletions or inoperability will involve the addition of something at some stage (such as an enzyme to excise the gene to be deleted). In that sense, for eg, there may be a 'process producing such a substance by mere admixture'.

[223] IP Australia, *Patent Manual of Practice and Procedure*, Vol 2 – National (Cth of Australia, Canberra, 2002), [8.7.2]-[8.7.4], cited in J W Dwyer et al, 1 *Lahore. Patents, Trade Marks & Related Rights* (Reed International Books Australia Pty Ltd, Sydney, 2001, looseleaf), [12,390].

Further, it has been suggested in academic comment that the purpose of the provision seems to have been to lend support to the principles of novelty and obviousness.[224] Accordingly the provision should not be used to deny patent protection to products which, despite their component parts, are neither obvious nor lacking in novelty.

Finally, an objection on the basis of s 50(1)(b) would be difficult to justify given that it has never been raised as an objection to food products produced using classical agricultural techniques, such as cross-breeding or hybridisation.

General inconvenience exception

(i) Relevance of Policy

To be patentable an invention must be a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*.[225] The *Statute of Monopolies 1623* (Eng)[226] was the first statutory basis of the English patent system.[227] Section 6 provides, in modern English:

> VI. Provided also (and be it declared and enacted) that any declaration before mentioned shall not extend to any letters patent and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures which others at the time of making such letters patents and grants shall not use, so as also they be not contrary to the law or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient.[228]

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[224] Y M Cripps, 'Genetic Engineering - A Problem for the Patent Office?' [1979] *New Zealand Law Journal* 232, 237.

[225] *Patents Act 1990* (Cth) s 18(1)(a). The definition of 'invention' in Sch 1 also refers to the *Statute of Monopolies*.

[226] 21 Jac I c3.

[227] The purpose of the statute was to bar all present and future trading monopolies. However, those monopolies that encouraged the promotion of new industries and industrial techniques were excepted and allowed. Such monopolies being expressly preserved by s 6. S Ricketson, *The Law of Intellectual Property* (Law Book Co, Sydney, 1984), [48.8]. See also B Sherman and L Bently, *The Making of Modern Intellectual Property Law. The British Experience, 1760 – 1911* (Cambridge University Press, Cambridge, 1999); J Pila, 'Inherent patentability in Anglo-Australian law: A history' (2003) 14 *Australian Intellectual Property Journal* 109.

[228] D Young et al, *Terrell on the Law of Patents* (14th ed, Sweet and Maxwell, London, 1994), p 4. For original text see *Halsbury's Statutes of England and Wales* (4th ed, Butterworths, London, 1997, 2003 reissue), vol 33 Patents and Designs, p 9.

It seems that all of s 6 is imported into the Australian patents legislation by virtue of the reference to it in s 18(1)(a) and in the definition of 'invention'.[229] Therefore the exceptions to patentable subject matter included in the later part of s 6 are also incorporated into the current scheme.[230]

The 'general inconvenience' exception included in s 6 has been used in Australia to deny patent claims for subject matter to which the public expect free access, such as a method of operating a computer.[231] It is claimed to also provide the courts and Patent Office with a clear mandate to take into account policy when considering patent applications.[232] Therefore if GMOs or their products are, for example, considered morally deleterious, patent protection may be denied.[233] Further, if the availability of patent protection increases the level of research into a particular field, the policy arguments with respect to the actual use of the technology will also need to be considered.[234] Finally, the economic repercussions of a patent may justify the refusal of protection.[235]

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[229] See *Patents Act 1990* (Cth) s 3 and Sch 1 – Dictionary.

[230] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 (Fed Ct, Full Ct). At least Lockhart and Sheppard JJ seem to consider the generally inconvenient exclusion is relevant to modern law. See also first instance decision in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (1998) 41 IPR 467 at 479-82 and decision on appeal *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553 at [17]-[18] (Black CJ and Lehane J) and [100] and [131] (Finkelstein J). Also see Patents Regulations 1991 (Cth) Sch 1, reg 7(a), which provides that patent documents to be filed must not contain material 'contrary to morality or public order'.

[231] *Telefon A/B L. M. Ericsson's Application* [1975] FSR 49. See also, for eg, *Clayton Furniture Ltd's Application* [1965] AOJP 2303; *Boccari's Application* [1967] AOJP 1380; *Re Application by Beecham Group Ltd* (1984) 3 IPR 26. See also, with respect to UK law, *Rolls-Royce Ltd's Application* [1963] RPC 251. Cf the position under EPC, Article 53(a) where it is the act of publication or exploitation of the particular invention to which the moral test must be applied and not the morality of the act of patenting itself. R S Crespi, 'Biotechnology patents and morality' (1997) 15 *Trends in BioTechnology* 123, 123-4.

[232] D R C Chalmers et al, 'Current Research: Project on the Legal and Ethical Aspects of Genetic Research in Australia' (1995) 3 *Journal of Law and Medicine* 30. See also P Drahos, 'Biotechnology Patents, Markets and Morality' [1999] *European Intellectual Property Review* 441, 441; M Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *Australian Intellectual Property Journal* 202, 215-8.

[233] S Ricketson, 'Patentability of living organisms', in D J Galligan (ed), *Essays in legal theory. A collaborative work* (Melbourne University Press, Melbourne, 1984), Chap 5; R Dresser, 'Ethical and Legal Issues in Patenting New Animal Life' (1988) 28 *Jurimetrics Journal* 399; R P Merges, 'Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies' (1988) 47 *Maryland Law Review* 1051. McKeough et al suggest 'an invention may be regarded as generally inconvenient where it presents some danger to the public'. J McKeough et al, *Intellectual Property. Commentary and Materials* (3rd ed, Lawbook Co, Sydney, 2002), p 270.

[234] Commentators, such as Sherman (B Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery' [2003] *European Intellectual Property Review* 301, 305) and Drahos (P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 *European Intellectual Property Review* 441, 449), have pointed out that patents, by promoting technical innovation or investment in innovation, regulate behaviour. B Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery' [2003] *European Intellectual Property Review* 301, 305 fn 29.

[235] W van Caenegem, 'The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' (2002) 13 *Australian Intellectual Property Journal* 41, 58.

The Patent Office approach is to treat all arguments based solely on matters of social or economic policy as irrelevant when deciding what subject matter is patentable.[236] Such objections are therefore unlikely to be raised at the examination stage.[237] Nevertheless, if there was sufficient agitation by GM opponents the Patent Office may change its approach.[238] Further, any person may initiate an opposition to the grant of a patent on the ground, amongst others, that the invention is not a patentable invention because it is not a manner of manufacture within s 6 of the *Statute of Monopolies*.[239] Accordingly, those opposed to GM, upon learning of the acceptance of a relevant patent application could lodge a Notice of Opposition[240] and a Statement of Grounds and Particulars.[241] This would compel the Patent Office to consider policy. Furthermore, if the matter reaches the courts, policy, including social and economic concerns arising from the release of GMOs, will probably be found relevant. In addition, it has recently been proposed that the legislation be amended to expand the circumstances in which social and ethical considerations may be taken into account in decisions regarding the grant of patent protection.[242] The relevance and effect of policy is therefore a justified concern for commercialisers.

(ii) Would Patenting of GMOs and their Products be 'Generally Inconvenient'

Public opinion has had a huge impact outside Australia in the field of biotechnology, particularly in Europe where it delayed the passage of a Directive of the European

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[236] IP Australia, *Patent Manual of Practice and Procedure,* Vol 2 – National (Cth of Aust, Canberra, 2002), [8.1.2] cited in Australian Law Reform Commission, *Gene Patenting and Human Health* Issues Paper 27 (July 2003), [9.74].

[237] Wells has stated that, during the Patent Office hearing with respect to the patent application for a GM pig, there was no discussion of the social, ethical or environmental consequences of granting the patent. A J Wells, 'Patenting New Life Forms: An Ecological Perspective' [1994] *European Intellectual Property Review* 111, 112, n 19. See also IP Australia, *Patent Manual of Practice and Procedure*, Vol 2 – National (Cth of Aust, Canberra, 2002), [8.1.2] which specifically notes that policy considerations are not grounds on which patent applications may be rejected. Cited in ALRC Discussion Paper 68, [7.69].

[238] As to whether there should be an express public interest requirement in the *Patents Act* see, for eg, R S Crespi, 'Innovation in Plant Biotechnology: The Legal Options' [1986] *European Intellectual Property Review* 262; D Kell, 'Expanding the Frontier of Patentability: Methods of Medical Treatment of the Human Body. Anaesthetic Supplies Pty Ltd v Rescare Ltd' [1995] *European Intellectual Property Review* 202, 206 n 53. As to other methods of incorporating the public's views into the patenting process, see M Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *Australian Intellectual Property Journal* 202, 228-9.

[239] *Patents Act 1990* (Cth) s 59(b); Patents Regulations 1991 (Cth) reg 5.3(1). This is the same as the position under the EPC. EPC, Article 99(1). See also D Young et al, *Terrell on the Law of Patents* (14th ed, Sweet & Maxwell, London, 1994), [3.58]. Cf the position under the previous Australian legislation, *Patents Act 1952* (Cth), where the person concerned needed to be an interested person to have standing.

[240] Patents Regulations (Cth) reg 5.3(1).

[241] Patents Regulations (Cth) reg 5.4(1). There are time limits which must be complied with. See *Patents Act 1990* (Cth) s 59 and Patents Regulations (Cth) regs 5.3(3) and 22.11(3)(a).

[242] ALRC Discussion Paper 68, Proposal 7-3.

Parliament and of the Council on the Legal Protection of Biotechnological Inventions.[243] The Directive had to be redrafted to take into account such opinion. Further, at least one Australian judge has been willing to deny an invention patent protection on the basis that such protection would be 'generally inconvenient'.[244]

There is only limited information available regarding the Australian public's perception of GT. It seems there is community support for the use of GM technology to achieve desired goals, such as improved health, better foods and development of pest resistant crops.[245] There is also little doubt of the beneficial effects that may follow from research into, and the production of, GMOs and their materials.[246] Nevertheless, as discussed in earlier Chapters there is public concern regarding the social and economic effects of GMO releases. Their value does not mean that GMOs and their products would not be considered by a court to be objectionable on policy grounds and the patenting of them 'generally inconvenient'.[247]

Policy arguments for and against patenting of GMOs, as well as the actual use of the technology, have been well canvassed by legislative bodies[248] and in the literature.[249]

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[243] *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions.*

[244] See Sheppard J (in dissent) in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 (in relation to a procedure for treating a life-threatening disease). See also Heerey J in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (1998) 41 IPR 467 at 479-81 (decision at first instance - overturned on appeal on, amongst other things, this point). But now see *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553 at [17]-[18] (Black CJ and Lehane J) and [140]-[142] (Finkelstein J) with respect to methods of medical treatment.

[245] See, for eg, Aust, International Social Science Survey, *Public Perceptions of Genetic Engineering: Australia, 1994*, Final Report to the Dept of Industry, Science and Technology (May 1995); Senator Chris Schacht, Cth Minister for Small Business, Customs and Construction, Media Release (untitled) (22 May 1995). But cf J Norton et al, 'Consumer misgivings over genetically engineered foods' (1998) 19 *Australasian Science* 23.

[246] The risks are not always as clear.

[247] Llewelyn suggests the public benefit to be gained from an invention is not an appropriate yardstick to determine morality, especially where the subject matter of the invention is a living creature. M Llewelyn, 'Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States' [1994] *European Intellectual Property Review* 473, 478.

[248] See, for eg, Aust, House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (AGPS, Canberra, 1992) ('*Threat or the Glory* Report'), Chap 7; ALRC Discussion Paper 68, Chaps 3 and 7.

[249] See, for eg, R P Merges, 'Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies' (1988) 47 *Maryland Law Review* 1051; R G Adler, 'Controlling the Applications of Biotechnology. A Critical Analysis of the Proposed Moratorium on Animal Patenting' (1988) 1 *Harvard Journal of Law and Technology* 1; US, Office of Technology Assessment, Congress of the US, *New Developments in Biotechnology: Patenting Life* (Marcel Dekker, Inc, New York, 1990); D Manspeizer, 'The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland' (1991) 43 *Rutgers Law Review* 417; W Lesser (ed) *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989); R Moufang, 'Protection for Plant Breeding and Plant Varieties. A Frontier of Patent Law' (1992) 61 *Nordiskt Immateriellt Rättsskydd* 330; M E Sellers, 'Patenting Nonnaturally Occurring, Man-Made Life: A Practical

Despite this, the Patent Office and courts are likely to have difficulty evaluating them. As noted in an American study, policy considerations are usually speculative and rely on factual assertions that have yet to occur or be proven. They are also based largely on theological, philosophical, spiritual or metaphysical considerations which are difficult to resolve.[250] Parties would have to call evidence concerning the actual effect that the particular GMO or product concerned and/or a patent on it would have on their social and economic interests.[251] Finkelstein J in *Bristol-Myers* said with respect to competing policy concerns identified by him:

> How is a court to resolve these competing contentions? None of them are supported by evidence. Some may not even be capable of proof. Even if evidence was called to make good the unsubstantiated assertions, on what basis is the court to decide how the public interest will best be served?[252]

Nevertheless, if the *Patents Act*, by virtue of its reference to s 6 of the *Statute of Monopolies*, requires policy to be considered the relative difficulty of doing so is irrelevant.[253]

The policy considerations relevant to this issue will not be repeated here.[254] There is a real risk to patentability because of these considerations. Parliament, for example, could

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Look at the Economic, Environmental, and Ethical Challenges Facing "Animal Patents"' (1994) 47 *Arkansas Law Review* 269; A J Wells, 'Patenting New Life Forms: An Ecological Perspective' [1994] *European Intellectual Property Review* 111; R S Crespi, 'Biotechnology patents and morality' (1997) 15 *Trends in BioTechnology* 123; UK, Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (Latimer Trend & Co, Plymouth, UK, 1999) (http://www.nuffieldfoundation.org/fileLibrarypdf/gmcrop.pdf) (copy on file with author). For views against the technology see, for eg, G Scrinis, *Colonizing the Seed. Genetic Engineering and Techno-Industrial Agriculture* (Friends of the Earth, Melbourne, 1995).

[250] US, Office of Technology Assessment, Congress of the US, *New Developments in Biotechnology: Patenting Life* (Marcel Dekker, Inc, New York, 1990), p 17.

[251] W van Caenegem, 'The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' (2002) 13 *Australian Intellectual Property Journal* 41, 58-9.

[252] (2000) 46 IPR 553 at [140].

[253] It is relevant to whether the law should be amended so that policy considerations would no longer be relevant. With respect to this note that the House of Representatives Standing Committee on Industry, Science and Technology concluded that the patent system was not the appropriate vehicle for regulating the use of particular technologies on ethical grounds. *Threat or the Glory* Report, [7.99]. Others have reached similar conclusions. See, for eg, M Llewelyn, 'The Legal Protection of Biotechnological Inventions: An Alternative Approach' [1997] *European Intellectual Property Review* 115. Cf P Drahos, 'Biotechnology Patents, Markets and Morality' [1999] *European Intellectual Property Review* 441.

[254] Briefly, they include the morality of treating living organisms as property (see, for eg, *Threat or the Glory* Report, pp 230-1; P Drahos, 'Biotechnology patents, markets and morality' [1999] *European Intellectual Property Review* 441), that creating and patenting living organisms is 'playing God', that modifying organisms contravenes the rights of species to their genetic integrity (R S Crespi, 'An Analysis of Moral Issues Affecting Patenting Inventions in the Life Sciences: A European Perspective' (2000) 6 *Science and Engineering Ethics* 157, 163), the appropriateness of interfering with farmers' rights to use harvested seed as they wish (G Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century*

exclude GMOs from patentable subject matter. This must be of ongoing concern to commercialisers facing ever changing public opinion on GMOs and their products.[255] However, it is submitted that patent protection should and would not be denied to GMOs and their materials on this basis for three reasons.[256]

First, there is no clear argument against patenting GMOs and their materials.[257] For example, many concerns arise regarding the spread of GMOs from commercialisers' land. The ability to spread and reproduce is a unique trait of living organisms. Yet, even if a GMO is one that may spread,[258] such concerns are valid only in certain places and following certain uses. It seems heavy-handed to refuse all patent protection to GMOs because of them. Regulation of the *use* of GMOs and their products should also 'remain a concern outside patents law'.[259] Patent claims are drafted primarily to define the invention rather than as 'conditions of use'. Whilst claims are drafted to avoid including non-patentable subject matter, such as human beings, courts have not required them to contain limits on the use of the disclosed invention to achieve social or economic objectives.[260]

There is also the possibility that legislative limits on the patentability of GMOs or their products could be contrary to the TRIPS Agreement.[261] That Agreement requires Australia

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History (Ashgate Publishing Ltd, England, 2003), pp 22 and 36. See also *Threat or the Glory* Report, pp 237-238 and see pp 233-4 of that Report with respect to rights of animal breeders). In regard to whether GM of animals or their patenting is contrary to animal welfare see *Threat or the Glory* Report, pp 231-2.

[255] But see D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 365 who state that European experience suggests that the consideration of arguments based on ethical or moral grounds or the introduction of an *ordre public* or morality clause into the patents legislation 'would be unlikely to unduly impede patenting of biotechnology inventions'.

[256] With respect to the uneasy relationship between patent law and ethics, see L Bently and B Sherman, 'The Ethics of Patenting: Towards a Transgenic Patent System' (1995) 3 *Medical Law Review* 275.

[257] For discussion of how to weigh arguments for and against patenting organisms see the decisions in respect of the European patent application for the Harvard oncomouse. See, for eg, *In re President and Fellows of Harvard College* OJ EPO 1992, 588; (1993) 24 IIC 103. But cf criticisms in M A Bagley, 'Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law' (2003) 45 *William and Mary Law Review* 469, 521. Also cf refusal to use balancing test in *Greenpeace v Plant Genetic Systems* [1995] EPOR 357, 373 (Technical Board of App). See also *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Articles 6.1 and 6.2(d). See also *Threat or the Glory* Report, p 243.

[258] Briefly, GM pigs and carnations are unlikely to spread whereas GM canola is likely to do so.

[259] W van Caenegem, 'The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia' (2002) 13 *Australian Intellectual Property Journal* 41, 58. Van Caenegem makes this submission with respect to technology generally. Nicol and Nielsen also observe 'it is inappropriate for the Patent Office to intervene in the use of patents it has granted'. D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 372.

[260] For eg, a patent on a new gun would not include a proviso that it only be used for legal purposes.

[261] *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organisation)*, 1995 ATS 8 ('TRIPS Agreement'). The provisions of the Agreement are incorporated into Australian domestic law pursuant to the *Patent (World Trade Organisation Amendments) Act 1994* (Cth).

to provide a minimum standard of IP protection. In particular, patent protection must be available to any inventions in all fields of technology.[262] However, the Agreement provides for some exceptions – importantly here they include inventions the commercial exploitation of which would be contrary to *ordre public*[263] or morality[264] or to avoid serious prejudice to the environment[265] and plants and animals[266]. Further, the Agreement provides that the protection and enforcement of IP rights should be 'in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.[267] Member states may also 'adopt measures necessary to ... promote the public interest in sectors of vital importance to their socio-economic and technological development'.[268] This, Lawson and Pickering submit, means that Australian law exempting some genetic materials from patenting on the basis that exclusion is justified to promote the social and economic welfare in Australia in the agricultural biotechnology sector which is potentially of vital importance to Australia's socio-economic and technological development may be valid.[269] Alternatively, the Australian Parliament could direct the Patent Office and the courts to consider s 6 of the *Statute of Monopolies* and exclude claims on the broad grounds set out in that section.[270] Parliament could elaborate that these grounds include social and economic concerns.

However, it is submitted that Parliament is unlikely to do this. Parliament has had the opportunity to exclude GMOs from patentable subject matter and has not done so.[271] Lockhart and Wilcox JJ in *Rescare*[272] and Black CJ and Lehane J in *Bristol-Myers*[273]

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[262] TRIPS Agreement Article 27(1).
[263] This term has been explained as meaning 'the proper order of society'. P W Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology. Fundamentals of Global Law, Practice and Strategy* (3rd ed, Clarendon Press, Oxford, 1999), p 256.
[264] TRIPS Agreement Article 27(2).
[265] TRIPS Agreement Article 27(2).
[266] TRIPS Agreement Article 27(3).
[267] TRIPS Agreement Article 7.
[268] TRIPS Agreement Article 8(1).
[269] C Lawson and C Pickering 'Controlling Access to Genetic Resources under the Environment Protection and Biodiversity Conservation Act 1999 (Cth) Requires an Assessment of the Effects of the Patents Act 1990 (Cth)' (2002) 13 *Australian Intellectual Property Journal* 109, 119. Cf Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (Canadian Biotechnology Advisory Committee, Ottawa, June 2002), p 6 fn 9 which states that it is unlikely separate rules dealing with general social implications of biotechnological inventions would be allowed under the TRIPS Agreement.
[270] C Lawson and C Pickering 'The Conflict for Patented Genetic Materials under the Convention on Biological Diversity and the Agreement on Trade Related Aspects of Intellectual Property Rights' (2001) 12 *Australian Intellectual Property Journal* 104, 115.
[271] See, for eg, Cth, *Parliamentary Debates*, Senate, 20 September 1990, 2653-4 (J Coulter); Cth, *Parliamentary Debates*, Senate, 27 June 1996, 2332-5 (N Stott Despoja); Cth, *Parliamentary Debates*, Senate, 27 September 2001, 28193-7 (N Stott Despoja). See also *Patents Act 1990* (Cth) s 18(3).
[272] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 19 and 42-43.

considered this significant with respect to the patentability of another controversial subject matter.[274]

The second reason for submitting that patent protection would and should not be denied to GMOs on policy grounds is that where the opportunity has arisen for the court to take policy into account in relation to patenting the court has not refused a patent on that basis.[275] Finkelstein J in *Bristol-Myers* concluded that whether a particular invention should be excluded from patentability on the basis of policy was a matter for Parliament.[276]

Finally, it is inappropriate that social and other matters of concern to the whole community be determined in proceedings between private individuals.[277] It is preferable if such impacts are weighed up by Parliament or an agency such as the GTR or State regulatory authority under the moratorium legislation rather than by the Patent Office or the courts. First, the social and economic impacts of GMOs may be expected to change over time. Regulatory decisions can be more easily changed to reflect changing social mores than patenting decisions where, if a patent is refused on the basis of such grounds, it is impossible to go back and grant the particular patent after those mores have changed. More importantly, all relevant information may not be available to the Patent Office or court.

4.3.3 *Novelty*

Patentable inventions must be novel.[278] At first glance, if a GMO or its material has a characteristic which is new when compared with what publicly existed before its creation, it is novel. However, science is generally limited to endowing organisms or products with characteristics which already existed, although perhaps in different organisms or products, rather than creating characteristics de novo. Therefore the outcomes of GM may not be novel. Further, organisms or materials may already exist in nature in Australia with the same characteristics as the outcome of GM. That existence may be known or unknown. The consequences of this are examined below.

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[273] *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553 at [16].
[274] Methods of medical treatment.
[275] See *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 18; *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553 [17]-[18], [141-142]. See also *Welcome Real-Time SA v Catuity Inc* (2001) 51 IPR 327 at [131]-[132].
[276] (2000) 46 IPR 553 at [141].
[277] As patent proceedings often are.
[278] *Patents Act 1990* (Cth) s 18(1)(b)(i).

Novelty is of concern because it can be raised as a ground for objection at all stages of the patent's life. The patent examiner can raise an objection on the basis of novelty during examination and re-examination. More importantly, it is a ground for opposition and revocation. In the later two cases, prior non-documentary and documentary public disclosure anywhere in the world are considered.

The next section summarises the relevant principles with respect to the novelty requirement. The relevant law is then applied to GMOs and their products. How different a GMO or its material must be from existing subject matter to be novel is considered. In particular, whether genetic differences not giving rise to phenotypic differences will provide 'novelty' is examined. Finally, whether the existence or possible existence of the same organism or material in nature will deprive an outcome of GM of novelty is discussed.

(a) Determination of novelty

Novelty requires the invention be new as at the priority date of the invention. That is, it must teach those skilled in the art something which they did not already know. For examination purposes, that prior knowledge, or 'anticipation', may come from disclosure in a document publicly available anywhere in the world.[279] Where novelty is being considered for the purposes of opposition or revocation, the prior knowledge can also come from being 'publicly available through doing an act' anywhere in the world.[280] The whole invention must be anticipated by the prior publication or use.[281]

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[279] *Patents Act 1990* (Cth) s 7(1) and Sch 1 (definitions of 'prior art base' and 'prior art information'). A combination of documents or acts can be considered if a person skilled in the relevant art would treat them as a single source. See *George C Warner Laboratories Pty Ltd v Chemspray Pty Ltd* (1967) 41 ALJR 75; *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1990) 16 IPR 545; *Winner v Ammar Holdings Pty Ltd* (1993) 25 IPR 273. See also *Patents Act 1990* (Cth) s 45(1A) which expressly excludes information made publicly available only through the doing of an act (whether in or out of the patent area) from consideration during examination.

[280] *Patents Act 1990* (Cth) s 7(1) and Sch 1 (definitions of 'prior art base' and 'prior art information'). A combination of acts or documents can be considered in limited circumstances. See s 7(1)(b). For existing patents and patent applications filed before 1 April 2002, only acts in Aust are relevant.

[281] An invention can also be anticipated by an earlier patent specification (*Patents Act 1990* (Cth) s 7(1)(c) and Sch 1 (definition of 'prior art base')). A limited range of disclosures or uses by or with the consent of the inventor on or after 1 April 2002 will not affect novelty (*Patents Act 1990* (Cth) s 24; Patents Regulations 1991 (Cth) regs 2.2-2.3 amended per Patents Amendment Regulations 2002 (No 1) (Cth)). See W Condon and R Hoad, 'Amazing Grace: New Grace Period for Patents in Australia' (2002) 15 *Australian Intellectual Property Law Bulletin* 73; A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' [2002] *European Intellectual Property Review* 475; A Rollnik, 'Patent law change – A New Grace Period' (2003) 13 *Australasian Biotechnology* 21.

Determination of anticipation involves the same test as for determining infringement - the 'reverse infringement' test.[282] That is, if the prior use would be an infringement or the prior publication contained a description of the invention that would be an infringement of the later patent if performed, the later invention is not novel. The information given by the prior use or publication must also be such that a person knowledgeable in the area would be able to understand and put it into operation without further inquiry or the exercise of any inventive ingenuity.[283] As McKeough et al have expressed it, 'the prior disclosure must reveal the essential features of the invention'.[284]

The Act does not deal with how information is made publicly available through doing an act.[285] However, case law establishes that the prior use does not have to be known to many.[286] Further, the user does not have to understand the significance of the product they are using to anticipate an invention.[287] However, case law establishes that experimental use by the inventor or third parties[288] or prior use so trivial it can be disregarded as a matter of common sense[289] and, it seems, accidental use (in the sense of a freak factor occurring which is unlikely to ever be repeated)[290] do not deprive an invention of novelty.[291]

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[282] *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457 at 485-6; *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228; *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 259; *R D Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 13 IPR 513 at 517; *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1990) 16 IPR 545 at 549; *MJA Scientifics International Pty Ltd v SC Johnson & Son Pty Ltd* (1998) 43 IPR 287 at 303; *Root Quality Pty Ltd v Root Control Technologies Pty Ltd* (2000) 49 IPR 225 at 243.

[283] See *Hill v Evans* (1862) 31 LJCh 457 at 466; *Van der Lely NV v Bamfords Ltd* [1963] RPC 61 at 72-3; *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457 at 486; *Washex Machinery Corp v Roy Burton & Co Pty Ltd* (1974) 49 ALJR 12 at 18; *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1990) 16 IPR 545 at 549.

[284] J McKeough et al, *Intellectual Property in Australia* (3rd ed, LexisNexis Butterworths, Australia, 2004), p 351.

[285] Previous Acts used different language. Pursuant to the *Patents Act 1952* (Cth) s 59(1)(e) the question was whether an invention 'was published in Australia before the priority date of the claim' and under s 59(1)(h) whether the invention was 'otherwise not novel in Australia' before that date.

[286] *Acme Bedstead Co Ltd v Newlands Bros Ltd* (1937) 58 CLR 689; *Longworth v Emerton* (1951) 83 CLR 539; *Fomento Industrial SA v Mentmore Manufacturing Co Ltd* [1956] RPC 87; *Sunbeam Corp v Morphy-Richards (Aust) Pty Ltd* (1961) 35 ALJR 212 at 218.

[287] See, for eg, *Carpenter v Smith* (1842) 9 M&W 300; 11 LJR (Exch) 213; *Humpherson v Syer* [1887] 4 RPC 407; *Acme Bedstead Co. Ltd v Newlands Bros Ltd* (1937) 58 CLR 689; *Griffin v Isaacs* (1938) 12 AOJP 739 (HC); *Fomento Industrial SA v Mentmore Manufacturing Coy Ld* [1956] RPC 87; *Bristol-Myers Co (Johnson's) Application* [1975] RPC 127.

[288] There are limitations on what is 'experimental'. Testing to determine whether an invention will be commercially successful is not experimental for this purpose.

[289] See *Morgan v Seaward* (1837) 2 M & W 544 at 559-60; 150 ER 874 at 880; *Birtwhistle v Sumner Engineering Co Ld* (1929) 46 RPC 59 at 72; *Bristol-Myer Co (Johnson's) Application* [1974] AC 646; and *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* (1984) 3 IPR 498 (CA).

[290] In *Bristol-Myers Co (Johnson's) Application* [1974] AC 646 two of their Lordships left open the question whether accidental use would be sufficient to anticipate an invention - Lord Reid (at 665) and Lord Diplock (at 684). See also *Harwood v The Great Northern Railway Company* (1860) 29 LJQB 193; *Boyce v Morris Motors Ld* (1926) 44 RPC 105.

Importantly for commercialisers undertaking field trials, public working of an invention for the purposes of a reasonable trial does not destroy novelty.[292]

Novelty problems could be avoided by drafting the patent claim narrowly so as to be in respect of the organism or its material as produced by a defined process, which would be the GM process used to create the organism. Even where the resulting organism or material is equivalent to a naturally occurring entity, the organism or material is then likely to be novel because it will not have been created in that way.[293] However, as noted in Part 4.1 because such protection is of limited value such patents are not considered.

(b) Application to GMOs and their products

Phenotypic v genetic differences

GMOs and their products will be genetically different to non-GM matter. However, not all GMs result in an alteration of the appearance or other observable characteristic (the phenotype) of the organism or product.

Whether or not genetic differences are sufficient to endow novelty depends in part on the patent claims. However, where the genetic difference does not result in altered phenotypic traits it is unlikely to endow novelty. This view is supported by a decision of the Federal Court. The Court has held that the mere replacement of inessential integers with something which is a mechanical equivalent does not endow novelty.[294] Arguably this is all that a GM, resulting in no phenotypic change, is. This is not of great concern for commercialisers. They are unlikely to commercialise a product only on the basis that it is genetically different to other products.

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[291] See also *Patents Act 1990* (Cth) s 24 and Patents Regulations 1990 reg 2.2 which provide for other matters not affecting the novelty of an invention.

[292] *Patents Act 1990* (Cth) s 24(1)(a); Patents Regulations 1991 (Cth) reg 2.2(2)(d). Provided, because of the nature of the invention, it is reasonably necessary for the working to be in public and a patent application is made within 12 months. *Patents Act 1990* (Cth) s 24(1)(a); Patents Regulations 1991 (Cth) reg 2.3(1)(c).

[293] This is clearly the case in Germany. For eg, in the *Naturstoffe* decision GRUR 1978, 238 of the German Federal Patent Court patent protection for a natural substance, antamanide, prepared using a synthetic process was not excluded just because antamanide also occurred in nature. In the *Menthonthiole* decision GRUR 1978, 702 the same Court found that the discovery of the active ingredient of a natural scent and then the invention of a process for its synthetic production was patentable notwithstanding that the product also occurred in nature. Both cited by V Vossius, 'The Patenting of Life Forms Under the European Patent Convention and German Patent Law: Patentable Inventions in the Field of Genetic Manipulations', in D W Plant et al (eds), *Banbury Report Number 10. Patenting of Life Forms* (Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 1982), pp 149 and 159.

[294] *Advanced Building Systems Pty Ltd v Ramset Fasteners (Australia) Pty Ltd* (1993) AIPC ¶ 91-017 (Fed Ct).

Degree of phenotypic variation required

Commercialisers will be concerned with GMs which result in organisms or products with a desirable phenotypic characteristic. That characteristic may be new with respect to that type of organism (such as a blue carnation) or an altered pre-existing one (such as a leaner pig). In either case, the characteristic is not created de novo. Nevertheless, provided that the resulting organism or product is distinguishable from what was known to exist prior to the GM, the result should be considered novel.[295]

It seems that the degree of phenotypic variation required between the existing and the new matter to be novel need not be great. In *Ranks Hovis McDougall Ltd's Application*[296] ('*Ranks*') human made variants of a microorganism derived from a naturally occurring microorganism were considered novel. This was despite it not being clear from the specification in what way the variants differed from their parent. The only explanation of the difference between the variants and the founder organism was a reference to 'morphological differences'.[297] Commentators have suggested though on the basis of that decision that new variants of organisms must have improved or altered useful properties, rather than merely changed morphological characteristics having no effect on the working of the organism.[298] As with genetic differences, it is unlikely that commercialisers would pursue a GMO or product unless it has some improved or altered useful property.

Possible equivalent in existence

Given enough time, equivalent results to some of those achieved using GM may be produced through natural GM.[299] The likelihood of this happening depends upon the modification involved. If it is assumed that it is possible, GM opponents may seek to use it as the basis for arguing that a GMO or its product is not novel. Mark states that the possibility of an equivalent in nature prevents patent protection in the USA.[300] Whether

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[295] S A Bent et al, *Intellectual Property Rights in Biotechnology Worldwide* (Stockton Press, New York, 1987), pp 14-8.
[296] (1976) 46 AOJP 3915.
[297] As to whether patentees should exclude the organism or material present in the natural environment to ensure validity see A W White, 'The Patentability of Naturally Occurring Products' [1980] *European Intellectual Property Review* 37.
[298] J W Dwyer et al, 1 *Lahore. Patents, Trade Marks & Related Rights* (Reed International Books Australia Pty Ltd, Sydney, 2001, looseleaf), [12,275].
[299] Transfer of genes between species has been identified in the wild. For eg, haemoglobin genes (from animals) have been found in plants; chlorophyll genes (from plants) have been found in insects.
[300] D A Mark, 'All Animals Are Equal, But Some Are Better Than Others: Patenting Transgenic Animals' (1991) 7 *The Journal of Contemporary Health Law & Policy* 245, 253 n 56.

the possible existence of an equivalent anticipates the GM product in Australia depends upon whether that possible existence is a 'public act' for these purposes.

A 'natural' equivalent may exist in a domestic or wild environment. Where the unknown natural equivalent exists in the wild, it is submitted that because there will be no disclosure of the essential integers of the invention, its existence should not anticipate the outcome of GM.[301] There is contrary authority. In *Ranks*[302] an organism discovered in a soil sample was considered to be lacking in novelty. Human made variations of that organism were found to be novel only on the assumption that such variations did not occur naturally in Australia at the priority date.[303]

It is submitted that the assumption made in *Ranks* should be irrelevant. The unproven existence of an organism in the wild, even putting aside the possibly insurmountable problems of proof, can hardly be considered to have made an invention publicly available. The possibility of its existence should therefore not anticipate equivalent GMOs or their products. There is some case law in support of that view. In *Genentech Inc.'s Patent*[304] data consisting of the genetic sequence of a protein which existed in nature was nevertheless considered to be novel. The data was novel because it was not previously available to the public in a useable form. An organism or product is also not available to the public until it is discovered.

It could be argued that existence of a natural equivalent in a domestic environment may be a public act which anticipates the outcome of GM. For example, the natural equivalent may be one in a field of canola plants which is harvested and processed in the usual way without the farmer realising the nature of the plant. As noted above, it is not necessary that the user understand the significance of the product they are using to anticipate an invention. It will also be 'public' use.[305] A GM equivalent to that natural organism may therefore not be novel. Again, it is submitted that such an unknown existence of a natural equivalent should not anticipate equivalent GMOs and their products. Such existence should be treated in the same way as other trivial uses and disregarded.

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[301] Cf M L Rohrbaugh, 'The Patenting of Extinct Organisms: Revival of Lost Arts' (1997) 25 *AIPLA Quarterly Journal* 371, 383 and 387.
[302] (1976) 46 AOJP 3915.
[303] (1976) 46 AOJP 3915 at 3917. The restriction of acts to acts in Aust was removed by amendment of the 1990 Act. See *Patents Amendment Act 2001* (Cth) Sch 1, item 12.
[304] [1987] RPC 553.
[305] See *Taylor's Patent* (1896) 13 RPC 482.

Known equivalent in existence

If an organism or material of the same type as the outcome of GM was known to exist before the priority date with the relevant 'modified' characteristic, the invention may not be novel.[306] To deny novelty to the GM outcome though, the pre-existing matter must have been made publicly available through the doing of an act or being described in a document.[307]

With respect to products of GMOs which were previously produced by a different organism (such as cows' milk produced by a GM pig), only if there is a distinguishable difference between the material produced by the GMO and that already in existence (cows' milk produced by a cow) would the material itself be novel. Derivation from a different organism alone would not be sufficient to endow novelty to the product although it may endow novelty to the organism.

4.3.4 *Inventive Step*

If the creation of a GMO or its products is obvious, or not inventive, the organism or material will not be patentable.[308] An objection on this basis can, like novelty, be raised on examination, re-examination, opposition and revocation. It is submitted that this requirement will cause the most difficulties for commercialisers. The next subsection describes what is required for an invention to be inventive. It then discusses why many GM outcomes are likely to be obvious.

(a) Requirements for inventiveness

An invention is obvious if it does not involve an inventive step when compared with the prior art base before the priority date of the patent.[309] Whether there is an inventive step is

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[306] Where the material occurred in a mixture (that is, in association with significant quantities of other materials), that mixture being known prior to a GM resulting in its production, its existence in mixture form only should not deprive the material of novelty. See A Christie, 'Patents for Plant Innovation' [1989] *European Intellectual Property Review* 394, 400. Christie makes the point that although that conclusion seems right it is still debatable given the decision at first instance in *Genentech Inc.'s Patent* [1987] RPC 553 where Whitford J disallowed claims to a pure form of a substance known to occur in nature in a non-pure form, one ground for that decision being that the invention was not new. That point was not directly addressed by the Court of Appeal decision in *Genentech Inc.'s Patent* (1989) RPC 147.

[307] Note, this could include by being shown in a publicly available photograph. See, for eg, *C. Van Der Lely NV v Bamfords Ltd* [1963] RPC 61. See also *Windsurfing International Inc v Petit* [1984] 2 NSWLR 196.

[308] *Patents Act 1990* (Cth) s 18(1)(b)(ii).

[309] *Patents Act 1990* (Cth) ss 18(1)(b)(ii) and 7(2) and Sch 1 (definitions of 'prior art base' and 'prior art information').

judged on the basis of the common general knowledge[310] in Australia of a 'skilled person' at the priority date, alone or combined with certain other prior art information.[311] As with novelty, the other information that may be combined with the common general knowledge must be publicly available although it itself does not have to be part of common general knowledge.[312] It includes information from one or more documents or available through doing one or more acts provided the 'person' could reasonably have been expected to have ascertained, understood, regarded as relevant and, if relevant, combined it. [313] Such documentary and non-documentary disclosures can occur anywhere in the world.[314] Non-documentary disclosure, however, is not considered at examination or re-examination.[315]

The English Court of Appeal in *Genentech Inc.'s Patent*[316] stated that for the purposes of recombinant DNA technology a person 'skilled in the art' may include a notional team of scientists consisting of members with basic bench skills, those with experience, some with a probing intellect and others with a combination of all three attributes, that notional team having sufficient time and the best available equipment to carry out the research.[317] Such team was not to be 'particularly imaginative or inventive'.[318]

Inventiveness has been considered recently by the High Court. In *Aktiebolaget Hässle v Alphapharm Pty Ltd*[319] (*'Aktiebolaget'*) the Court[320] held that for an invention to be

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[310] Common general knowledge is distinct from public knowledge. What it consists of is a question of fact in each case. *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 294. See also *Sunbeam Corp v Morphy - Richards (Australia) Pty Ltd* (1961) 35 ALJR 212; *R D Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 13 IPR 513; *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 54 IPR 449. However, it has been pointed out that because the courts treat the skilled worker in the field of biotechnology as a team of specialists who routinely access all relevant patents and undertake comprehensive literature reviews, their common general knowledge will soon be indistinguishable from public knowledge. P E Montague, 'Biotechnology Patents and the Problem of Obviousness' (1993) 4 *Australian Intellectual Property Journal* 3, 10.

[311] *Patents Act 1990* (Cth) s 7(2) and Sch 1 (definitions of 'prior art base' and 'prior art information').

[312] Information found as part of a literature search is likely to be publicly available but may not be part of the common general knowledge. Whether it is depends upon whether it generally accepted and assimilated in Aust. See *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [31], [45] and [49]. The decision is with respect to the *Patents Act 1952* (Cth). However, although the law with respect to combining information has been changed by the *Patents Act 1990* (Cth), the law with respect to common general knowledge does not seem to have been. See also K O'Connell and J Cooke, Case Comment 'Australia: A Patentee's Paradise' [2003] *European Intellectual Property Review* 481.

[313] *Patents Act 1990* (Cth) s 7(3) and Sch 1 (definitions of 'prior art base' and 'prior art information').

[314] *Patents Act 1990* (Cth) s 7(1) and Sch 1 (definitions of 'prior art base' and 'prior art information').

[315] *Patents Act 1990* (Cth) ss 45(1A) and 98(1) and (2).

[316] (1989) 8 RPC 147. This issue was not specifically addressed by the House of Lords in *Biogen Inc v Medeva plc* [1997] RPC 1, 28 IIC 740 (1997).

[317] The characteristics of the skilled person were not challenged in *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [30], discussed below, which also involved a research team.

[318] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [30].

[319] (2002) 56 IPR 129. The case concerns the *Patents Act 1952* (Cth) rather than the current legislation but it would seem that the inventiveness test is intended to be the same pursuant to both Acts even if the information against which it is to be judged is different.

obvious it must be 'very plain'.[321] Whilst something routine[322] could be said to be obvious, routine in such circumstances did not mean 'worth a try'.[323] To be obvious the notional research group at the priority date needed to 'have been led directly as a matter of course to pursue one avenue in the expectation that it might well produce the [patented result]'.[324] 'The tracing of a course of action which was complex and detailed, as well as laborious, with a good deal of trial and error, with dead ends and the retracing of steps is not the taking of routine steps to which the hypothetical [skilled worker] was taken as a matter of course'[325] and is therefore not obvious. If experimental steps are 'part of' the inventive step claimed in the patent, they are not obvious.[326]

(b) Inventiveness of GMOs and their products

Opponents may claim that GMOs or their products are obvious. Such claims could be based on the fact that they are only combinations of preexisting things, because it is obvious to produce such things or because equivalents already exist. As with novelty, some problems with obviousness could be avoided by claiming not the organism or its material per se but the organism or materials produced using a particular process. In such a case the inventive step is found in the route to the end product rather than the end product itself.[327] Therefore if the gene sequence inserted into the organism was identified, isolated or developed in an inventive way or the method used to introduce the GM was inventive, the resulting organism or material should be considered the product of a non-obvious process and therefore patentable.[328] However, as noted above, the protection secured by such patents will be limited.[329]

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[320] In a joint judgment by Gleeson CJ, Gaudron, Gummow, and Hayne JJ.
[321] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [34] quoting from *General Tire & Rubber Company v The Firestone Tyre and Rubber Company Ltd* [1972] RPC 457.
[322] See *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) CLR 262 at 286 (Aickin J).
[323] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [53] and [70].
[324] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [53]. See also *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd* [1970] RPC 157 at 187.
[325] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [58].
[326] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [53].
[327] S A Bent et al, *Intellectual Property Rights in Biotechnology Worldwide* (Stockton Press, New York, 1987), p 210.
[328] N Peace and A Christie, 'Intellectual Property Protection for the Products of Animal Breeding' [1996] *European Intellectual Property Review* 213, 221.
[329] With respect to the differences between process patents, product patents and use patents in plant biotechnology see J V Funder, 'Rethinking Patents for Plant Innovation' [1999] *European Intellectual Property Review* 551.

Combination patents

That the outcomes of GM could be only a new combination of existing parts does not of itself deprive the result of inventiveness. Provided it was inventive to combine the parts to produce some new effect the outcome itself is also inventive.[330]

Outcomes with no known equivalent

For most GMOs and their products there is no known, and could be no unknown, equivalent. Such inventions may nevertheless be obvious if a research group would have been led as a matter of course to pursue one method to develop them. This already seems to be the case with respect to organisms produced using traditional techniques.[331] The methods used will be well-known and any improvements to the organism will be gradual making it more likely that the resulting organism will be obvious.[332]

The more reasonable the expectation of success in combining an organism (or product) and characteristic, the more obvious it is.[333] Heitz has suggested that, for example, the first introduction of herbicide resistance into a plant makes that resistance obvious in respect of all plants of the same species and perhaps other species.[334] However, if an organism is produced with an unexpected characteristic or the extent of an altered trait is unpredicted, using such methods, the organism may be inventive.[335]

As noted above, obviousness is determined by comparing the claimed invention against the existing prior art and asking whether a non-inventive skilled worker would have found it obvious to take the step taken by the inventor.[336] In determining obviousness, the method

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[330] For eg, *Willmann v Petersen* (1904) 2 CLR 1; *British United Shoe Machinery Co Ltd v A Fussell & Sons Ltd* (1908) 25 RPC 631; *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253; *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [6], [41], [65] and [72].

[331] Cf J W Dwyer et al, 1 *Lahore. Patents, Trade Marks & Related Rights* (Reed International Books Australia Pty Ltd, Sydney, 2001, looseleaf), [29,030].

[332] For eg, the US Patent Office rejected as obvious claims to soybean plant and seeds that were the product of traditional plant breeding. The novel soybean was held to have been obvious in light of the prior art. *Ex parte C* 27 USPQ 2d 1492 (1992) (US PTO Board of Patent Appeals & Interferences).

[333] G Van Overwalle, *The Legal Protection of Biotechnological Inventions in Europe and in the United States. Current Framework and Future Developments. Technical and Ethical Approach* (Leuven University Press, Belgium, 1997), p 58.

[334] A Heitz, 'Intellectual Property in New Plant Varieties and Biotechnological Inventions' [1988] *European Intellectual Property Review* 297, 300.

[335] N Peace and A Christie, 'Intellectual Property Protection for the Products of Animal Breeding' [1996] *European Intellectual Property Review* 213, 221. See, for eg, *Beecham Group Ltd's (Amoxycillin) Application* [1980] RPC 261 at 290-1.

[336] *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 293; *Wellcome Foundation Ltd v VR Laboratories (Australia) Pty Ltd* (1981) 148 CLR 262 at 270; *WR Grace &*

used to produce the organism or product may be taken into account. There is no clear definition of the level of inventiveness required. It has been suggested that there need only be a scintilla of invention.[337] However, as the methods used in producing GMOs become better known and attempts to genetically modify organisms for specific purposes become more common and industrialised, the less likely it is that the result will be inventive.[338]

Such a result was reached by the English Court of Appeal in *Genentech Inc.'s Patent*.[339] The case concerned patents to a genetically engineered drug, human tissue plasminogen activator (t-PA).[340] The t-PA produced by the patentee was identical to that found in nature. The drug was the result of lengthy work requiring great skill. Nevertheless the patent was found to be invalid.[341] Although revocation was based on a number of grounds, two members of the court, Dillon and Mustill LJJ, decided that the invention was obvious. The third member, Purchas LJ, found that the invention involved an inventive step and was therefore not obvious.[342]

The finding of obviousness was largely on the basis of how the t-PA was produced.[343] Prior to the patentee's work, t-PA was of known value in combating blood clotting. The relevant technology used to produce the t-PA also already existed although it had not been

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Co v Asahi Kashi Kabushiki Kaisha (1993) 25 IPR 481 at 492; *Leonardis v Sartas No 1 Pty Ltd* (1996) 35 IPR 23; *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129.

[337] *Samuel Parks & Co Ltd v Cocker Bros. Ltd* (1929) 46 RPC 241 at 248; *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228 at 249; *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 56 IPR 129 at [48].

[338] See P E Montague, 'Biotechnology Patents and the problem of obviousness' (1993) 4 *Australian Intellectual Property Journal* 3, 29 where Montague suggests that as the technology becomes more familiar and of increasing range that the Australian courts will adopt a more rigorous test in determining obviousness. See also R S Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71, 75 who stresses that inventiveness must be judged on a case-by-case basis.

[339] (1989) 8 RPC 147. The decision was on the basis of the *Patents Act 1977* (UK) which made significant changes to the UK law in this area. Nevertheless the issues and general principles are similar enough to make consideration of the case worthwhile. See also *Chiron Corp v Organon Teknika Ltd (No 3)* [1994] FSR 202.

[340] t-PA dissolves blood clots.

[341] The English Court of Appeal upheld the High Court's decision in *Genentech Inc.'s Patent* [1987] RPC 553.

[342] Purchas LJ used a different approach to determining obviousness compared with the rest of the Court. He adopted the test suggested by Diplock LJ in *American Cyanamid Company (Dann's) Application* [1971] RPC 425 at 451 pursuant to which a degree of technical proficiency, time and expense may be sufficient to satisfy inventiveness in certain circumstances. Purchas LJ nevertheless held the patent invalid on other grounds.

[343] For a discussion of the decision on obviousness see B Sherman, '"Genentech and Another v Wellcome Foundation Ltd.": A Step Backwards In Protecting Biotechnological Inventions?' (1990) 21 *International Review of Industrial & Copyright Law* 76 and P E Montague, 'Biotechnology Patents and the Problem of Obviousness' (1993) 4 *Australian Intellectual Property Journal* 3, 15-8. Note also the statement of the Australian Deputy Commissioner of Patents that because the applicant made very significant concessions that would have had a great bearing on the finding with respect to inventive step, the decisions in *Genentech Inc.'s Patent* (1989) 8 RPC 147 and *Biogen Inc v Medeva plc* [1997] RPC 1 were not of assistance with respect to inventiveness.

used to synthesise t-PA. Dillon and Mustill LJJ found the claims invalid for obviousness because the patentee merely applied known DNA technology to determine the relevant sequence and produce the recombinant t-PA.[344] It now seems though, following the decision in *Aktiebolaget* that the threshold for inventiveness is lower in Australia than the UK.[345] The High Court also suggests caution in relying on UK decisions with respect to inventiveness under the current UK patent legislation.[346] Therefore the invention may not have been obvious in Australia.

Outcomes with known equivalent

Where an outcome of GM is created which is the same as an organism or product known to exist,[347] inventiveness is even less likely unless it is the subject of a process claim or claimed by virtue of possessing an 'inventive' gene sequence.[348]

Where the patent is in respect of the GM outcome and not the process used to produce it, a further difficulty arises where the outcome of GM does not have a 'new' property but instead there is a difference in degree of that property. For example, the GM pig is 'leaner' and grows 'faster' than non-GM pigs. It is unclear what quantitative superiority in properties, or scintilla of invention, is required for inventiveness.[349]

4.3.5 *Other Requirements for Patentability*

The *Patents Act* provides for a number of other requirements for a patentable invention. These are that the invention be useful (utility), that it be fully described in the complete specification (sufficiency), that the claims be clear and succinct (ambiguity) and fairly based on the matter described in the provisional specification (fair basis),[350] that the invention not have been secretly used by the patentee[351] before the priority date of the claim (secret use)[352] and that the patentee be entitled to the patent (obtaining)[353] and not

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[344] [1989] RPC 147 at 243 (per Dillon LJ) and 276 (per Mustill LJ).
[345] See K O'Connell and J Cooke, Case Comment 'Australia: A Patentee's Paradise' [2003] *European Intellectual Property Review* 481, 486.
[346] As to whether there is still a need for invention under UK legislation, see *Biogen Inc v Medeva plc* [1997] RPC 1.
[347] The pre-existing organism or material could have been produced with or without human assistance.
[348] It may also not be novel.
[349] P Ducor, 'Recombinant Products and Nonobviousness: A Typology' (1997) 13 *Santa Clara Computer and High Technology Law Journal* 1, 27.
[350] *Patents Act 1990* (Cth) s 40(3).
[351] Or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention. See *Patents Act 1990* (Cth) s 18(1)(d).
[352] *Patents Act 1990* (Cth) s 18(1)(d). This is only relevant on revocation and is irrelevant at all other stages. *Patents Act 1990* (Cth) s 138(3)(b). See also *Azuko Pty Ltd v Old Digger Pty Ltd* (2001) 52 IPR 75 and L

obtain the patent by false suggestion.[354] The requirements that there be no ambiguity and that the claims in a complete specification be fairly based on the matter in the provisional specification are unlikely to pose unique difficulties for commercialisers of GM outcomes.[355] Nor is the requirement that the invention not have been secretly used by the patentee before the priority date of the claim or that the patentee be 'entitled' to the patent. They will therefore not be considered further.

The remaining requirements may cause practical problems for commercialisers of GM outcomes. The most significant are discussed below. None have proven insuperable to date. Nevertheless a court may, when given the opportunity, find one or more grounds for denial of patent protection.

(a) Utility

Patentable inventions must be useful.[356] That is, the end result claimed in the patent application must be capable of being achieved following the teaching of the complete specification.[357] If it is not, the patent will be invalid for inutility.[358] The end result must also serve some purpose. Use in the agricultural industry is a suitable use for these purposes.[359] The organism or product produced using the description in the patent specification must also be what is claimed as the invention. This is distinct from the case where the invention cannot be produced because of deficiencies in the information given in the complete specification. That is insufficiency which is discussed below.

Livingston, 'Revocation of a patent for prior secret use by a patentee' (2003) 14 *Australian Intellectual Property Journal* 5. As to the relevance of secret use by someone other than the patentee see A Monotti, 'Balancing the Rights of the Patentee and Prior User of an Invention: The Australian Experience' [1997] *European Intellectual Property Review* 351.

[353] *Patents Act 1990* (Cth) ss 59(a), 138(3)(a).

[354] *Patents Act 1990* (Cth) s 138(3)(d).

[355] As to the meaning of 'fair basis' see *Re Mond Nickel Co Ld's Application* [1956] RPC 189; *Société des Usines Chimiques Rhône-Poulenc v Commissioner of Patents* (1958) 100 CLR 5; *Re Imperial Chemical Industries Ltd's Application* [1960] RPC 223; *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 180 CLR 236; *Coopers Animal Health Australia Ltd v Western Stock Distributors Pty Ltd* (1986) 67 ALR 390, affirmed (1987) 76 ALR 429; *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260. See also *F Hoffman-La Roche & Co AG v Commissioner of Patents* (1971) 123 CLR 529.

[356] *Patents Act 1990* (Cth) ss 18(1)(c), 138(3)(b). Lack of utility can be raised in revocation proceedings. It is indirectly relevant at examination, opposition and re-examination as part of the 'manner of manufacture' requirements. The ALRC has proposed that the legislation be amended to include usefulness as a requirement in the assessment of applications for standard patents and include it as a basis for opposition. ALRC Discussion Paper 68, Proposal 6-3.

[357] *Lane Fox v Kensington and Knightsbridge Electric Lighting Company* [1892] 3 Ch 424 at 430-1.

[358] With respect to suggested reforms of the way an invention's usefulness is addressed see ALRC Discussion Paper 68, [6.184] – [6.191] and Proposals 6-3 and 6-4.

[359] Eg, *NRDC* (1959) 102 CLR 252.

Depending upon how a claim to a GMO or its product is drafted, it may include inoperable elements. That is, it may include embodiments which cannot perform the promise of the invention. For example, with respect to a GMO possessing a particular protein, the patentee may claim organisms possessing a number of different DNA sequences on the assumption that because of the degeneracy of the genetic code[360] all will produce the same result. That may not be the case. Case law shows that if a claim exceeds what is useful, it is invalid. It does not matter that no skilled worker would seek to apply the patent to that wider purpose.[361]

Nevertheless it is unlikely, although possible, that a court would find the fact that some inoperable embodiments have been included in a patent specification sufficient to justify a finding of inutility.[362] Case law establishes that regard must be paid to the fact that the claim is addressed to persons skilled in the art and construed accordingly.[363] For inutility therefore it must be shown that the invention so far as claimed will not work as described or with any modification which the addressee can properly be expected to make.[364] It is submitted that inoperable embodiments would be readily discernible to addressees in this area of science and undue experimentation to practise the claimed invention would be unnecessary.

(b) Sufficiency

Complete specifications lodged to describe inventions must do so fully, including the best method known to the applicant of performing the invention.[365] That is, it must be an enabling disclosure.[366] The reader is a person skilled in the relevant art.[367] If an informed

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[360] That is, for most amino acids (which make up proteins) there is more than one codon coding for it.
[361] *Coopers Animal Health Australia Ltd v Western Stock Distributors Pty Ltd* (1986) 67 ALR 390.
[362] *Chiron Corp v Organon Teknika Ltd (No 3)* [1994] FSR 202.
[363] *Martin Engineering Co v Trison Holdings Pty Ltd* (1989) 14 IPR 330 at 339. See also *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 230-1.
[364] *Valensi v British Radio Corp Limited* [1973] RPC 337 at 378; *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd* (1988) 81 ALR 79 (Fed Ct); *Patent Gesellschaft AG v Saudi Livestock Transport & Trading Co* (1997) 37 IPR 523 (Fed Ct, Full Ct). This is similar to the US practice where a minor number of inoperable embodiments which are readily discernible so that one of ordinary skill does not have to experiment unduly in order to practice the claimed invention does not defeat the claim. See *In re Cook* 169 USPQ 298 (CCPA 1971); *Atlas Powder Comp v E I Du Pont de Nemours & Comp* 750 F 2d 1569 (Fed Cir 1984).
[365] *Patents Act 1990* (Cth) s 40(2)(a).
[366] Skene has suggested that the reason patenting of organisms has only arisen comparatively recently is that breeding of new organisms by ordinary breeding techniques could not be reproduced by someone else and it was only when GM enabled the new organism to be both 'described' and reproduced that patenting of organisms could be attempted. L Skene, 'Legal Issues in Patenting Life-forms' (1991) 14 *Intellectual Property Forum* 39, 42. See also the decision of the German Federal Supreme Court in Red Dove (Rote Taube) 1969 GRUR 672; 1 IIC 136 (1970) where a patent was refused on this basis.

reader with reasonable skill in the trade at the date on which the complete specification was lodged[368] could not perform the invention using the information in the specification, the patent will be invalid for 'insufficiency'.[369]

It is not yet possible to reduce all living organisms descriptively to their constituent elements or specify their complete nucleotide sequence.[370] Even when that is possible, such a description would not necessarily describe how to create 'life' from the raw materials. Therefore any patent description needs to be on the basis of how to produce an organism or product with a particular characteristic beginning with another organism or product. However, even if the relevant steps are accurately set out in the patent specification the reader may not obtain the same result as the patentee.[371] This may be because of genetic differences between the starting material used by the reader and that used by the patentee. Generally, each organism has a unique genetic identity.[372] Additional genetic differences are introduced if sexual reproduction is required to 'make' the invention. Genetic changes may also occur during the modification process itself.[373] There is therefore uncertainty as to whether a written description of a GMO is sufficient.[374]

If the patented organism or product is described by reference to its appearance, or phenotype, then so long as the reader's organism or product shows the same phenotypic characteristics as the described matter, differences in genetic sequence should not matter.[375] At least with respect to European patents, it seems it is not necessary that

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[367] *Kimberley-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1 at 16.
[368] *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 223.
[369] *Edison & Swan United Electric Light Co v Holland* (1889) 6 RPC 243 at 279; *Samuel Taylor Pty Ltd v SA Brush Co Ltd* (1950) 83 CLR 617 at 624-5.
[370] This may soon be incorrect. In 1995 the first full DNA sequences of two bacteria were determined. J L Fox, 'Full bacterial DNA sequences boost genomics' (1995) 13 *BioTechnology* 644. Final sequencing of the human genome by the Human Genome Project was completed in April 2003. National Human Genome Research Institute, *Home Page* (http://www.nhgri.nih.gov accessed 16/03/04). The sequences of the entire genomes of other higher organisms have been or are being determined.
[371] B Rowland, 'Are the Fruits of Genetic Engineering Patentable?' in D W Plant et al (eds), *Banbury Report Number 10. Patenting of Life Forms* (Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, 1982), p 141, p 147. Techniques have greatly improved since this observation was made but the same issue is still relevant in some cases.
[372] This is not true of all plants and inbred lines of animals, such as mice, used for research.
[373] For eg, during synthesis of the plasmid, growth of transformants, changes occurring in the plasmid or during insertion. There can also be differences in expression patterns because of different sites of insertion.
[374] Lawson also reaches this conclusion. C Lawson, '"Sufficiency" for living organism inventions under the Patents Act 1990 (Cth)' (2004) 11 *Journal of Law and Medicine* 373, 377 .
[375] J Straus, 'Discussion: Session 3' in E Vogel and R Grunwald (eds), *Patenting of Human Genes and Living Organisms* (Springer-Verlag, Berlin, 1994), p 117 (in relation to German law) and F-K Beier and R Moufang, 'Patentability of Human Genes and Living Organisms: Principles of a Possible International Understanding' in E Vogel and R Grunwald (eds), *Patenting of Human Genes and Living Organisms* (Springer-Verlag, Berlin, 1994), p 208; D Schertenleib, 'The Patentability and Protection of Living Organisms in the European Union' [2004] *European Intellectual Property Review* 203, 206. See also T

genetic identity be guaranteed by the written description for there to be adequate disclosure.[376] If the organism is described by reference to its genetic makeup the differences may be significant although the degree of DNA homology necessary for two organisms or products to be identical is not clear.[377]

To ensure that readers achieve the claimed result it may be necessary to make the patentee's starting organism or the GMO available.[378] Such a method also relieves the patentee from the burden of describing an organic invention in words. Where a GMO is made available, readers can then 'repeat' the invention by propagating from it. Deposits of material in recognised patent depositories is in some cases allowed by the *Patents Act* in place of written descriptions.[379] These provisions reflect Australia's obligations under the *Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure*.[380] The depositories maintain the material in a viable condition and make samples available to the public.[381] The procedure was established for

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281/86 (UNILEVER/ Preprothaumatin) OJ EPO 1989, 202; (1989) 20 IIC 726; T 292/85 (GENENTECH I/ Polypeptide expression) OJ EPO 1989, 275; (1989) 20 IIC 725.

[376] R Moufang, 'Protection for Plant Breeding and Plant Varieties. A Frontier of Patent Law' (1992) 61 *Nordiskt Immateriellt Rättsskydd* 330, 341. Moufang refers to a number of EPO decisions as showing that in many instances the concept of genetic identity cannot be used as an appropriate yardstick for sufficiency of disclosure, including T 281/86 (UNILEVER/ Preprothaumatin) OJ EPO 1989 202; (1989) 20 IIC 726; T 292/85 (GENENTECH I/ Polypeptide expression) OJ EPO 1989 275; (1989) 20 IIC 725. See also G Paterson, *The European Patent System. The Law and Practice of the European Convention* (Sweet & Maxwell, London, 1992), [3-32].

[377] I Sela, 'Legal Protection of Living Organisms from the Point of View of Scientists in Plant Breeding' in E Vogel and R Grunwald (eds), *Patenting of Human Genes and Living Organisms* (Springer-Verlag, Berlin, 1994), p 78.

[378] The US PTO has recognised a public deposit of biological material representative of either the invention or starting material is an acceptable adjunct to written patent disclosure which otherwise may be non-enabling. US, Dept of Commerce, Patent and Trade Mark Office (1987) Deposit of Biological Materials for Patent Purposes: Advance Notice of Proposed Rulemaking. Fed Reg., 52 (Sept 9): 34080-93 and (1988) Deposit of Biological Materials for Patent Purposes: Notice of Proposed Rulemaking. Fed Reg., 53 (Oct 6): 39420-32 cited by R Foote, 'The Technology and Costs of Deposits' in W Lesser (ed), *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989), p 51. But see *Enzo BioChem, Inc v Gen-Probe Inc* (US Court of Appeals for the Federal Circuit 01-1230 (2 April 2002)), (reversed on appeal (US Court of Appeals for the Federal Circuit 01-1230 (July 2002)) referred to in L Taliadoros, 'Deposit of micro-organisms – US Court warns of limitations' (2002) 1 *Biotechnology Law and Policy Reporter* 109. The same position also exists in Europe. See *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Article 13.

[379] *Patents Act 1990* (Cth) ss 6 and 41, Patents Regulations 1991 (Cth) reg 5 and Schs 1 and 1A. In some cases deposit is mandatory. See *Patents Act 1990* (Cth) s 41(2). See also *Commonwealth Scientific and Industrial Research Organisation v Bio-Care Technologies Pty Ltd* (1999) 45 IPR 483.

[380] [1987] ATS 9 which entered into force generally in 1980 and came into force in Australia on 7 July 1987. The text is contained in Sch 1 to the Patents Regulations 1991 (Cth).

[381] For a discussion of the development of deposit requirements see B L Wickline, 'The Impact of the Deposit Requirement for Patenting Biotechnology: Present Concerns, Proposed Solutions' (1991) 24 *Vanderbilt Journal of Transnational Law* 793. Also see R Foote, 'The Technology and Costs of Deposits' in W Lesser (ed), *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989), pp 51-7; R S Crespi, 'The Microorganism Deposit System in European Patent Law - An Appraisal of Current Proposals' (1993) 24 *International Review of Industrial & Copyright Law* 1.

the patenting of microorganisms. However, plasmids, vectors, plant tissues, seeds and other biological materials that are not generally available or reproducible without undue experimentation by persons skilled in the field have been deposited overseas.[382] Some of these are treated as within the scope of 'microorganism' by the Australian Patent Office.[383]

It is not clear whether such a deposit would be sufficient in Australia with respect to GMOs.[384] First, it is not certain what is included within 'microorganism'. Plant tissues, seeds and animal semen, for example, are not organisms but rather parts of organisms if a scientific understanding of the term is adopted.[385] No definition of the term is included in the legislation or the Budapest Treaty.[386] Secondly, it is not clear whether such deposit is compulsory or permitted where material other than a microorganism in the scientific sense is concerned.

Further, although the deposit of biological material may solve some problems, it is not ideal for commercialisers.[387] First, making a sample available to the public gives the public more than usual when a patent is published. The living organism is not only the invention but is also the 'factory' used to produce the new product. The depositor not only tells the public how to make the invention (as is usual) but also gives away the means for making it.[388] This problem is addressed to a great extent by the limitations on availability

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[382] US, Office of Technology Assessment, Congress of the US, *New Developments in Biotechnology: Patenting Life* (Marcel Dekker, Inc, New York, 1990), p 18.

[383] Namely, 'hosts containing materials such as vectors, cell organelles, plasmids, DNA, RNA, genes and chromosomes'. IP Australia, *Patent Manual of Practice and Procedure*, Volume 2 – National (Cth of Aust, Canberra, 2002), [6.1.5] quoted by Australian Law Reform Commission, *Gene Patenting and Human Health* Issues Paper 27 (July 2003), [8.9] fn 294.

[384] Such a method was used for the first animal patent in the US, US 4,736,866. The description requirements were satisfied by the deposit of plasmids bearing the cancer-causing genes intended for transfer into an animal. The patent specification then described in detail how to insert the plasmid into mouse embryos to produce transgenic mice. US, Office of Technology Assessment, Congress of the US, *New Developments in Biotechnology: Patenting Life* (Marcel Dekker, Inc, New York, 1990), p 18.

[385] Cf more expansive understanding of the term used by the EPO and Japan Patent Office. See G Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Ashgate Publishing Ltd, England, 2003), p 69. See also *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Article 2(1)(a)(definition of 'biological material').

[386] Lawson concludes that there are no impediments to the *Patents Act 1990* (Cth) being amended to require living organism inventions outside the term 'microorganism' being deposited. See C Lawson, '"Sufficiency" for living organism inventions under the Patents Act 1990 (Cth)' (2004) 11 *Journal of Law and Medicine* 373.

[387] Nor is it without problems for the Patent Office. See US, Office of Technology Assessment, Congress of the US, *New Developments in Biotechnology: Patenting Life* (Marcel Dekker, Inc, New York, 1990), Chap 9.

[388] G M Hoffman and G M Karny, 'Can Justice Keep Pace with Science?' [1988] *European Intellectual Property Review* 355. As pointed out by Heitz if the process to produce the organism is patented, the process to make the organism could be 'so time-consuming, complex and expensive that it becomes pointless to reproduce them once genetically consistent propagating material of the new species is available'. A Heitz, 'Intellectual Property in New Plant Varieties and Biotechnological Inventions' [1988] *European Intellectual*

of samples in the Regulations.[389] Nevertheless, the patentee loses their rights to physically control the invention.[390] Finally, description of an invention by deposit provides narrower protection than description in words. Description by deposit limits the invention to the precise organism deposited - if the organism becomes nonviable or mutates it will be virtually impossible for the patentee to prove infringement of the original invention. Accordingly, where possible, sequence data should be included in the specification with or without a deposit being made.[391]

Insufficiency and therefore invalidity may also arise where a patentee claims the invention in more than one type of organism although they have not actually attempted to create a modified organism of that particular type.[392] Living materials, such as microorganisms or cultured cells, and other aspects of biochemistry and GM are routinely considered unpredictable in the US.[393] The Australian Patent Office has taken a similar view with respect to higher organisms. It requires the disclosure to be sufficiently enabling so that a person in the art could duplicate all of the invention without undue experimentation.[394] However, this may be a short term problem. As the view that GMOs and their materials are obvious gains acceptance, it will be difficult to maintain the contradictory view that such products are in an unpredictable art.[395] The patentee would then have to argue that it was not obvious that the invention could be made successfully but, on the other hand, the few working examples given make it clear that everything else within the scope of the claim will work.[396]

Property Review 297, p 300 citing H G Heise, 'Zur Patentierung von Züchtungen' (1969) 12 GRUR, 644 -53 (not seen).

[389] See Patents Regulations 1991 (Cth) regs 3.25-3.28.

[390] B L Wickline, 'The Impact of the Deposit Requirement for Patenting Biotechnology: Present Concerns, Proposed Solutions' (1991) 24 *Vanderbilt Journal of Transnational Law* 793, 807. See, for eg, Patents Regulations 1991 (Cth) reg 3.25.

[391] L Taliadoros, 'Deposit of micro-organisms – US Court warns of limitations' (2002) 1 *Biotechnology Law and Policy Reporter* 109, 114. For methods that could be used by authorities to address the problem see A Cantor, 'Using the Written Description and Enablement Requirements to Limit Biotechnology Patents' (2000) 14 *Harvard Journal of Law & Technology* 267.

[392] See, for eg, claims in the patent application considered in *The Austin Research Institute v Bresagen Ltd* (2004) AIPC ¶ 91-941. Roberts considers that such claims are of concern because they slow down or stop the introduction of useful technology. T Roberts, 'Broad Claims for Biotechnological Inventions' [1994] *European Intellectual Property Review* 371.

[393] B P O'Shaughnessy, 'Patent pitfalls among the unpredictable arts' (1996) 14 *Nature Biotechnology* 1028; K G Chahine, 'Enabling DNA And Protein Composition Claims: Why Claiming Biological Equivalents Encourages Innovation' (1997) 25 *AIPLA Quarterly Journal* 333.

[394] *The Austin Research Institute v Bresagen Ltd* (2004) AIPC ¶ 91-941. This decision actually concerned lack of fair basis pursuant to s 40(3) but the facts provide a useful illustration of the issues here.

[395] R Saliwanchik, *Protecting Biotechnology Inventions. A Guide for Scientists* (Science Tech Publishers, Madison, 1988), p 89.

[396] T Roberts, 'Broad Claims for Biotechnological Inventions' [1994] *European Intellectual Property Review* 371, 372.

(c) False suggestion

A patent obtained by 'fraud, false suggestion or misrepresentation' may be revoked.[397] Many of the problems giving rise to difficulties with respect to inutility and insufficiency will also give rise to problems with respect to false suggestion if there has been a material deception resulting in the grant of the patent.[398]

4.3.6 *Scope of Protection*

If patent protection is available to commercialisers, their next concern will be the scope of that protection. The economic value of a patent depends upon its scope.[399] As with availability of protection, there is considerable uncertainty regarding the scope of protection offered to GMO commercialisers.

A patent gives the patentee exclusive rights to exploit the invention[400] for 20 years[401] in the patent area.[402] 'Exploit' is defined to include, where the invention is a product, making, hiring, selling or otherwise disposing of the product, offering to do those things, using or importing the product or keeping it for the purposes of doing any of those things.[403] Infringement is not defined in the legislation. It occurs when one or more of the patentee's exclusive rights are taken by another.[404] The protection offered to commercialisers therefore depends upon the breadth of exclusive privileges granted to the patentee. This is largely determined by the meaning of 'exploit' when applied to GMOs.

Three significant issues arise with respect to the scope of protection offered by patent law to commercialisers. These are:

(a) whether patents with respect to organisms or products cover progeny or products produced from them;

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[397] *Patents Act 1990* (Cth) s 138(3)(d).
[398] See *Prestige Group (Australia) Pty Ltd v Dart Industries Inc* (1990) 19 IPR 275; *Procdes Pty Ltd v Staniite Electronics Pty Ltd* (1995) 35 IPR 259. See also M Gething, 'Patents Obtained by Fraud, False Suggestion or Misrepresentation' (1994) 5 *Australian Intellectual Property Journal* 152.
[399] R P Merges and R R Nelson, 'On the Complex Economics of Patent Scope' (1990) 90 *Columbia Law Review* 839, 839.
[400] *Patents Act 1990* (Cth) s 13(1). There are exceptions to these rights. See, for eg, ss 118 and 119.
[401] *Patents Act 1990* (Cth) s 67. That term may be changed following the signing of the Australia-US Free Trade Agreement in February 2004.
[402] That is, Aust, its continental shelf and water and air above. *Patents Act 1990* (Cth) Sch 1 (definition of 'patent area').
[403] *Patents Act 1990* (Cth) Sch 1.
[404] *Sykes v Howarth* (1879) 12 Ch D 826.

(b) whether the use of a patented GMO or its materials to produce progeny or other products is a patent infringement by purchasers of GMOs or products;[405] and

(c) when other users of the patented organism or product infringe the patent.

(a) Progeny and products of patented organisms

Some patents in respect of GMOs claim progeny produced by natural breeding.[406] Even with respect to those patents which do not, the general view is that given that patents protect inventions, patentees' rights extend to anything embodying the claims in the patent regardless of the source of the allegedly infringing device.[407] Therefore patents with respect to GMOs cover not only the organisms sold by the patentee but also any progeny produced from the original matter.[408] However, this will be the case only if they carry the specialised trait of the patented invention.[409] A patent with respect to a GMO will not give the patentee a monopoly on the existing genomic content of the organism. Only the new subject matter can be claimed.[410] Therefore a monopoly could only be granted with respect to progeny possessing the GM.[411] Further, a patent for a GMO would not cover

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[405] It is assumed that such use occurs within the 'patent area'. See *Patents Act 1990* (Cth) Sch 1 (definition of 'patent area').

[406] Such as the Harvard oncomouse patent (US Patent No 4,736,866 Leder et al reproduced in Appendix 2 in W Lesser (ed), *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989), p 161). The progeny are claimed via claims to a 'transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage' (claim 1).

[407] See, for eg, Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (Canadian Biotechnology Advisory Committee, Ottawa, June 2002), p 12. The Committee considered that this is a significant increase in the usual scope of rights given to patentees.

[408] This does not mean the patentee 'owns' any progeny or products produced from patented organisms, although if infringement occurs a court may order 'delivery up' of such things. R S Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71, 72. See also *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Articles 8 and 9.

[409] W Lesser, 'Implications for Breeders' in W Lesser (ed), *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989), p 96. See also T Zeleny, 'Property Rights in Living Things: Difficulties with Reproduction and Infringement' (1994) 2 *San Diego Justice Journal* 209, 232; S A Chambers, 'Exhaustion Doctrine in Biotechnology' (1994-5) 35 *IDEA* 289, 293. Also see N Peace and A Christie, 'Intellectual Property Protection for the Products of Animal Breeding' [1996] *European Intellectual Property Review* 213.

[410] The progeny of GMOs will not necessarily receive the unique trait of its parent(s), or if it does, receive it to the same degree because although GMs are commonly inherited, their expression is not necessarily predictable or stable. *Transgenic Animal Patent Reform Act of 1989: Hearings on H.R. 1556 Before the Subcommission on Courts, Intellectual Property, and the Administration of Justice of the House Commission on the Judiciary*, 101st Congress, 1st Sess 246 (1989) at 581 (not seen) cited by D A Mark, 'All Animals are Equal, But Some Are Better than Others: Patenting Transgenic Animals' (1991) 7 *The Journal of Contemporary Health Law & Policy* 245, 255 n 69. See also Monsanto's patent in *Schmeiser* discussed in subsection (c) below.

[411] See R S Crespi, 'Patents and Plant Variety Rights: Is There an Interface Problem?' (1992) 23 *International Review of Industrial & Copyright Law* 168, 182.

products (other than progeny), such as oil, produced by such organisms unless claimed in the patent.

(b) Purchaser's use of patented organisms or patented products

Patent rights continue to exist even after the sale of patented products.[412] However, the purchase and possession of a patented organism or product in itself is not exploitation of the invention.[413] It is therefore not a patent infringement.

The purchaser, by virtue of possessing the organism or its product, may be able to produce additional organisms or products. That production may be 'making' (and therefore exploitation) of the patented invention.[414] Reproduction itself may also be 'use' of the patented invention.[415] This would be the case even if the organism or material produced from the organism or product purchased from the commercialiser is only used as a transitory step in the production of an article which in its final form differs from the invention.[416] Possession combined with the intention of using the invention in trade can also be infringement.[417]

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[412] *National Phonograph Company of Australia, Ltd v Menck* [1911] AC 336 (PC). Unlike the US and Europe, Aust does not have a general doctrine of exhaustion of patent rights. S A Chambers, 'Exhaustion Doctrine in Biotechnology' (1994-5) 35 *IDEA* 289, 290, citing D S Chisum, *Patents* (1994), [20.03] [7][b][i] (not seen). However, since reproduction of biological material is not only use but also a making of new products and of the patented invention, the patent right may not be exhausted in this respect for the purposes of that doctrine. See, for eg, S A Bent et al, *Intellectual Property Rights in Biotechnology Worldwide* (Stockton Press, New York, 1987), pp 279-85; J L Jeffers, 'Restriction of Propagation of Patented Bacteria Sold by Patentee - Can It Be Done?' (1988) 70 *Journal of the Patent and Trade Mark Office Society* 137; A Christie, 'Patents for Plant Innovation' [1989] *European Intellectual Property Review* 394, 404-6; R Moufang 'Protection for Plant Breeding and Plant Varieties' (1992) 61 *Nordiskt Immateriellt Rättsskydd* 330, 342. See also L Bently and B Sherman, *Intellectual Property Law* (Oxford University Press, New York, 2001), pp 510-1 regarding exhaustion and farmers' privilege in the UK.

[413] *Nobel's Explosives Co Ltd v Jones, Scott & Co* (1882) 8 App Cas 5 (HL); *British Motor Syndicate Ltd v John Taylor & Sons Ltd* (1900) 17 RPC 723 (CA); *Pessers, Moody, Wraith and Gurr Ltd v Newell & Co* (1914) 31 RPC 510.

[414] See subsection (c) below with respect to when 'making' occurs in these circumstances.

[415] See W Lesser, 'Implications for Breeders' in W Lesser (ed) *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989), p 96. Note that the two US plant protection Acts, which were specifically drafted to deal with living organisms, include reproduction in the definition of infringement. In the EC, pursuant to *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Articles 8 and 9, multiplication of patented organisms, without permission (express or implied) of the patentee, is also infringement. See also Recitals 46-51.

[416] *Bedford Industries Rehabilitation Inc v Pinefair Pty Ltd* (1998) 40 IPR 438 at 450. This is provided that its use in the production of the article is not an unimportant or trifling part of that production. *Saccharin Corp Ltd v Anglo-Continental Chemical Works Ltd* (1900) 17 RPC 307; *Bedford Industries Rehabilitation Inc v Pinefair Pty Ltd* (1998) 40 IPR 438.

[417] *Pfizer v Ministry of Health* [1965] AC 512 at 572.

Nevertheless, production of additional organisms or products by purchasers using the patented material are unlikely to be unauthorised exploitations of the invention.[418] Purchasers are presumed to have an implied licence to carry out the monopoly acts to enable them to enjoy the natural use of the product unless notified otherwise.[419] It will also not, it seems, be an infringing use of the patent if the GMO or its product is made for the purposes of bona fide experimentation.[420] If the use has a commercial purpose though, the defence will not apply.[421]

The primary foreseeable buyers of living GMOs are farmers, plant nursery operators and researchers.[422] These groups often need to reproduce the organism in order to obtain a continuous supply of it. The production of progeny by the purchaser is likely to be permissible pursuant to the relevant implied licence.

Purchasers of the products of GMOs include those wanting to use the product to produce the organism which produced it, such as plant nursery operators and purchasers of semen from patented animals. Retailers of the products (or manufacturers who use the products in the manufacture of their own products) will also purchase such products. Commercialisers could, by express notice to the purchaser at the time of purchase, restrict further dealings with the patented product sold by them,[423] subject to competition law

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[418] The equitable defence of estoppel may also arise if the commercialiser by acts or words leads the infringer to believe that their patent rights would not be enforced and the alleged infringer relied on that understanding to their detriment. See *Woodbridge Foam Corporation v AFCO Automotive Foam Components Pty Ltd* [2002] FCA 883 at [12].

[419] *Betts v Willmott* (1871) LR 6 Ch 239; *Société Anonyme des Manufactures de Glaces v Tilghman's Patent Sand Blast Company* (1883) 25 Ch D 1 at 9; *Heap v Hartley* (1888) 5 RPC 603 at 610; *National Phonograph Company of Australia, Ltd v Menck* [1911] AC 336 (PC). See A Christie, 'Patents for Plant Innovation' [1989] *European Intellectual Property Review* 394, 405 for a discussion of implied licences and their justifications.

[420] N Peace and A Christie, 'Intellectual Property Protection for the Products of Animal Breeding' [1996] *European Intellectual Property Review* 213, 222. The experimentation must be on the invention and not using it in experiments for something else. See *Frearson v Loe* (1878) 9 Ch D 48 at 66-7; *Proctor v Bayley & Son* (1889) 6 RPC 538; *Smith Kline & French Inter-American Corp v Micro Chemicals Ltd* (1970) 60 CPR 193. See also Australian Law Reform Commission, *Gene Patenting and Human Health* Issues Paper 27 (July 2003), [14.7]-[14.20]; Advisory Council on Intellectual Property, *Patents and Experimental Use* Issues Paper (February 2004).

[421] It is unclear when a use becomes one for a commercial purpose. This issue is outside the scope of this study but see Advisory Council on Intellectual Property, *Patents and Experimental Use* Issues Paper (February 2004).

[422] T Zeleny, 'Property Rights in Living Things: Difficulties with Reproduction and Infringement' (1994) 2 *San Diego Justice Journal* 209, 233. Abattoir operators also purchase living animals but are unlikely to reproduce the animals.

[423] *The Incandescent Gas Light Co Ld v Cantelo* (1895) 12 RPC 262 at 264; *Badische Anilin und Soda Fabrik v Isler* [1906] 1 Ch 605 at 610; *National Phonograph Company of Australia, Ltd v Menck* [1911] AC 336 at 353 (PC); *Columbia Gramophone Co Ltd v Fossey* (1927) 27 SR (NSW) 246 at 249-50; *Time-Life International (Nederlands) B.V. v Interstate Parcel Express Co. Pty Ltd* [1978] FSR 251 at 270-2. Cf *Russell v Bruyeres* (1865) 4 SCR(NSW) Eq 1.

principles.[424] Alternatively loss of protection could be reflected in the sale price of the original organism or product or a royalty[425] could be imposed on all progeny or products.[426] However, in many cases the protection afforded by these arrangements will interfere with the commercialiser's exploitation of the invention. Further, the protection given will be uncertain in some cases. For example, unless the organism is part of an inbred line, where sexual reproduction is used to replicate the organism, not all progeny will receive the patented trait. Therefore any obligation to pay a royalty may have to be limited to progeny possessing the relevant trait. Further, to be workable, simple and cheap methods for determining this need to be available. Simple methods for collecting and paying the royalty would also need to be devised.

(c) Infringement by other users of patented organisms or patented products

Infringement of a product patent occurs, as noted above, when the patent is exploited. GMOs are self-replicating and capable of moving to another's property without human intervention. If the use, reproduction or sale of contaminated organisms is exploitation for these purposes infringement by 'innocent' third parties whose property is inadvertently contaminated is readily foreseeable. Therefore, if GM pollen pollinates another farmer's plants and seed from those plants are kept and planted for the following year's crop, there would arguably be keeping and use infringing the patent. In Australia, patentee's rights are

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[424] Examples of the types of contracts which could be used to restrict the use of the product after sale include licensing agreements, secrecy agreements, conditions of sale agreements and 'restricted use' labels on the product as used on hybrid seed bags. See R J Jondle, 'Overview and Status of Plant Proprietary Rights' in ASA Special Publication Number 52, *Intellectual Property Rights Associated with Plants* (Crop Science Society of America, Inc, American Society of Agronomy, Inc, Social Science Society of America, Madison, Wisconsin, 1989), p 7. Restrictions include total prohibition of propagation using the relevant organism or a requirement that all progeny sold by the purchaser be sterilised before sale. See also contractual arrangements used in the exploitation of the Flavr Savr tomato. See B J Mazur, 'Commercializing the products of plant biotechnology' (1995) 13 *Trends in BioTechnology* 319; M Francisco, 'Calgene moves into the black, brown, blue, and red' (1996) 14 *Nature Biotechnology* 1072. However, contracts will be largely irrelevant in the scenarios considered in this study.

[425] For eg, a percentage royalty based on some measure of production (such as tonne of virus resistant potatoes). S Bent, 'Issues and Prospects in the USA' in W Lesser (ed), *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989), p 13. See also J S Hudson, 'Biotechnology Patents After the "Harvard mouse": did Congress really intend "everything under the sun" to include shiny eyes, soft fur and pink feet?' (1992) 74 *Journal of the Patent and Trade Mark Office Society* 510, 526 n 109; R P Merges, 'Intellectual Property Rights in Higher Life Forms: The Patent System and Controversial Technologies' (1988) 47 *Maryland Law Review* 1051.

[426] Note that if the patentee intends to impose a royalty on progeny there will be many difficulties to be overcome, depending upon the industry involved. See, for eg, A A Sorensen, 'Perspectives of Farmers in the USA' in W Lesser (ed), *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989), p 118; R S Crepsi, 'Prospects for International Cooperation' in W Lesser (ed), *Animal Patents. The Legal, Economic and Social Issues* (Macmillan Publishers Ltd, Hants, UK, 1989), pp 37-8; W Lesser, 'Royalty Collection for Patented Livestock' [1994] *European Intellectual Property Review* 441.

not subject to exceptions such as farmer's privilege as PBRs are.[427] Similarly, if a GM animal escapes onto another's land and inseminates an animal belonging to a third party, with the offspring then being used in the same way as other non-GM offspring the patent would be infringed through use. Patentees could sue for damages and/or an injunction to stop further infringement. However, in such cases a court may decline to award damages or an account of profits.[428] An injunction, being a discretionary remedy, may also be refused where the court must decide between a commercialiser whose GMO has contaminated another's property and someone who has innocently infringed a patent.

The activities included in the definition of exploit are not defined in the legislation. During the second reading speech for the Patents Bill 1989, it was said that 'the word "exploit" here bears a sensible, usual meaning.'[429] Dictionaries do not define the term as requiring any commercial purpose.[430] Nevertheless, many commentators consider that there must be commercial use of the invention to be infringement.[431] Certainly the case law concerns commercial use, even if that use is limited.[432] There is no clear authority that domestic or private use does not infringe. Arguably such use is still infringing use because the defendant's use does not have to cause actual loss to the patentee.[433]

If exploitation for commercial purposes is not required, using a GMO or its products or progeny for private purposes, for example for a pet or in a home-garden, would be infringement. However, such use is unlikely to cause damage to the commercialiser justifying the granting of a remedy.[434] Further, it will be unusual for agricultural organisms contaminated by GMOs or their products not to be used for commercial purposes.

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[427] Such rights could allow farmers to collect and reuse seeds from patented plants and to breed animals for their own use. See Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (Canadian Biotechnology Advisory Committee, Ottawa, June 2002), pp 12-3 recommending such an exception be included in Canadian patent law. See also *Directive 98/44 of the European Parliament and of the Council of 6 July, 1998 on the Legal Protection of Biotechnological Inventions*, Article 11.

[428] *Patents Act 1990* (Cth) s 123. See B Sherman, 'Biological Infringement and the Problem of Passive Infringement' (2002) 13 *Australian Intellectual Property Journal* 146, 149.

[429] Cth, *Parliamentary Debates*, House of Representatives, 1 June 1989, 3479 (Jones, Minister for Science, Customs and Small Business).

[430] See *The Oxford English Dictionary* (2nd ed, Clarendon Press, Oxford, 1989).

[431] See, eg, J McKeough et al, *Intellectual Property. Commentary and Materials* (3rd ed, Law Book Co, Sydney, 2002), [14.1]. See also ALRC Discussion Paper 68, [14.7]; S Ricketson and M Richardson, *Intellectual Property: Cases, Materials and Commentary* (2nd ed, Butterworths, Sydney, 1998), [15.3.2].

[432] With respect to limited use see, for eg, *British Motor Syndicate Ltd v John Taylor & Sons Ltd* (1900) 17 RPC 723 (CA).

[433] *Watson, Laidlaw & Co Ltd v Potts, Cassels & Williamson* (1914) 31 RPC 104 at 118; *Smithkline v DDSA Pharmaceuticals Ltd* [1978] FSR 109 at 113-4.

[434] A McBratney et al, *Submission P47* (22 October 2003) cited in ALRC Discussion Paper 68, [14.114].

There are three important uncertainties relevant to such conclusions. These are discussed below. The first subsection though discusses a useful Canadian decision in the area. It will be submitted in section 4.3.7 that where GM contamination results in GMOs or their progeny growing with the contaminated organisms, there will be infringement in many cases.

Schmeiser's case

A well known example of infringement of a GMO patent is provided by the Canadian decision of *Monsanto v Schmeiser*[435] ('*Schmeiser*'). Pollen from GM canola spread onto a third party's, Schmeiser, farm and his non-GM canola. Monsanto held a patent in respect of the GM canola[436] and sued Schmeiser for patent infringement. It was not clear how the GM canola came to be on Schmeiser's land although Schmeiser claimed he had not brought it there.[437] The GM canola was resistant to certain herbicides manufactured by Monsanto,[438] commonly known as Roundup. Schmeiser noticed that some canola plants on his property survived spraying with Roundup. He confirmed this by spraying three acres of his crop with Roundup. About sixty percent of the crop survived and he saved the seeds from the survivors for planting his entire crop the following year.[439] Schmeiser raised the fact, amongst others, that the GM canola had spread to his property without his knowledge or agreement. Therefore, it was argued, there was no infringement. It should be noted that the patent under consideration did not claim the plant or its progeny. Further, Schmeiser did not sell any of the seed, instead collecting, saving and planting it for his own use. The Canadian Federal Court of Appeal affirmed the trial judge's finding of infringement. On appeal, the Canadian Supreme Court also ruled that the patent was valid

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[435] *Monsanto Canada Inc v Schmeiser* 2001 FCT 256. Confirmed in the full Federal Court, *Schmeiser v Monsanto Canada Inc* 2002 FCA 309. Appeal allowed (only with respect to remedy) in *Schmeiser* v *Monsanto Canada Inc* 2004 SCC 34.

[436] More particularly, including claims to a particular gene and to plant cells containing that gene. The GM plant itself was not claimed. See subsection 4.3.2(b)(i) with respect to the difficulties of patenting higher life forms in Canada.

[437] Possibilities include it being brought there by wind drift of seeds from neighbouring properties, passing trucks dropping seed or cross-pollination from GM crops on other farms. *Monsanto Canada Inc v Schmeiser* 2001 FCT 258 [117]. The trial judge found none of these sources reasonably explained the concentration or extent of GM canola of a commercial quality in Schmeiser's crop. *Schmeiser* v *Monsanto Canada Inc* 2004 SCC 34 at [6].

[438] Glyphosate herbicides.

[439] 95-98 percent of Schmeiser's 1998 canola crop was GM canola. *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [6].

and that Schmeiser had infringed it.[440] The Supreme Court emphasised that this was not a case where Schmeiser had innocently discovered contamination of his crops.[441]

The Canadian Supreme Court in *Schmeiser* found there was use of the patented cells.[442] Schmeiser had sown and actively cultivated the plants, through testing, isolating and planting the seed and tending until harvest. The crop had not 'merely "grown itself"'.[443] It is not clear whether there would be use if there had not been the active selection of GM seeds by Schmeiser.

Schmeiser also submitted that he had legal title to the invading GM plants because he owned the property they grew on.[444] Therefore, it was asserted, he had the right to save seed from the plants. The Canadian Supreme Court rejected that argument, finding that property rights in the plants do not displace patent rights in the invention embodied in the plants.[445] It is submitted that this is also true under Australian law.

Defendant's state of mind

Under Australian law, patent infringement does not require that the alleged infringer know or ought to know they are infringing a patent, only that exploitation occur.[446] Further, it is not necessary that the defendant know they are using the patented article.[447]

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[440] *Schmeiser* v *Monsanto Canada Inc* 2004 SCC 34. Several remedies were awarded by the Court including an order to deliver up any seed containing the patented gene. However, there was no account of profits awarded because there was insufficient evidence that Schmeiser intentionally made use of the benefits of the patented invention.

[441] *Schmeiser* v *Monsanto Canada Inc* 2004 SCC 34 at [2].

[442] *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [88] and [90]-[97].

[443] *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [92].

[444] For discussion of the ramifications of this argument see M Lee and R Burrell, 'Liability for the Escape of GM Seed: Pursuing the "Victim"' (2002) 65 *Modern Law Review* 517, 525-7.

[445] *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [96].

[446] See *Proctor v Bennis* (1887) 4 RPC 333; *Young and Neilson v Rosenthal and Co* (1884) 1 RPC 29 at 39; *M'Lean v Kettle* (1883) 9 VLR (E) 145; *Wright v Hitchcock* (1870) LR 5 Ex 37 at 47; *Stead v Anderson* (1846) 2 Web Pat Cas 147 at 165; 136 ER 724 at 736. Cf with the recommendation of the Canadian Biotechnology Advisory Committee that limited protection be introduced for 'innocent' bystanders who do not know that GMOs are on their property. Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*, (Canadian Biotechnology Advisory Committee, Ottawa, June 2002), Recommendation 4. See also H Preston, 'Drift of Patented Genetically Engineered Crops: Rethinking Liability Theories' (2003) 81 *Texas Law Review* 1153. For discussion of why intention is irrelevant to infringement, see B Sherman, 'Biological Infringement and the Problem of Passive Infringement' (2002) 13 *Australian Intellectual Property Journal* 146.

[447] The cases with respect to secret use illustrate this. Eg, *R v Patents Appeal Tribunal, ex parte Beecham Group Ltd* [1974] AC 646.

The Canadian Federal Court in *Schmeiser*, in obiter,[448] suggested that GMOs may be a novel category for these purposes because they can reproduce without human intervention. They can be on another's property without the landowner being aware of it or causing it. The Court suggested that in such cases, the infringer's intention may be relevant. The Canadian Supreme Court in *Schmeiser* also considered this issue. It concluded that the legislation did not support a different approach in such cases. It was up to Parliament to respond to the problem.[449] Therefore even inadvertently contaminated farmers could infringe a commercialiser's patent where they plant, harvest or otherwise use the invention. It seems though that, subject to use by possession as described in the next subsection, a plaintiff inadvertently allowing a GMO which has contaminated their land to grow on that land is not use for the purposes of infringement.[450] It would instead be mere possession, which is not itself infringing use.[451] Where GMOs are grown and harvested or otherwise used with the defendant's other organisms, regardless of how they came to be growing there, there would be use of a patented article. The defendant would not be merely in possession of the GMO in such cases.

The Canadian Biotechnology Advisory Committee has recommended patent law changes in light of the self-reproducibility of GMOs. It recommends that the reproduction of GMOs on a person's property without their knowledge should not be patent infringement if that lack of knowledge is proven by them.[452] They consider that this addresses the problem of infringement where the 'infringer' is not responsible for the patented invention being on their land or for the reproduction of the invention or where they unknowingly harvest or otherwise use the invention.

The TRIPS Agreement allows for exceptions to the exclusive rights conferred on patentees.[453] Such exceptions though must not unreasonably conflict with the normal exploitation of the patent nor unreasonably prejudice the legitimate interests of the

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[448] On the facts Schmeiser was not an 'innocent' infringer because he knew the GM canola was on his property and deliberately saved seed from it.
[449] *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [95].
[450] See *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [86]-[87].
[451] *British Motor Syndicate Ltd v John Taylor & Sons Ltd* (1900) 17 RPC 723 at 731-2 (Vaughan Williams LJ); *Smith Kline and French Laboratories Ltd v R D Harbottle (Mercantile) Ltd* [1980] RPC 363 at 374 (Oliver J); *Pfizer Corporation v Ministry of Health* [1965] RPC 261 at 320 (Lord Wilberforce).
[452] Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (Canadian Biotechnology Advisory Committee, Ottawa, June 2002), p 14 and Recommendation 4. See also H Preston, 'Drift of Patented Genetically Engineered Crops: Rethinking Liability Theories' (2003) 81 *Texas Law Review* 1153; N Siebrasse, 'The Innocent Bystander Problem in the Patenting of Higher Life Forms' (2004) 49 *McGill Law Journal* 349.
[453] TRIPS Agreement Article 30.

patentee. However, this is subject to the legitimate interests of third parties. This final proviso may be a basis on which the Australian Parliament could act to protect third parties from patent liability following GM contamination. It is submitted that Parliament is unlikely to do so. Innocent infringement of a patent monopoly is not a concern unique to GMOs although the unique traits of GMOs mean that it may be a more common problem than for other inventions.

Not taking advantage of characteristic introduced by the GM

That the third party does not take advantage of the characteristic endowed by the GM may be claimed by defendants to mean there is no 'use' of the invention. It is submitted that such an argument should fail.

As noted above, mere possession is not of itself infringing use. It was submitted above that accordingly the mere presence of pollen or other part of or entire GMO on another's land will not usually of itself be an infringement. However, infringement occurs where the possession of the patented invention itself amounts to use of the invention.[454] In the case of GMOs therefore the defendant will need to show that they have not taken advantage of what the Canadian Supreme Court called, the stand-by or insurance utility of the GM properties of the organism.[455] By this the Court meant use through having a GMO present, the characteristics of which could be taken advantage of if the need arose. The Court held that this can be 'use' of the patented organism even if the need doesn't arise and the GM property is never taken advantage of. So, for example, it would be an infringing use of GM canola if it is grown because the farmer knows that if the need to use Roundup arises, it can be safely used. Further, infringement can also occur where possession is for the purpose of some later commercial transaction.[456]

'Make'

It is not clear whether the reproduction of the GMO with another's organisms would be sufficient of itself for infringement. For example, where a GM animal inseminates another's conventional animal, has the third party 'made' the patented invention and

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[454] *Betts v Neilson* (1868) LR 3 Ch App 429.
[455] *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [84]. See also *McDonald v Graham* [1994] RPC 407 at 431.
[456] *British Motor Syndicate Ltd v John Taylor & Sons Ltd* (1900) 17 RPC 723 at 732 (Vaughan Williams LJ); *Pfizer Corporation v Ministry of Health* [1965] RPC 261 at 320 (Lord Wilberforce); *Morton-Norwich Products Inc v Intercen Ltd* [1976] FSR 513 at 525 (Graham J); *Hoffmann-La Roche & Co AG v Harris Pharmaceuticals Ltd* [1977] FSR 200 at 207.

therefore 'exploited' it? The organism is reproducing and expressing the modification. In *Schmeiser* Monsanto argued that planting and cultivating GM seed was 'making' the patented gene or cell.[457] The Canadian Supreme Court disagreed.[458] New patented cells had been created when new plants grew from the seed. Nevertheless, the Court observed without finally deciding the point that Schmeiser had not created or constructed the cells.[459]

The court will need to assess whether the human intervention involved is sufficient for there to be an infringing act. It is submitted that it is not. Unlike the commercialiser in the discussion on manner of manufacture, the invaded farmer has not taken any earlier steps, such as creating the GMO, which satisfied the requirement in the earlier discussion.

Additionally, it is not clear when infringement on the basis of 'making' would actually occur. For example, does it occur when the non-GM animal is inseminated by the GMO or when progeny possessing the GM are born? Infringement requires that the whole product be made and making is not complete until the final step is carried out which results in the complete infringing article.[460] It is possible therefore that only fertilisation is necessary.

4.3.7 *Conclusion with respect to Case Studies*

In principle, the case studies meet the requirements for patentability. The founder organism for each of the three case studies, and the products of such organisms, should be considered 'inventions' as required by the first part of s 18(1) *Patents Act* and 'manners of manufacture' for the purposes of s 18(1)(a). Of particular importance in this regard is that they will be capable of commercial application. That they are, or are derived from, living matter should not be an obstacle to these conclusions. Further, while it is true that the outcomes of GM are essentially derived from preexisting materials, they should be treated as combinations rather than mere collocations. The materials, or 'integers', interrelate with each other to produce a new result.

The most difficult issue, because of the lack of clear case law on the point, will be whether there has been sufficient human intervention involved in the production of GMOs and their products for the result to be considered a manner of manufacture rather than a mere discovery. It is timely that this issue be considered in light of the emergence of this issue

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[457] *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [25].
[458] *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [26].
[459] *Monsanto Canada Inc v Schmeiser* 2004 SCC 34 at [26]-[27].
[460] *Bedford Industries Rehabilitation Inc v Pinefair Pty Ltd* (1998) 40 IPR 438 at 449.

as an important one in the Canadian decisions referred to above. It is a significant issue, particularly as an objection on the basis that the patented 'invention' is not a manner of manufacture can be raised at all but the re-examination stage. It has been submitted that there is sufficient intervention. It seems that the Australian courts adopt a quantitative rather than qualitative approach to the issue. The intervention involved in creating the case studies and their products is more than the creation of artificial conditions for growth. It includes identifying, isolating and reproducing the relevant gene sequence and carrying out the modification. That the organism itself expresses the modified characteristic should not, on the basis of the limited Australian case law, be sufficient to deny that there has been the requisite degree of intervention for the organism or its products to be patentable.

The uniqueness of GMOs is also relevant to the related issue of whether GMOs are only discoveries rather than manners of manufacture because they are created from pre-existing natural components. It has been submitted that the fact human intervention is required to create the case studies means they are 'different' and are not merely discoveries. That their individual components may be able to be found in nature should not negate this.

The case studies, particularly the pig and canola which are destined for the food market, still face possible exclusion from patentable subject matter pursuant to s 50(1)(a). This requires that their use contravene other legislation, such as certain provisions of the *Food Act 1984* (Vic) or *GT Act*. However, it has been submitted that this is unlikely. They are also unlikely to be excluded pursuant to s 50(1)(b) of the *Patents Act* as being food or medicine that consists of a mere mixture of known ingredients. There is a real risk though that all of the case studies may be excluded from patentability pursuant to the general inconvenience exception arising from the reference to s 6 of the *Statute of Monopolies* in s 18(1)(a). GMOs' uniqueness and socio-economic concerns arising from their release are particularly relevant to this issue. It has been submitted that such exclusion is unjustified and, it would seem from the case law, unlikely. However, changes in public opinion mean that this could change in the future.

The unique characteristics of GMOs and their products are also relevant to novelty and inventiveness. The case studies are likely to be considered novel because it seems the degree of variation between existing and new matter need not be great. With respect to the differentness of GMOs and their products, it has been submitted that phenotypic rather than only genetic differences will usually be required to satisfy the novelty requirement. The degree of phenotypic difference required is not certain although it has been submitted

that if the organism is distinguishable from other known organisms, the result is novel. Additional uncertainty exists regarding the 'differentness' required in the degree to which an organism possesses a pre-existing but now improved property. It has been submitted that the required degree of phenotypic variation, or difference, is not great. That the GMO may not be different to an unknown 'natural' equivalent should also not deprive the GMO of novelty. However, where the natural equivalent is known, even though in the case of GM products it is sourced from a different organism, the organism or product will not be novel.

The most difficult requirement to satisfy will be that of inventiveness. As with novelty, determination of this requires a complete search of the prior art at the time of their creation. Assuming there were no similar organisms, the case studies are likely to have been inventive at the time of their creation. However, patentability will become more difficult for later GM outcomes as the techniques used become more commonplace even with the threshold described by the High Court in *Aktiebolaget*. An important difficulty, and one that arises again in Chapters 5 and 6, is that of measuring 'difference'. With respect to inventiveness it is unclear what quantitative superiority in properties is needed. It should be noted here that this is a question of fact.

Of the other patentability requirements, those of utility, sufficiency and that there be no false suggestion could result in the denial of patent protection for the case studies. However, it has been submitted that this is unlikely, particularly if sequence data is included in the specification.

If patent protection is obtained that protection will, in many respects, be superior to that obtained pursuant to other IP regimes. In particular, a patent in respect of the founder organism will cover progeny carrying the GM. If the patent claims products of the organism, products produced either by the GMO or its progeny will also be covered. Additionally, patent rights are not subject to a farmer's privilege exemption. Nevertheless the protection offered has limitations because of GMOs' unique characteristics. In particular, GMOs' ability to spread and reproduce without human intervention is a concern. Although the production of progeny or materials using a patented organism or product will prima facie be an infringement, many purchasers will have an implied licence to reproduce the organism or make the product unless expressly restricted at the time of purchase. Commercialisers' rights against non-purchasers who 'exploit' the patented GMO or product are also likely to be limited. Infringement does not require knowledge by

the alleged infringer that infringement is occurring. However, the mere possession of a patented organism or product is not in itself exploitation and therefore not infringement of a patent. Nevertheless, exploiting the invention through, for example, using or perhaps making the patented organism or product will be infringement. Therefore the contamination of a third party's land by a GMO and the organism's subsequent reproduction or other use by the third party may be infringement. This result is uncertain though because of the 'differentness' of GMOs from other inventions. GMOs may spread and reproduce without human intervention. It has been submitted that the self-reproducibility of GMOs means that the third party has not 'made' the patented invention for the purposes of infringement. Nevertheless there will still be infringement through use or keeping for use. It is unlikely though that a court would award a remedy where the defendant was unaware of the GMO's presence.

4.4 CONFIDENTIAL INFORMATION

The legal requirements for information to be protected as confidential information ('CI') are summarised in section 4.4.1.[461] The principles are then applied to information concerning GM outcomes. It will be shown that although such information can be protected as CI, such protection is unlikely to be of much practical value to commercialisers.

4.4.1 *Legal Requirements for Protection as Confidential Information*

(a) Basic principles

CI is essentially any information which is not public or common knowledge.[462] An obligation of confidence is most commonly imposed where a contractual relationship exists between the parties. However, the High Court has recognised that actions for breach of confidence enable parties to protect CI even if there is no contractual relationship.[463]

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[461] For a general account of the doctrine of CI, see R Dean, *The Law of Trade Secrets and Personal Secrets* (2nd ed, Law Book Company, Sydney, 2002).

[462] *Ansell Rubber Co Pty Ltd v Allied Rubber Industries Pty Ltd* [1967] VR 37.

[463] See, for eg, *Commonwealth v John Fairfax & Sons Ltd* (1980) 147 CLR 39; *Moorgate Tobacco Co. Ltd v Philip Morris Ltd [No 2]* (1984) 156 CLR 414; *Johns v Australian Securities Commission* (1993) 178 CLR 408. The source of the court's jurisdiction to protect CI is not certain. Nevertheless in the usual situation where an everyday product is sold to a consumer, bases such as breach of fiduciary duty of confidentiality and fidelity or breach of contract are unlikely to arise. Therefore breach of an equitable duty of confidence is the most relevant and will be the only one considered here.

Protection, subject to any relevant contract, is governed by the common law and equitable principles.[464]

To succeed in an action for breach of confidence the information must be clearly identifiable[465] and confidential. It must have been imparted in circumstances imposing an obligation of confidence where that obligation is reasonable. Finally, there must be an actual or contemplated unauthorised use or disclosure of the information.[466]

(b) *Franklin v Giddins*

Franklin v Giddins[467] (*'Franklin'*) is one of the few cases where rights in a genetically unique organism have been considered by the courts. It is also unusual for a second reason: there was no initial communication in confidence to a confidant who then made an unauthorised use of the information. The CI was obtained by the 'confidant' by unauthorised taking.

The plaintiff had developed[468] a nectarine tree which produced abundant fruit which ripened earlier than most other varieties. Although he sold the fruit, the plaintiff did not allow anyone cuttings of budwood. The defendant secretly took budwood from the plaintiff's orchard, eventually establishing an orchard of some six hundred trees from the stolen material. The Court ordered that all the trees be destroyed.

The Court said '[t]he "information" which the genetic structure of the wood represented was of substantial commercial value'. That value seems to have arisen because of the time and effort of the owner in developing it, the fact that it could not, at that time at least, be duplicated by anybody else and the great market demand for the fruit produced by the plant.[469] The Court held that the information in the plant's genetic sequence was CI which,

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[464] Pursuant to the TRIPS Agreement, Aust is obliged to protect confidential or undisclosed information against breach of confidence, breach of contract and other acts contrary to honest commercial practices. Aust must also protect undisclosed test and other data submitted to governments in order to obtain marketing approval for pharmaceutical or agricultural chemical products against unfair commercial use although such information may be disclosed where it is necessary to protect the public. See Aust, Dept of Foreign Affairs and Trade, *Uruguay Round Outcomes - Intellectual Property* (1994), p 9. See also A Stewart, 'Part II Protecting Trade Secrets under the TRIPS Agreement. How useful are these remedies for breach of confidence?' (1996) 9 *Australian Intellectual Property Law Bulletin* 25.

[465] *Corrs Pavey Whiting & Byrne v Collector of Customs (Vic)* (1987) 14 FCR 434 at 443.

[466] The requirements that the information be confidential, imparted in circumstances importing an obligation of confidence and that there be unauthorised use were summarised by Megary J in *Coco v AN Clark (Engineers) Ltd* [1969] RPC 41 at 47-8.

[467] [1978] Qd R 72.

[468] Modern techniques of GM were not used.

[469] [1978] Qd R 72 at 80.

whilst not property, was enforceable against third parties in an action for breach of confidence.

4.4.2 *Application to GMOs and their Products*

(a) Information concerning GMOs and their products

Information concerning GMOs or their materials could satisfy the requirements necessary for protection as CI. Although trivial information may not be protected[470] it seems unnecessary that the information has an established commercial value to be protected.[471] Therefore such information can be protected even before sales of the organism or product occur and the value of such articles demonstrated.

In the course of field trialling GM outcomes for market, there may be sale and/or disclosure to others besides the public. Provided this is done in circumstances where an obligation of confidence arises, such as under contractual arrangements to keep the information confidential, such sale or disclosure will not prevent protection being available. However, care needs to be taken that the group to whom the information is disclosed is not so large that the relative secrecy of the information is lost.[472] Further, the circumstances of a GMO spreading onto another's property is likely to be relevant to the court's assessment of whether the commercialiser intended the information with respect to the GMO to be confidential and also whether the information retained its quality of confidence.

Once GMOs or their material, containing the relevant GM, are sold to the public it is arguable that the GM has entered the public domain and its confidential nature lost.[473] It is submitted that although the genetic sequence responsible for the modification is in the public domain, the modification is still not publicly known. This is supported by the decision in *Franklin* where the fruit had been sold to the public but the information in its genetic sequence was still protected.

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[470] See, for eg, *McNicol v Sportsman's Book Stores* [1930] Mac G CC 116; *Coco v AN Clark (Engineers) Ltd* [1969] RPC 41 at 48; *Attorney-General (UK) v Guardian Newspapers Ltd (No 2)* [1990] 1 AC 109; *Coulthard v State of South Australia* (1995) 63 SASR 531 at 547.

[471] *Argyll v Argyll* [1967] Ch 302 at 329. See also A Stewart, 'Part II. Protecting Trade Secrets under the TRIPS Agreement. How useful are these remedies for breach of confidence?' (1996) 9 *Australian Intellectual Property Law Bulletin* 25, 26.

[472] See *Interfirm Comparison (Australia) Pty Ltd v Law Society of NSW* (1975) 5 ALR 527 at 541-3; *Stephens v Avery* [1988] 2 WLR 1280 at 1285. In determining what size the group can be before this occurs, the competitive nature of the industry would be taken into account. See R Dean, *The Law of Trade Secrets and Personal Secrets* (2nd ed, Law Book Company, Sydney, 2002), p 84.

[473] *Johns v Australian Securities Commission* (1993) 178 CLR 408.

Case law establishes that if work is required to deduce CI from the product made available to the public, the information does not necessarily lose its confidential nature even where it is released to the public.[474] Therefore, a confidant who possesses CI is not necessarily released from their obligation of confidentiality merely because the confider has released the product into the public domain. Pursuant to a rule known as the springboard doctrine, the confidant is not allowed to use the information they obtained in confidence as a springboard for activities detrimental to the confider[475] until a person without the benefit of the CI could ascertain and use the CI from the information released to the public, except as permitted by the confider.

In the case of GMOs and their products sold to the public, work would still be required to deduce the particular GM from the available genetic material. That work is unlikely to be equal to the original effort in initially creating the modification. However, it is likely to be significant. Therefore secrecy with respect to the GM should not be lost simply by virtue of sales to the public.[476] Nevertheless, protection will continue only for as long as it takes a competitor to reverse engineer the invention using, for example, nucleic acid and protein sequencing.[477]

The co-existence of natural, known or unknown, or other GM equivalents to the GMO will not necessarily destroy secrecy. Prior use or existence is only relevant if it has caused the commercialiser's information to enter the public domain.[478]

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[474] *Saltman Engineering Co. Ld v Campbell Engineering Co Ld* (1948) 65 RPC 203; *Terrapin Ld v Builders' Supply Co (Hayes) Ld* [1960] RPC 128; *Ackroyds (London) Ltd v Islington Plastics Ltd* [1962] RPC 97; *Ansell Rubber Co Pty Ltd v Allied Rubber Industries Pty Ltd* [1967] VR 37 at 45; *Potters-Ballotini Ltd v Weston-Baker* [1977] RPC 202; *Harvey Tiling Co (Pty) Ltd v Rodomac (Pty) Ltd* [1977] RPC 399 (Sup Ct of Sth Africa); *Half Court Tennis Pty Ltd v Seymour* (1980) 53 FLR 240; *British Franco Electric Pty Ltd v Dowling Plastics Pty Ltd* [1981] 1 NSWLR 448; *Mainbridge Industries Pty Ltd v Whitewood* (1984) 73 FLR 117.

[475] *Terrapin Ltd v Builders' Supply Co (Hayes) Ltd* [1967] RPC 375 at 391-2.

[476] N Peace and A Christie, 'Intellectual Property Protection for the Products of Animal Breeding' [1996] *European Intellectual Property Review* 213.

[477] Casey and Moss draw a distinction between non-informing public use of an invention where competitors can reverse engineer the new product starting from the commercialiser's product (the invention can be protected as CI until then) and secret use where the product can be sold without disclosing that the invention exists. W L Casey and L S Moss, 'Intellectual Property Rights and Biotechnology' (1986) 27 *IDEA* 251. Depending upon the labelling requirements and marketing strategy adopted (for eg, the product may be marketed on the basis that there is some improvement due to the GM) secret use may not be possible with respect to GMOs and their products.

[478] See R Dean, *The Law of Trade Secrets and Personal Secrets* (2nd ed, Law Book Company, Sydney, 2002), p 20.

(b) Practical value of protection as confidential information

GMOs and their products will often be released to the environment during trialling. Once the public has one of the organisms or, in some instances, a product of the organism, replication of the organism or product will often be possible using common methods of reproduction and propagation. It will not be necessary to know or replicate the CI behind its creation.

Such replication is unlikely to be a breach of confidence. Unlike the facts in *Franklin*, purchasers would be replicating from material which was legitimately acquired. If the defendant in *Franklin* had created his orchard using, for example, the fruit sold by the plaintiff, it is unlikely there would have been a breach of confidence.[479] Nor will protection of CI prevent independent creation of the same organism or material. Where a GMO has spread to another's property, it is also unlikely to be a breach of confidence for the 'invaded' party to replicate the organism or product.

An action for breach of confidence is therefore of very limited value to commercialisers.[480] Such an action will only be successful in protecting the information concerning the organism or material from unauthorised disclosure or misappropriation for a significant period in two limited circumstances: where the organism is a non self-replicating one[481] or where the organism or material can be exploited without actually releasing the genetic material to the public. In other circumstances, even in the light of the springboard doctrine, once the GM outcome is released, protection as CI will be, or will quickly become, unavailable. Even where an action is possible, there are a number of defences which may be relevant. These include disclosure where there was a 'just cause or excuse'.[482] It may be, for example, that a commercialiser is not correctly labelling their products as GM. A confidant would perhaps have a defence to an action brought with respect to the disclosure of that fact including, perhaps, how the modification was made on

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[479] See *Crowder v Hilton* [1902] SALR 82; *The Exchange Telegraph Co (Ltd) v Howard* (1906) 22 TLR 375; *Ashburton v Pape* [1913] 2 Ch 469; *Commonwealth v John Fairfax & Sons Ltd* (1980) 147 CLR 39; *Francome v Mirror Group Newspapers Ltd* [1984] 2 All ER 408; *Johns v Australian Securities Commission* (1993) 178 CLR 408; *Minister for Mineral Resources v Newcastle Newspapers Pty Ltd* (1997) 40 IPR 403 regarding the improper acquisition of CI.

[480] Protection as CI has the advantage that it is free and is potentially perpetual. See ALRC Discussion Paper 68, [29.65]-[29.78] with respect to the advantages and disadvantages in using CI as a form of IP protection.

[481] Alternatively, it may replicate but its progeny may not be as attractive as the parent. For eg. seed from first generation progeny of crosses between two different inbred varieties of certain plants, such as corn, do not produce plants as vigorous as the plants which produced the seed. N J Seay, 'Protecting the Seeds of Innovation: Patenting Plants' (1988-89) 16 *AIPLA Quarterly Journal* 418, 425-6.

[482] *Fraser v Evans* [1969] 1 QB 349 at 362.

such a basis. However, it is submitted that concern that the GMO may have adverse socio-economic repercussions for some members of society would not be sufficient for this defence.

4.5 CONCLUSION

IP protection offered to commercialisers of GMOs and their products in Australia is not as extensive as is often claimed. The unique traits of GMOs: that they are living, can move and reproduce without human assistance and that there may be equivalents in the wild, limit the availability and the usefulness of such protection. Protection under PBR legislation or as CI will almost certainly be available. Social and economic concerns regarding the GMO or its products will not generally affect that protection. Nevertheless, the scope of protection offered by these regimes is limited. PBR protection is available only to certain organisms, most particularly only to plants. It is also subject to certain exemptions. Most importantly, the saving of seed by farmers for later planting from GMOs or plants contaminated by GMOs may not be an infringement. Protection as CI is also of limited value to commercialisers. Once release occurs, protection will quickly become unavailable.

The availability of patent protection is not certain. Possible problems arise with respect to nearly every requirement for patentability. Even assuming that all the submissions made during the discussion of this topic are accepted, the requirement of inventiveness is likely to prevent many patents for GMOs and their products. For those patents that are secured, there are uncertainties as to the scope of protection given to patentees because of GMOs' unique traits.

The exploitation of any IP rights by commercialisers will also be subject to the IP rights of others[483] and laws with respect to the use of GMOs and their products. It has been submitted that the IP regime is not the appropriate place to impose conditions on the use of

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[483] It is assumed commercialisers will have obtained all relevant IP licences to enable them to commercialise the GMO or its products. With respect to problems arising because of pre-existing patents see M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698; D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347; Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices. Evidence and Policies* (OECD, France, 2002); ALRC Discussion Paper 68.

patents[484] to address social and economic impacts arising from GMO releases.[485] Whether the courts can and will react to such impacts in another legal regime, that of torts, and how they will react to the unique traits of GMOs is considered in the next Chapter.

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[484] A submission also made in D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 372.

[485] Dutfield has concluded that there can be little or no expectation that IP rights can balance the interests of IP owners and other stakeholders while optimally inducing welfare-enhancing innovation. G Dutfield, *Intellectual Property Rights in the Life Science Industries. A Twentieth Century History* (Ashgate Publishing Limited, England, 2003), p 245.

CHAPTER 5

TORT LIABILITY FOR GMO RELEASES

5.1 INTRODUCTION

This Chapter examines commercialisers' liability in tort for the socio-economic impacts of GMO releases described in Chapter 1. In particular, it considers whether such liability arises despite the commercialiser complying with the *GT Act* and relevant State legislation. For example, would the contamination of an organic crop be a private nuisance? Will releasing a GMO with GTR approval be negligent? It also considers the significance to tort actions of the failure of the GTR to consider socio-economic consequences in making licensing decisions under the *GT Act* and of the recent introduction of State laws intended to protect non-GM agriculture.

Neither the *GT Act* nor the State moratorium legislation gives immunity to commercialisers who comply with the legislation but nevertheless cause harm to others. The Commonwealth Parliament intended that questions of liability for harm arising from GMO releases be determined by common law principles rather than compliance with the legislation.[1] The State moratorium legislation also does not purport to replace the common law although, as we have seen, in some States compensation is available under that legislation. Environmental legislation discussed in Chapter 6, also specifically preserves individual's common law rights to damages.[2]

The principal function of torts is to compensate 'worthy' harms.[3] What is 'worthy' for these purposes changes with changing social values.[4] But it is determined by two factors: the interest of the plaintiff that has been invaded and the nature of the conduct by which the invasion took place (that is, whether it was intentional, negligent or accidental).[5] Of

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[1] Interim Office of the Gene Technology Regulator, Submission No 77 to the Senate Committee on Community Affairs for its report on the Gene Technology Bill 2000 (Cth) (Canberra, October 2000), p 146; See also Aust, Senate Committee on Community Affairs, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report on the Gene Technology Bill 2000* (November 2000) Tabled 1/11/00 PP No 263/00 ('*Cautionary Tale* Report'), pp 151-2; Aust, House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution. Primary Producer Access to Gene Technology* (Canberra, June 2000), [7.108].

[2] See *Environment Protection and Biodiversity Protection Act 1999* (Cth) s 501; *Environment Protection Act 1970* (Vic) s 65(1).

[3] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 9.

[4] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 9.

[5] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 9.

particular interest to commercialisers is whether impacts caused by GMOs are worthy of compensation in tort. The unique qualities of GMOs and the regulatory environment under which they are released add to the uncertainty in predicting liability in tort.

There have been no reported Australian decisions regarding liability following a GMO release into the environment. There is also surprisingly little Australian case law with respect to the analogous situation of the spread of conventional organisms from one property to another.[6] The scant case law regarding agricultural contamination generally may suggest there is no strong need for a private legal remedy even in the case of GM contamination. However, the consequences that can follow GMO releases and the increasing use of diverse farming practices, such as organic agriculture, as marketing tools justify reappraisal. Improvements in methods of detection of contamination further justify an examination of the area.[7] Some have asserted that farmers should be able to cultivate the crops they choose, be it GM, conventional or organic.[8] However, GMO releases may affect the real value of that choice. Whether the choice of non-GM agriculture will be treated preferentially by the common law is an uncertainty further justifying examination.

To contain the study within manageable limits only two of the most commonly used torts are examined. These examples illustrate the legal concerns arising for commercialisers selecting GMOs for commercialisation in Australia. The torts studied are those of private nuisance[9] and negligence.[10] To some extent the circumstances in which causes of action in

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[6] Parliament intended that liability with respect to GM contamination be consistent with how contamination is dealt with in other areas. Aust, Dept of Agriculture, Fisheries and Forestry - Australia, *Liability Issues Associated with GM Crops in Australia* by Science and Economic Policy Branch, Scoping study (September 2003), p 5 citing *Cautionary Tale* Report, pp 140 and 146.

[7] '[G]enetic modification per se does not change the frequency with which admixture of genetic material occurs. It is the substantially increased power of detection of modern molecular biological techniques that permits very low levels of genetic mixing to be discovered. It represents the level of mixing that has existed and still exists in current non-GM seed and food production chains. This level was considered to be well within accepted and acceptable limits.' A J Conner et al, 'The release of genetically modified crops into the environment. Part II. Overview of ecological risk assessment' (2003) 33 *The Plant Journal* 19, 36.

[8] European Commission, *Communication on co-existence of genetically modified, conventional and organic crops*, (2003) (not seen) quoted in G Brookes, *Co-existence of GM and non GM crops: economic and market perspectives* (2003) (http://www.monsanto.co.uk/news/ukshowlib.phtml?uid=7282 accessed 15/7/03), p 1. Cf, for eg, N D Hamilton, 'Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms' (2001) 6 *Drake Journal of Agricultural Law* 81, 109. The Australian National Farmers Federation's policy is also to allow farmers to adopt the method of farming best suited to their business. T Anderson, 'GM Crops: a bandwagon worth missing?' (2002) 17 *Australian Environment Review* 13, 13.

[9] In *R v Secretary of State for Environment and MAFF, ex parte Watson* [1998] EWCA Civ 1250 (21 July 1998) Buxton LJ suggested in dicta that a claim in respect of GM contamination 'sounds like one in private nuisance'.

[10] There is also a possibility of an action in trespass. It is assumed by this study that commercialisers will not intentionally hurt others by, for eg, knowingly planting at a distance virtually certain to cause commingling damage to the neighbour's crop. Therefore there will not be an intentional direct interference with another's land as required for trespass. Presumably such acts would also be contrary to the GTK's approval. The

nuisance and negligence are available are identical.[11] Commercialisers may therefore be liable in both torts for the same act.[12] Nevertheless the different scopes of the torts make it worthwhile examining both torts.[13]

The study does not use an economic efficiency approach to its analysis of commercialisers' liability. Such an approach is sometimes advanced as a method of predicting or explaining the outcome of new questions in tort law.[14] However, it has attracted little Australian judicial interest.[15] Rather this study will use an analysis of precedent to illustrate the uncertainties facing commercialisers and predict the outcome of torts claims against them.

Part 5.2 of this Chapter examines potential liability in private nuisance for the impacts described in Chapter 1. Part 5.3 considers liability in negligence in those circumstances. Conclusions are brought together in Part 5.4. It will be submitted that the most significant uncertainty for commercialisers is how such impacts will be classified for the purposes of each tort. It will also be submitted that differences in considerations relevant to the GTR when making licensing decisions and to courts in torts proceedings, and the lack of clarity in relevant considerations under the State moratorium legislation, add uncertainty in predicting tort liability.

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possibility exists in Aust of negligently trespassing on another's property or goods. See *Williams v Milotin* (1957) 97 CLR 465. In that case, many of the same issues may arise as are considered here with respect to the tort of negligence. Trespass is not considered further in this study. See further D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 145-6.

[11] The tort of public nuisance may also be relevant to commercialisers. It shares many similarities with private nuisance but, amongst other things, the standing requirements are significantly different. An action in private nuisance is more likely where a GMO or part of it enters a neighbouring property because of the difficulties of proving standing in public nuisance. Many complaints on behalf of the public good, such as claims that the GMO release could have a detrimental effect on biodiversity, do not give rise to an actionable public nuisance because the plaintiff would be unlikely to suffer greater injury in such a case than anyone else. The tort is not considered further in this study.

[12] *Miller v Jackson* [1977] 1 QB 966.

[13] In the past there was a special regime imposing strict liability for the escape of dangerous things, perhaps such as a GMO, from the defendant's land which injured someone where the defendant had occupation or control of the land. This was known as the 'rule in *Rylands v Fletcher*'. That regime has now been subsumed into the law of negligence in Aust and will not be considered any further in this study. See *Burnie Port Authority v General Jones Pty Ltd* (1994) 179 CLR 520.

[14] Two well known egs are W Landes and R Posner, *The Economic Structure of Tort Law* (Harvard University Press, Massachusetts, 1987); R Posner, *Economic Analysis of Law* (5th ed, Aspen Law & Business, New York, 1998).

[15] J Stapleton, 'Comparative Economic Loss: Lessons From Case-Law-Focused "Middle Theory"' (2002) 50 *University of California Los Angeles Law Review* 531, 533. See also R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 16 noting that such interest is only 'occasional'.

5.2 PRIVATE NUISANCE

5.2.1 *Legal Requirements for Actions in Private Nuisance*

Private nuisance has been defined as 'unlawful interference with a person's use or enjoyment of land, or of some right over, or in connection with it'.[16] The required title to sue is an interest in the land affected.[17] What that interest must be is not entirely settled but possession or a right to possession of the land being interfered with seems sufficient.[18] If the defendant's activity is found to be a nuisance, they will be liable for it if they bear 'some degree of personal responsibility'.[19]

'The forms which nuisance may take are protean'.[20] In all cases, though, there must be an interference with the plaintiff's interest in land and that interference must be substantial and unreasonable. Only some interests in land are recognised as being protected by the tort of nuisance.[21] Other interests are not protected by nuisance even though interference with them could cause devaluation in land value or other harm to the plaintiff.[22] What interests are protected has been described as a political question, largely in the courts' discretion.[23] Trindade and Cane conclude with respect to the interests that are or are not protected by nuisance that the pattern does not seem to be based on any set principles but is simply the result of *ad hoc* value judgments.[24] In any case, material damage to the land is clearly an

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[16] T E Lewis, *Winfield on Tort. Textbook of the Law of Tort* (6th ed, Sweet & Maxwell Ltd, London, 1954), p 536 quoted with approval in, inter alia, *Gartner v Kidman* (1962) 108 CLR 12 at 22 (Windeyer J) and *Hargrave v Goldman* (1963) 110 CLR 40 at 59 (Windeyer J).

[17] *Oldham v Lawson (No 1)* [1976] VR 654; *Tate & Lyle Industries Ltd v Greater London Council* [1983] 2 AC 509 (HL).

[18] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), pp 490-1. See also F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), pp 636-7; C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), pp 16-13–16-14; M Davies and I Malkin, *Torts* (4th ed, LexisNexis Butterworths, Sydney, 2003), pp 333-4.

[19] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 492 quoting *Sedleigh-Denfield v O'Callaghan* [1940] AC 880 at 897 (Lord Atkin) (HL).

[20] *Sedleigh-Denfield v O'Callaghan* [1940] AC 880 at 903 (Lord Wright) (HL). As Viscount Maugham (at 888) notes, nuisance can refer to damage resulting from many different things such as 'water, smoke, fumes, gas, noise, heat, electricity, disease-germs, trees, *vegetation, and animals*, as well as in other matters....In my opinion the legal duty of the owner of land towards an adjoining owner may be very different in some of these cases, and may depend on very different considerations.' (Emphasis added.)

[21] As to what is an interest in land, see *Mayor of Bradford v Pickles* [1895] AC 587 (HL). See also *Phipps v Pears* [1965] 1 QB 76 (CA); *Langbrook Properties, Ltd v Surrey County Council* [1969] 3 All ER 1424; *Elston v Dore* (1982) 149 CLR 480. In both *Phipps* and *Langbrook* damage to plaintiffs' property was not remediable because no protected rights were infringed.

[22] For eg, as discussed in section 5.2.3, an attractive view is not an interest protected by nuisance even though the blocking of such a view can have significant repercussions on the land value.

[23] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 534.

[24] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 636.

interference with an interest in land for these purposes.[25] Some interferences with the plaintiff's use or enjoyment of their land are also sufficient.[26] The categories of protected use and enjoyment have been said to be expanding in response to changes in prevailing community attitudes towards the usage and enjoyment of land.[27]

The second element that must be proven by the plaintiff is that the interference with the protected interest was unlawful; that is, substantial and unreasonable. Causing material damage to the plaintiff's property[28] will be a substantial and unreasonable interference unless the defendant can prove that their use of land was reasonable in the circumstances.[29] Where there is no material damage, the court considers a number of factors to determine whether there has been such an interference with the use and enjoyment of land as to be a nuisance. Factors include the nature of the defendant's conduct, compliance with relevant legislation, the plaintiff's sensibilities, the locality in which the interference occurred, precautions taken by the defendant against interference, the frequency, duration and time of the interference and the defendant's motive.

5.2.2 *Application to GMOs*

Standing to sue and establishing legal responsibility for the nuisance are unlikely to pose unique problems in cases involving GMOs. Neighbours of commercialisers, whether landowners or tenants, could be expected to have sufficient interest in the land affected to have standing to sue because of their possession of the land except where a claim is based only on fear of harm to agriculture generally. In the latter case, there will be no standing to sue. Individuals with no interest in the land affected would also not have standing to sue.[30]

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[25] It could be asserted that material damage is not a different kind of interference to interferences with the use or enjoyment of land. Rather it is a question of substantiality, material damage being the most substantial interference.

[26] Nuisance can also result if there is an interference with a property right of the plaintiff such as the right to light through defined channels or the right of support of land in its natural state. Such rights are not relevant to this study.

[27] J S Gillespie, *Private Nuisance as a Means of Protecting Views Enjoyed By an Occupier of Land From Obstruction* (Master of Laws thesis, Monash University, 1984), p 65. For eg, see *Nor-Video Services Ltd v Ontario Hydro* [1978] 84 DLR (3d) 221 at 232. Cf *Bridlington Relay Ltd v Yorkshire Electricity Board* [1965] Ch 436 at 447. See also *Hunter v Canary Wharf Ltd* [1997] AC 655 (HL).

[28] The meaning of property for these purposes is discussed in section 5.2.3(b) below.

[29] *Kraemers v Her Majesty's Attorney-General for the State of Tasmania* [1966] Tas SR 113 (where defence failed on the facts but the Court said there was such a defence and the burden of proof was on the defendant). See also *Cambridge Water Company v Eastern Counties Leather plc* [1994] 2 AC 264 at 299 (HL); *Corbett v Pallas* (1995) Aust Torts Reps 81-329 at 62,241 (NSW CA).

[30] For eg, if the plaintiff is growing a crop on the affected land only as a contractual licensee pursuant to a commercial arrangement. The licensor would need to bring the proceedings in such a case. C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 525. See also *Malone v Laskey* [1907] 2 KB 141; *Oldham v Lawson (No 1)* [1976] VR 654.

If there has been a nuisance, the commercialiser who released the organism would be responsible subject to any available defences.[31]

The following sections, 5.2.3 and 5.2.4, discuss the two elements of the tort that raise particular difficulties for nuisance actions arising following GMO releases. Section 5.2.3 considers whether any or all of the consequences following GMO releases are interferences with an interest in land for the purposes of the tort. Whether the interference is substantial and unreasonable is then examined in section 5.2.4. Defences are discussed in section 5.2.5. Remedies available to plaintiffs are described in section 5.2.6. Conclusions with respect to liability in nuisance are suggested in the final section, section 5.2.7.

5.2.3 *Interference with an Interest in Property*

The first element of private nuisance requires the plaintiff to show that the defendant has interfered with a use or enjoyment of land or other property right protected by nuisance. The essence of the wrong, according to Dixon J in *Victoria Park Racing and Recreation Grounds Co Ltd v Taylor* ('*Victoria Park*'), is the detraction from the occupier's enjoyment of natural rights belonging to the occupation of land.[32] As noted above, not every use and enjoyment that is of benefit to the occupier is protected. For example, as discussed in subsection (b) below, the High Court has held that interference with the plaintiff's business is insufficient in itself to constitute the tort.[33] It is difficult to predict whether a particular fact situation is a type of interference that will be compensated by the tort because, as Baker notes, cases turn to some extent on the degree as well as the nature of the interference suffered by the plaintiff.[34] Nevertheless, to properly consider common law liability in nuisance arising from GMO releases it is necessary to address this matter.

In this section whether the harms described in Chapter 1 are interferences with an interest protected by nuisance is considered. The issues of substantiality and unreasonableness of any interference are discussed in section 5.2.4.

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[31] There is no requirement that the thing that is the nuisance come from the defendant's land. *Southport Corporation v Esso Petroleum Co Ltd* [1953] 2 All ER 1204 at 1207-8, affd [1956] AC 218; *Halsey v Esso Petroleum Co, Ltd* [1961] 2 All ER 145 at 158; *Hargrave v Goldman* (1963) 110 CLR 40 at 60; *Fennell v Robson Excavations Pty Ltd* [1977] 2 NSWLR 486. The person who creates or has assisted in the creation of the nuisance is liable whether or not they are the owner or occupier of the premises from which it emanates and even if they lack the power to abate the nuisance. *Thompson v Gibson* (1841) 7 M & W 456; 151 ER 845; *Kraemers v Her Majesty's Attorney-General for the State of Tasmania* [1966] Tas SR 113 at 118 and 153; *Fennell v Robson Excavations Pty Ltd* [1977] 2 NSWLR 486; *Attorney-General v Whangarei City Council* [1987] 2 NZLR 150; *Pantalone v Alaouie* (1989) 18 NSWLR 119 at 129-30.

[32] *Victoria Park* (1937) 58 CLR 479 at 507.

[33] *Victoria Park* (1937) 58 CLR 479.

[34] C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-4.

(a) Social impacts

GM opponents may consider a field of blue carnations unnatural and distressing. However, freedom from looking at unsightly things on neighbouring properties is not an interest protected by nuisance. The common law also does not recognise the right to prospect nor protect a decent view.[35] Accordingly, claims that seeing GMOs on the commercialiser's land causes distress are unlikely to be successful in nuisance.

However, unsightliness coupled with other factors, such as offensiveness or immoral behaviour, may be a nuisance.[36] Even mere knowledge of offensive behaviour may be sufficient.[37] In these cases the plaintiff's use or enjoyment of their land is interfered with for the purposes of nuisance.[38] Interlocutory injunctions have been granted in nuisance to prevent defendants using premises in offensive ways.[39] For example, a sex shop near the plaintiffs' houses, where the nature of the business was apparent, was held to be such an affront to the reasonable susceptibilities of ordinary people that it was a nuisance.[40] Similarly, the sight of prostitutes coming and going to the defendant's premises which were used as a brothel was a nuisance to residents adjoining or near to the brothel.[41] That the character of the relevant locality could be changed for the worse if the defendant's use was allowed to continue was noted as relevant in those cases.[42]

GM opponents may claim that GMOs are offensive and immoral. In some circumstances, allowing releases to occur in a particular locality could also change the nature of the locality. For example, it may cause the locality to lose its' GM-free status. By analogy with the above decisions, a claim of distress based on the knowledge or sight of the GMO release may be found to be an interference with the use or enjoyment of land protected by nuisance.

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[35] *Gartner v Kidman* (1962) 108 CLR 12 at 46; *Bathurst City Council v Saban [No 2]* (1986) 58 LGRA 201 at 206. See also *Aldred's Case* (1610) 9 Co Rep 57b; 77 ER 816; *Phipps v Pears* [1965] 1 QB 76 at 83 (obiter); [1964] 2 All ER 35 (CA); *Day v Pinglen Pty Ltd* (1981) 34 ALR 545 at 552. See also *Bathurst City Council v Saban [No 2]* (1986) 58 LGRA 201 at 206.

[36] *Bathurst City Council v Saban [No 2]* (1986) 58 LGRA 201 at 206. See also *Elwood v Pioneer Concrete (WA) Pty Ltd* [2002] WASC 32 (Unreported, Master Sanderson, 7 March 2002).

[37] See *Laws v Florinplace Ltd* [1981] 1 All ER 659. Knowledge of a GMO release may also cause the plaintiff to take precautions against contamination. This is considered in subsection (b) below.

[38] *Laws v Florinplace Ltd* [1981] 1 All ER 659; *Bathurst City Council v Saban [No 2]* (1986) 58 LGRA 201 at 207.

[39] *Thompson-Schwab v Costaki* [1956] 1 All ER 652; *Laws v Florinplace Ltd* [1981] 1 All ER 659; *Bathurst City Council v Saban [No 2]* (1986) 58 LGRA 201. See also *Kent v Cavanagh* (1973) 1 ACTR 43 at 52-3.

[40] *Laws v Florinplace Ltd* [1981] 1 All ER 659 at 667.

[41] *Thompson-Schwab v Costaki* [1956] 1 All ER 652.

[42] *Thompson-Schwab v Costaki* [1956] 1 All ER 652 at 655; *Laws v Florinplace Ltd* [1981] 1 All ER 659 at 667.

There is no clear authority supporting a finding of nuisance in such cases. Whilst some GM opponents may consider the technology to be immoral by, for example, interfering with the ability of farmers to undertake non-GM agriculture, it is unlikely that general community standards place it in the same class as prostitution or sex shops. It is even less likely a court would agree that GMO releases are capable of corrupting or depraving ordinary members of the public as pornography sold in sex shops was found to be.[43] Further, in assessing what is offensive the locality where the release occurred is relevant. Licenses under the *GT Act* can specify the localities in which releases may, or may not, occur. States may also designate areas as GM-free. Some local governments have also adopted GM-free policies.[44] As commentators have noted '[s]uch bans are not recognised or enforceable under the current regulatory regime'.[45] That does not, however, mean such 'bans' are irrelevant in common law proceedings against commercialisers following a GMO release. Compliance with relevant legislation means the release is 'legal'. However, the defendant in one of the cases referred to above was also acting legally.[46] A plaintiff's claim may therefore succeed even if the release is GTR licensed and permitted under State law. Nevertheless, it is submitted that courts should be reluctant to interfere in such cases, particularly as there will be genuine conflicts of opinion as to whether such releases are offensive.[47] GM agriculture is a legitimate form of agriculture in the same way, for example, that there are different types of egg production farms. Some members of the community are opposed to battery farming and may claim such farms are offensive and distressful. Indeed, taken to one extreme vegetarians living near a field of steers could make the same claim. Such farming though is unlikely to be a nuisance.

If a court rejects the above submission and instead finds that distress caused by a commercialiser's activities is an interference with the use or enjoyment of land for the

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[43] *Laws v Florinplace Ltd* [1981] 1 All ER 659 at 668.
[44] M Hain et al, 'Regulating Biosciences: the Gene Technology Act 2000' (2002) 19 *Environmental and Planning Law Journal* 163, 175; Comment, 'GE free zones not easy to establish' (2002) 1 *Biotechnology Law and Policy Reporter* 80, 80. With respect to legality of council GM controls see also Tas, Parliamentary Joint Select Committee, *Report on Gene Technology* (2001), p 61.
[45] M Hain et al, 'Regulating Biosciences: the Gene Technology Act 2000' (2002) 19 *Environmental and Planning Law Journal* 163, 175.
[46] *Thompson-Schwab v Costaki* [1956] 1 All ER 652. The defendant in *Laws v Florinplace Ltd* did not have required planning permission but this factor was not emphasised in the judgment. See *Laws v Florinplace Ltd* [1981] 1 All ER 659 at 662. The defendant in *Bathurst City Council v Saban [No 2]* was also acting contrary to planning laws and that was significant in the way the proceedings proceeded rather than whether there was a nuisance. *Bathurst City Council v Saban [No 2]* (1986) 58 LGRA 201.
[47] See, for eg, *Kent v Cavanagh* (1973) 1 ACTR 43 at 53 (conflict regarding whether a tower was aesthetically unsightly or not).

purposes of nuisance, the next issue is whether that interference is substantial and unreasonable and therefore unlawful. That issue is taken up in section 5.2.4 below.

Rather than claiming to be distressed because the plaintiff is socially opposed to GMOs, a plaintiff may claim distress because of fear of harm that may be caused to them, their family, property (both land and organisms raised on it) or their business by the GMO release.[48] There is Canadian case law supporting this type of claim with respect to fear of harm to people and other organisms on the plaintiff's land. In *Newman v Conair Aviation Ltd*[49] ('*Newman*') the British Columbia Supreme Court held that it was a nuisance to spray an insecticide which, drifting over the property line, frightens and distresses a neighbour although it caused no actual property damage. In that case the insecticide spread to the plaintiffs' property. Further, and more importantly, the plaintiffs were not warned of the impending noise of the spray plane or advised of the harmlessness of the spray.[50] The Court said it was reasonable in those circumstances for the plaintiffs to fear that the spray was dangerous to their health and that of their animals and plants.[51]

The Court in *Newman* was willing to assume there had been an interference with the use or enjoyment of land for the purposes of nuisance. The deciding issue was the reasonableness of the interference rather than whether a property interest had been interfered with. This matter is addressed in section 5.2.4 below.

The Court in *Newman* did not consider whether claims of distress caused by fear of harm to their business constitute nuisance. In particular, the Court did not consider whether such fear is an interference with a relevant interest in nuisance. Given the decision of *Victoria Park* described in subsection (b) below, it is submitted that fear of economic consequences of GMO releases is insufficient by itself to establish an interference with the use or enjoyment of land for the purposes of nuisance in Australia. A finding otherwise is more worrying for commercialisers than a finding that fears regarding health and safety is such an interference. As discussed in section 5.2.4 below, a court must find in all cases that the plaintiff's fears are reasonable for an action in nuisance to succeed. However, such a finding seems less likely where there has been GTR or other regulatory approval of the release. Fears regarding the economic consequences of GMO releases are not, as

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[48] See, for eg, *Everett v Paschall* 61 Wash 47; 111 P 879 (1910) (neighbours' fear of a tuberculosis sanatorium considered to be a disturbance of their 'comfortable enjoyment' of land even if that fear was not scientifically justified).
[49] (1972) 33 DLR (3d) 474 (BCSC).
[50] (1972) 33 DLR (3d) 474 at 478 (BCSC).
[51] (1972) 33 DLR (3d) 474 at 477 (BCSC).

discussed in Chapter 2, addressed by the GTR. This may make it more difficult for commercialisers to assert that GTR approval of a release makes the plaintiff's fears unreasonable. However, the introduction of State moratorium legislation may also be relevant. Reasonableness is taken up in section 5.2.4.

(b) Economic impacts

Where there has been physical or genetic contamination of the plaintiff's property, the plaintiff may claim there has been material damage to their property. If the court agrees, commercialisers will prima facie be liable in nuisance unless they can prove that the GMO release was reasonable in all the circumstances.[52] The suitability of the locality where the alleged nuisance occurs is irrelevant in material damage cases.[53] Therefore whether a GMO release was in or out of a GM-free area will not, of itself, be relevant. To show material damage the plaintiff must show damage to property, that the damage was significant rather than trifling and that the damage caused a diminution of value of the property. These matters are discussed in turn below.

Damage to property

Property in nuisance means land, buildings, vegetation, crops attached to land and, maybe, chattels on the land.[54] Therefore damage to the plaintiff's crops by an invading GMO will be sufficient. Further, if damage to chattels on the land is sufficient to establish damage to property, contamination of the plaintiff's livestock whilst on the plaintiff's land will also be sufficient.[55] Whether or not damage to chattels is sufficient in itself will only be significant in cases where, for example, the plaintiff's livestock has been contaminated but there has been no contamination of the plaintiff's land itself. This may occur, for example, where a GM animal escapes onto the plaintiff's land and impregnates the plaintiff's

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[52] *Kraemers v Attorney-General (Tas)* [1966] Tas SR 113 at 122-3; *Cambridge Water Company v Eastern Counties Leather plc* [1994] 2 AC 264 at 299 (HL); *Corbett v Pallas* (1995) Aust Torts Reps 81-329 at 62,241 (NSW CA).

[53] *St Helen's Smelting Co v Tipping* (1865) 11 HLC 642. But see R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), pp 476-7.

[54] H Luntz and D Hambly, *Torts: Cases and Commentary* (4th ed, Butterworths, Aust, 1995), [14.1.6] (not included in 5th edition).

[55] Balkin and Davis conclude that 'damage to goods within the premises is sufficient' to constitute material injury to property for the purposes of nuisance. R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 476. Trindade and Cane also support this view. F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 628. They refer to damage to a shop's stock by dust (in *Harris v Carnegie's Pty Ltd* [1917] VLR 95) as an example of physical damage to property. Baker makes no comment on this point. C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002). For an historical perspective see F H Newark, 'The Boundaries of Nuisance' (1949) 65 *Law Quarterly Review* 480.

animals. There will then be damage to property for the purposes of nuisance only if damage to chattels on the plaintiff's property is sufficient.

More commonly though, if there has been contamination it will be of the plaintiff's land, vegetation or crops. The plaintiff's animals may then eat the contaminated crops or vegetation. In such cases, the land, vegetation or crops are property for these purposes, whether or not livestock is also property. Damages for livestock contamination will then be available as consequential loss.[56]

Significant material damage

If there has been damage to property, the damage suffered must be significant material damage rather than merely trifling.[57] Accordingly, the presence of insignificant amounts of GMOs or their par. on the plaintiff's property should not, of itself, be sufficient. As to what is a significant amount of contamination for these purposes, commentators have suggested that there is 'sensible material injury' if science can trace a deleterious physical change in the property.[58] Given that GM contamination is detectable at even very low levels this interpretation is of concern for commercialisers.[59]

There is no case law establishing that other methods cannot be used to determine whether there has been damage. James LJ in *Salvin v North Brancepeth Coal Company*[60] stated that it is not sufficient for the plaintiff to rely on scientific evidence 'such as the microscope of the naturalist, or the tests of the chemist'.[61] In *The Directors, etc of the St Helen's Smelting Company v Tipping*[62] a direction to the jury by Mellor J[63] stated, in part, 'therefore in the case of an alleged injury to property, ... the injury to be actionable must be such as visibly to diminish the value of the property;'. This was held by the House of

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[56] See, for eg, *Hunter v Canary Wharf Ltd* [1997] AC 655 at 706 (HL), where obiter supports a right to sue for damage to chattels and livestock in nuisance as consequential damage. Recovery is subject to satisfaction of the remoteness test. See section 5.2.6.

[57] *The Directors, etc of the St Helen's Smelting Company v Tipping* (1865) 11 HLC 642; 11 ER 1483. See also *Don Brass Foundry Pty Ltd v Stead* (1948) 48 SR(NSW) 482; *Harkness v Woodhead* [1950] SASR 54.

[58] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 476 relying on *Gaunt v Fynney* (1872) 8 Ch App 8 at 11-12 (Lord Selborne LC).

[59] See D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 150 who concludes that the deposit of GM pollen on organic crops is physical damage. He assumes that standards set by organic farmers are the appropriate standards.

[60] (1874) 9 Ch App 705.

[61] (1874) 9 Ch App 705 at 709. James LJ notes though that scientific evidence is admissible to prove that the visible damage was caused by the defendant's operations (at 709).

[62] (1865) 11 HLC 642; 11 ER 1483.

[63] (1863) 35 LJ QB 66.

Lords to be correct. Commentators have also suggested that the better view is that 'sensible material injury' means damage visible by ordinary persons conversant with the subject matter without having recourse to scientific evidence.[64]

Although a 'visible damage' approach is more favourable for commercialisers, it is submitted that a modern court considering a claim made with respect to GMO invasion would not use it as the sole test. Under the visible damage approach, the GMO or its part or the organism to which material had been transferred would have to be visually discernable from the plaintiff's other organisms for there to be sensible material injury. This may be possible in some cases. For example, blue GM carnations would stand out in a field of non-blue carnations when in flower. But in many cases visual differentiation would require that the plaintiff's organisms be subjected to the adverse event which the GMO was modified to withstand. For example, GM canola would survive spraying by the herbicide to which it is tolerant whilst its non-GM neighbours would not. The GMOs would presumably then be the only organisms left in good health. At other times, visual differentiation would be unlikely.[65]

It is submitted that courts would, and should, instead refer to the legislative and regulatory requirements in respect of the characteristic claimed to be adversely affected by the invasion as the measure of sensible material damage. The food regulations, for example, allow food or ingredients to have up to 10 g/kg or 1% GM content where that content is unintentional before labelling requirements become necessary.[66] It is submitted that contamination of a food crop below that threshold should not be treated as significant because it has no real adverse consequences for the plaintiff. Contamination above that threshold would be material because it has changed the nature of the plaintiff's organisms in an unwanted and legally relevant way.

Difficulties arise though with respect to claims based on matters to which no legislative standards apply. For example, plaintiffs may claim adverse consequences following contamination because purchasers will not purchase their product at all or on the same terms, although it can legally be sold. This is illustrated by claims regarding the loss of organic status. There is no legislative definition of 'organic'. Organic standards are set by

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[64] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 476.
[65] See, eg, *Monsanto Canada Inc v Schmeiser* [2001] FCT 256 at [38]-[59] where the Canadian Trial Court describes the rigorous and extensive testing necessary to determine the extent of GM canola on the Schmeisers' property.
[66] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1)(f). See Part 2.10 above.

voluntary certification schemes. The Australian Quarantine and Inspection Service ('AQIS') has implemented a National Standard for Organic and Bio-Dynamic Produce for products labelled as organic or bio-dynamic which are to be exported from Australia.[67] Accredited certifying organisations apply this standard as a minimum requirement to all products produced by operators certified under their inspection systems.[68] Such organisations are, however, free to stipulate additional requirements. The AQIS Standard does not apply to domestic produce. Any one of a range of thresholds could apply depending upon the plaintiff and the certifying organisation they belong to.

Even if the AQIS standard is taken as the domestic standard, significant objections can still be raised by commercialisers to its use as the measure for sensible material injury. Standard 3.1.4 of the AQIS National Standard prohibits the use of products comprised of or derived from GM on any organic farm.[69] Standard 3.1.8b provides that where unintentional GM contamination occurs, the contaminated product cannot be sold as organic. Contamination is not defined. The Organic Federation of Australia claims that AQIS's policy is that only detectable GM contamination renders product uncertifiable. The current level of detection is 0.1%. Therefore this is the current threshold for contamination.[70] If that is correct, the tolerance for GM contamination in organic standards is much lower than that provided for in the food legislation. Given that this tolerance is essentially a voluntary one, it is submitted that the court should not adopt it as the measure of 'material damage' the exceeding of which, prima facie, is a nuisance. Rather, for interferences causing loss of organic status or any other non-regulated consequence, the court should treat the matter as one where there has been an interference with the use or enjoyment of the plaintiff's land. Plaintiffs would then still need to prove that there has been an unreasonable interference with their interest to succeed in nuisance.[71] Commercialisers would then not be prima facie liable in nuisance simply because a standard the plaintiff or their customers have chosen to adopt has been

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[67] Australian Quarantine and Inspection Service, Organic Produce Export Committee, *National Standard for Organic and Bio-Dynamic Produce* (3rd ed, December 2002).
[68] For eg, Australian Certified Organic (ACO) is an accredited organisation. It is the certification arm of the Biological Farmers of Australia Co-op Ltd ('BFA'). The BFA, according to its website, is the largest representative group for the organic industry in Aust.
[69] See also Standard 3.1.11.
[70] S Statham, Organic Federation of Australia Inc, Genetic Engineering Sub-Committee, *Report to the OFA Membership on the Process of Govt Consultation through the Gene Technology Grains Committee* (12 September 2002) (http://www.bfa.com.au accessed 5/11/03), text accompanying fns 13 and 14.
[71] Whether they could do that is considered in section 5.2.4.

breached.[72] Instead the court would have the opportunity to weigh the interests of each party before imposing liability.

There is case law supporting the submitted approach. As far back as 1341 farmers have been reported as complaining of decreases in the value of their land and produce because of the spread of organisms, in those cases rabbits, from another's land.[73] However, there are no reported Australian decisions where the contamination of a farmer's agricultural organisms by a neighbour's organisms of the same species has resulted in a nuisance action.[74] Clearly, though, the spread of organisms of a different species to those raised by the plaintiff from the defendant's land to the plaintiff's land can be a nuisance.[75] In some cases it is the organisms themselves and in others it is the actions of the organisms on the plaintiff's land that is the basis for the finding.[76] In another series of cases, the conduct of animals on the *defendant's* land has been the nuisance. For example, smells[77] and noises[78] caused by animals can clearly be nuisances. An analogous group of cases are those concerning the spread of disease. In these cases it is a microorganism that spreads. Taking an animal infected with a disease that can spread to humans into a public place, has been held to be a nuisance.[79] Similarly taking an animal infected with a disease transmissible only to other animals into such a place is also actionable.[80] Keeping animals infected with a contagious disease on the defendant's own land though is not a nuisance, even if the

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[72] No food product (except perhaps laboratory produced food) will be 100% pure. G Brookes, *Co-existence of GM and non-GM crops: economic and market perspectives* (2003) (http://www.monsanto.co.uk/news/ukshowlib.phtml?uid=7282 accessed 15/7/03). Setting a zero tolerance in respect of organic products would therefore be a new precedent.

[73] G L Williams, *Liab[illegible] for Animals* (Cambridge University Press, Cambridge, 1939), p 238.

[74] This may be partly explained, with respect to animals, by the availability of an alternative cause of action in cattle-trespass in many States. Such an action is one of strict liability and does not require the defendant's actions to have been unreasonable.

[75] Eg, *Farrer v Nelson* (1885) 15 QBD 258 at 260; *Pratt v Young* (1952) 69 WN(NSW) 214. With respect to liability following the keeping of animals generally, see P M North, *The Modern Law of Animals* (Butterworths, London, 1972).

[76] For eg, in *Sparke v Osborne* (1908) 7 CLR 51 it was presence of the organisms, prickly pears, that was of concern. (Defendant not liable.) In *Farrer v Nelson* (1885) 15 QBD 258 it was the destruction of the plaintiff's crops by the defendant's pheasants that was the nuisance. See also *Curtis v Thompson* (1956) 106 L Jo 61 where the constant fouling of the plaintiff's land by the defendant's dog may have been a nuisance if pleaded.

[77] See, for eg, *Aldred's Case* (1610) 9 Co Rep 57b; 77 ER 816 (public nuisance); *Rapier v London Tramways Co* [1893] 2 Ch 588; *Drysdale v Dugas* (1896) 26 SCR 20 (Canada); *Attorney-General v Squire* (1906) 5 LGR 99 (public nuisance); *Munro v Southern Dairies Ltd* [1955] VLR 332.

[78] *Ball v Ray* (1873) 8 Ch App 467; *Broder v Saillard* [1876] 2 Ch D 692; *Rapier v London Tramways Co* [1893] 2 Ch 588; *Drysdale v Dugas* (1896) 26 SCR 20 (Canada); *Ruthning v Ferguson* [1930] Qd SR 325; *Painter v Reed* [1930] SASR 295; *Leeman v Montagu* [1936] 2 All ER 1677; *Fraser v Booth* (1949) 50 SR(NSW) 113; *Munro v Southern Dairies Ltd* [1955] VLR 332.

[79] *R v Henson* (1852) Dears CC 24; 169 ER 621 (public nuisance).

[80] *Palmer v Stone* (1759) 2 Wils KB 96; 95 ER 705.

disease spreads to other animals on adjoining lands.[81] However, the defendant must keep the animals on their land and there must be no negligence in their keeping.[82] Where seeds or parts of noxious weeds spread to the plaintiff's land, the defendant is liable in nuisance only if they are responsible for the weed being on their property by way of planting it or actively raising it.[83] In none of these cases does the court consider whether there has been material damage to the plaintiff's property, real or otherwise. If the matter of the type of interference is considered at all, the court proceeds on the basis that there has been an interference with the plaintiff's use of land. The issue then is whether the interference was unreasonable, which is considered in section 5.2.4 below.

Diminution in value

In those cases where there has been 'damage', the damage to be material must also cause diminution of the value of the property (land, crops or chattels). [84] If the result of the contamination is that the plaintiff has less produce, receives a lesser amount for their produce than they otherwise would have or can no longer sell their produce, this would be satisfied.[85]

Whether GM contamination is material damage

Subject to sufficient levels of contamination, GM contamination of the plaintiff's property could in some cases cause material damage. It has been submitted that material damage should be found only if there is some visible adverse consequence or an adverse consequence pursuant to a legislative or regulatory standard.[86] An action in nuisance would then, prima facie, be made out. The defendant may still escape liability in such a

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[81] *Ruhan v The Water Conservation and Irrigation Commission (NSW)* (1920) 20 SR(NSW) 439. Cf P M North, *The Modern Law of Animals* (Butterworths, London, 1972), p 174.
[82] *Ruhan v The Water Conservation and Irrigation Commission (NSW)* (1920) 20 SR(NSW) 439 at 444-5.
[83] *Sparke v Osborne* (1908) 7 CLR 51.
[84] Although depreciation in the value of land and buildings is not in itself 'material injury to property'. R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 476; C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-7.
[85] Although the GMO may have desirable characteristics of its own, and the desirability of newer characteristics are expected to be greater than those of current GMOs, the lack of purity of the plaintiff's contaminated organisms would probably mean that the plaintiff could not in the alternative take advantage of any premiums payable for GM produce.
[86] Cf Wilde who concludes that inadvertent genetic contamination of organic crops would be a material change and the resulting loss therefore consequential economic loss rather than pure economic loss. Note though that this is pursuant to UK law. M L Wilde, 'The Law of Tort and the 'Precautionary Principle': Civil Liability Issues Arising from Trial Plantings of Genetically Modified (GM) Crops' (1998) 6 *Environment Liability* 163, 171.

case if their use of their land was reasonable.[87] In that case the burden of proof with respect to reasonableness is on the defendant. Reasonable user seems to require that there has not been an unreasonable interference.[88] Unreasonable user is considered in section 5.2.4. In all other cases of contamination it has been submitted that the interference complained of by the plaintiff is at most an interference with their use and enjoyment of land.[89] In that case the plaintiff must show the interference was substantial and unreasonable to be successful.

Nuisance can protect agricultural or commercial use of land.[90] Plaintiffs may assert that the prevention of the use of their land for 'non-GM' or 'organic' farming because of GM contamination is an interference with their use of the land sufficient to found an action in nuisance.[91] However, the majority of the High Court in *Victoria Park* stated that interference with the plaintiff's business is not sufficient in itself to constitute the tort in Australia.[92]

In *Victoria Park* the plaintiff commenced an action in nuisance to prevent further interference and recover lost profits caused by the defendant's unauthorised surveillance and broadcast of its race meetings from adjoining land. By majority, the claim in nuisance was dismissed. Although there had been an interference with a recognised right of occupation of property there was no interference with a use or enjoyment of land protected by nuisance. Dixon J held that diversion of custom from a business by noise, fumes, obstruction of frontage or other interference with recognised rights of occupation of

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[87] *Kraemers v Attorney-General (Tas)* [1966] Tas SR 113 at 122-3; *Cambridge Water Company v Eastern Counties Leather plc* [1994] 2 AC 264 at 299 (HL); *Corbett v Pallas* (1995) Aust Torts Reps 81-329 at 62,241 (NSW CA). See also M Davies, 'Private Nuisance, Fault and Personal Injuries' (1990) 20 *University of Western Australia Law Review* 129, 132-6 and G Cross, 'Does Only The Careless Polluter Pay? A Fresh Examination of the Nature of Private Nuisance' (1995) 111 *Law Quarterly Review* 445.

[88] Reasonable user does not mean that the defendant has taken all reasonable precautions although the taking of such precautions is relevant. Eg, *Harris v Carnegie's Pty Ltd* [1917] VLR 95.

[89] See D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 150 who concludes that genetic contamination is likely to be an interference with the use and enjoyment of land rather than material damage. See also M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 530; A J Waldron, 'Transgenic Torts' [1999] *Journal of Business Law* 395, 404-6; J Thornton, 'Genetically Modified Organisms: Developing a Liability Regime' (2001) 9 *Environmental Liability* 267, 269.

[90] *McMahon v Catanzaro* [1961] QWN 22; C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-3.

[91] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 530.

[92] *Victoria Park* (1937) 58 CLR 479 at 493 (Latham CJ), 506-7 (Dixon J), 523-4 (McTiernan J) (Rich and Evatt JJ dissenting). In the strong dissent by Evatt J, Evatt J said that interference with the profitable enjoyment of the plaintiff's land causing actual pecuniary loss as a result of an intentional act of the defendant resulting in a devaluation of the plaintiff's land can be nuisance.

property are heads of damage but not the wrong itself.[93] Similarly, in *Metropolitan Asylum District v Hill (Appeal No 1)*[94] (*'Hill's case'*) Lord Blackburn, after noting that the erection of a smallpox hospital in any locality, even if there is no real danger to neighbours, has a tendency to deter persons from coming to reside in the area and therefore depreciates property values, said 'this, though it may be a source of serious pecuniary loss to the owner of that building land, is not a matter for which he can recover damages'.[95] In reaching their decision in *Victoria Park* the majority relied upon three main policy considerations.[96] First, the difficulty of formulating an objective test to ascertain the extent of non-physical interference to the use and enjoyment of land; secondly, the disruption of the construction industry that might be caused by the protection of land from unauthorised surveillance was not justified by the social benefit of enabling occupiers to enjoy their land in privacy; and thirdly, the Court foresaw considerable mechanical difficulties in uniformly adjudicating the extremely complex issues likely to arise in disputes of this nature.[97] These are considered in the context of GMO releases below.

Other Australian case law establishes that there must be an interference with the property right, not just inconvenience in its use and enjoyment for there to be a nuisance. In *Broderick Motors Pty Ltd v Rothe* a car with the word 'bomb' written on it was parked outside the plaintiff's business where the car had been bought.[98] The Court held that this was not a nuisance because there had been no interference with the plaintiff's use and enjoyment of the premises as business premises. The defendant did not attempt to prevent people entering the property even though it tried to dissuade them from doing so. Although the result is the same in practical terms, it was by psychological effect rather than physical and therefore not a nuisance.[99]

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[93] *Victoria Park* (1937) 58 CLR 479 at 507. It would therefore be relevant when assessing damages provided some other interference constituting the tort was first made out.
[94] (1882) 47 LT 29 (HL).
[95] (1882) 47 LT 29 at 32 (HL).
[96] J S Gillespie, *Private Nuisance as a Means of Protecting Views Enjoyed By an Occupier of Land From Obstruction* (Master of Laws thesis, Monash University, 1984), pp 64-5.
[97] For discussion of the considerations in *Victoria Park* decision see J S Gillespie, *Private Nuisance as a Means of Protecting Views Enjoyed By an Occupier of Land From Obstruction* (Master of Laws thesis, Monash University, 1984), pp 64-5.
[98] (1986) ATR 80-059. See also similar case of *McCoy Constructions Pty Ltd v Dabrowski* [2001] QSC 413 BC200106742 (Unreported, Jones J, 31 October 2001).
[99] Physical blocking or besetting is a nuisance. See *Dollar Sweets Pty Ltd v Federated Confectioners Association of Australia* [1986] VR 383; *Animal Liberation (Vic) Inc v Gasser* [1991] 1 VR 51; *Barloworld Coatings (Aust) Pty Ltd v Australian Liquor, Hospitality & Miscellaneous Workers Union* (2001) 108 IR 107 (NSW SC).

Commercialisers could assert that by analogy with the above cases, interference with a neighbour's business, for example by causing them to lose organic status or other market advantage that their produce may have had (such as no need to be labelled GM), is insufficient for an actionable nuisance. Commercialisers could argue that the three policy considerations outlined by the majority in *Victoria Park* also point to there being no nuisance in their case. It could be asserted that as in *Victoria Park* an objective test to ascertain the extent of interference to the use and enjoyment of land where a plaintiff claims they cannot use their land as they wish because of the GMO release would be extremely difficult to formulate; the disruption of the whole agricultural industry, GM or otherwise, that might be caused by the protection of land from contamination would not be justified by the social benefit of enabling occupiers to use their land entirely as they wish;[100] and there would be considerable mechanical difficulties in uniformly adjudicating the extremely complex issues that are likely to arise in disputes of this nature.

This argument is unlikely to be successful. First, the plaintiff in *Victoria Park* could have prevented the overlooking by building higher fences.[101] In many cases following GMO releases, there may be no further protective step available to the plaintiff.[102] More importantly, contamination of a person's land causing them to lose some particular status, even if there has not been material damage, is a physical interference unlike in *Victoria Park* or *Hill's case*. It is also not merely diverting custom from the person or causing them inconvenience. It is changing the nature of the land and the produce grown on it without the plaintiff's consent as a result of some intrusion on that land. Latham CJ in *Victoria Park* noted in finding no nuisance in that case that the plaintiff's 'racecourse is as suitable as it ever was for use as a racecourse.'[103] This may not be true of the plaintiff's land following GM contamination. Further, the courts have held that nuisance extends to numerous invasions, whether of tangibles such as dust[104] or intangibles such as electricity[105].[106] Even where there has been no GM contamination but the plaintiff loses some status because they are near a GMO release, there may be an interference with the plaintiff's use or enjoyment of land for the purposes of nuisance. Case law establishes that

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[100] This would particularly be the case if the court did not distinguish between GM contamination and contamination by any invading organism causing an adverse consequence to the plaintiff.
[101] *Victoria Park* (1937) 58 CLR 479 at 494.
[102] See further subsection 5.3.4(b).
[103] *Victoria Park* (1937) 58 CLR 479 at 493.
[104] *Matania v The National Provincial Bank Ltd* [1936] 2 All ER 633; *Andreae v Selfridge Co Ltd* [1938] Ch 1.
[105] *Bridlington Relay Ltd v Yorkshire Electricity Board* [1965] Ch 436.
[106] C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-3.

there can be a nuisance even where there has been no invasion.[107] Accordingly, interferences with others' farming caused by GMO releases is likely to be an interference with the use or enjoyment of the plaintiff's land.

It is submitted that the need to take, and cost of taking, precautions to prevent or remove contamination or to comply with legislation such as the *GT Act* or labelling laws would be treated in the same way as interference with the type of farming the plaintiff wishes to pursue. They are losses directly related to the use or enjoyment of land and therefore can be the basis of a nuisance action. However, it is also submitted that any loss brought about by the need for the plaintiff to pay patent licence fees because of contamination of their land by a patented GMO would not of itself be sufficient.[108] A court is unlikely to view such loss as directly related to the use or enjoyment of land.[109]

5.2.4 *Substantial and Unreasonable Interference*

The second element to be proven by plaintiffs in nuisance is that the interference with the protected interest was both substantial and unreasonable in the circumstances.[110] If there has been material damage to the plaintiff's property then there is, prima facie, a substantial and unreasonable interference and therefore a nuisance.[111] However, as noted,[112] if the defendant can show that there has been only reasonable user of their land by them, they will escape liability. Reasonable user seems to depend upon the same considerations as those relevant when determining whether there has been unreasonable interference. These are considered in this section. Where there is no material damage, the interference must be sufficiently substantial and unreasonable as to cause other damage to the plaintiff.[113]

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[107] Such as where defendant's activity outside the plaintiff's land causes a power failure on that land. C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-3. See, for eg, *British Celanese Ltd v A H Hunt (Capacitors) Ltd* [1969] 2 All ER 1252.

[108] This is also the conclusion reached by M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 530 with respect to UK law.

[109] See, for eg, *Field v South Australian Soccer Association* [1953] SASR 224; *Pride of Derby and Derbyshire Angling Association Ld v British Celanese Ld* [1953] 1 Ch 149.

[110] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), pp 477 and 483.

[111] That is, there is a rebuttable presumption of nuisance. *The Directors, etc of the St Helen's Smelting Company v Tipping* (1865) 11 HLC 642; 11 ER 1483; *Harris v Carnegie's Pty Ltd* [1917] VLR 95; *Halsey v Esso Petroleum Co, Ltd* [1961] 2 All ER 145; *Kraemers v Attorney-General (Tas)* [1966] Tas SR 113. See also R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), pp 477 and 489 and M Davies, 'Private Nuisance, Fault and Personal Injuries' (1990) 20 *University of Western Australia Law Review* 129, esp 132-6.

[112] See subsection 5.2.3(b) above.

[113] *Munro v Southern Dairies Ltd* [1955] VLR 332 at 334.

With respect to substantiality, the court is mostly concerned with the extent of the interference. The plaintiff must show that the interference is more than trivial. Trivial interference is not a nuisance.[114] A significant decrease in the market value of the plaintiff's land or produce would be evidence of such substantiality.

When assessing reasonableness, the law of nuisance attempts to balance two conflicting interests – the plaintiff's desire to use and enjoy their property without interference and the defendant's desire to undertake the activity causing the interference.[115] Everyone must put up with some degree of interference from their neighbours.[116]

As to the test used where reasonableness must be judged, Lord Wright in *Sedleigh-Denfield v O'Callaghan*, one of the most commonly cited nuisance cases, noted that it was impossible to give any precise or universal formula. However, he said that a useful test was 'what is reasonable according to the ordinary usages of mankind living in society, or more correctly *in a particular society*.'[117]

The meaning of 'ordinary usages of mankind' referred to by Lord Wright above was clarified in *Walter v Selfe*.[118] The interference must be:

> more than one of mere delicacy or fastidiousness, as an inconvenience materially interfering with the ordinary comfort physically of human existence, not merely according to elegant or dainty modes and habits of living, but according to plain and sober and simple notions among the English people.[119]

The test is therefore an objective one[120] determined by considering whether a reasonable person residing in the particular locality would regard the event as acceptable.[121] Trindade and Cane observe that '[a] person must endure noises and other interferences that are an

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[114] *Stormer v Ingram* (1978) 21 SASR 93.
[115] *Sedleigh-Denfield v O'Callaghan* [1940] AC 880 at 903.
[116] *Bamford v Turnley*(1862) 3 B & S 66 at 84; 122 ER 27 at 33 (Bramwell B).
[117] [1940] AC 880 at 903 (emphasis added). See also *The Directors, etc of the St Helen's Smelting Co v Tipping* (1865) 11 HLC 642; 11 ER 1483 at 1486.
[118] (1851) 4 De G & Sm 315 at 322; 64 ER 849 at 852. Approved in *Oldham v Lawson (No 1)* (1976) VR 654 at 655.
[119] (1851) 4 De G & Sm 315 at 322; 64 ER 849 at 852 (Sir JL Knight Bruce VC). See also *Kennaway v Thompson* [1981] QB 88 at 94 (CA) where Lawton LJ said:

> The question [on which liability depends] is whether the neighbour is using his property reasonably, having regard to the fact that he has a neighbour. The neighbour who is complaining must remember, too, that the other man can use his property in a reasonable way and there must be a measure of give and take, live and let live.

[120] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 483.
[121] *Clarey v Principal and Council of the Woman's College* (1953) 90 CLR 170.

ordinary incident of life in their locality; otherwise a person could, by using land for a purpose incompatible with established uses, put an end to those established activities.'[122] So, for example, smoke and soot caused by neighbouring domestic fireplaces is not a nuisance because the plaintiff suffers no more inconvenience than is to be expected in a densely populated district.[123]

GMOs will be released in agricultural areas. That is, areas where organisms of many types are released into the environment and can be expected on occasion to spread beyond the property on which they were released. Commercialisers could argue that the consequences following GMO releases are not unreasonable because they are not significantly different from the consequences following the release of any other organism in an agricultural area. Whether there has been an unreasonable interference is determined by common sense, with the court considering all relevant factors.[124] As noted above these factors include the nature of the defendant's conduct, compliance with relevant legislation, abnormal sensitivity of the plaintiff, the locality in which the interference occurred, precautions taken by the defendant against interference, the frequency, duration and time of the interference and the defendant's motive. Those factors are now considered.

(a) Purpose of defendant's conduct

The purpose of the defendant's conduct is taken into consideration in assessing reasonableness.[125] The purpose of GMO releases is improvement of agriculture and is economically important rather than merely a recreational pursuit.[126] Further, commercialisers could submit that if plaintiffs succeed in nuisance in GMO release cases, they will be able to do what the Commonwealth and State Parliaments have decided the public cannot – give legal effect to their determination that their area will or will not be GM-free. This may undermine the integrity of the regulatory scheme and State moratorium legislation.[127] Additionally, classification of GM contamination as

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[122] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 631.
[123] *Pittar v Alvarez* (1916) 16 SR (NSW) 618. In *Munro v Southern Dairies Ltd* [1955] VLR 332 at 337 Sholl J said '[i]n the present case it is, of course, material to consider the general nature of the locality of Willis Street, Hampton, and particularly whether the discomfort or inconvenience of which the plaintiff now complains is so characteristic of the general neighbourhood that he ought not to be heard to complain of what other people are accustomed habitually to put up with.'.
[124] *Oldham v Lawson (No. 1)* [1976] VR 654 at 655 (Harris J).
[125] *Harrison v Southwark and Vauxhall Water Co* [1891] 2 Ch 409 at 414.
[126] See section 1.3.1.
[127] McKendrick makes this submission with respect to decisions in nuisance where planning legislation is involved. E McKendrick, 'Public Nuisance and the Environment' (1993) 1 *Tort Law Review* 14, 15.

'unreasonable' could put an end to other more established agricultural practices. Concerns regarding contamination are not only relevant to GMOs. Other types of contamination may also cause concern. If GM contamination is considered a nuisance, contamination of, for example, one type of non-GM canola by another non-GM canola, causing similar market repercussions to GM contamination in many instances, should also be treated that way. This could render agriculture unworkable.

(b) Compliance with relevant regulations

Regulations are usually treated by the court as denoting a standard of acceptability and reasonableness in the community.[128] Certainly, if the commercialiser has not obtained GTR approval or State exemptions/permits (where relevant) prior to release it is unlikely the commercialiser could successfully assert reasonable use of their landowning rights. However, the reverse is not necessarily true. That is, compliance with the *GT Act* and State moratorium legislation is not necessarily enough to avoid liability in nuisance.[129] An activity does not have to be unlawful to be a private nuisance.[130] Lawful releases can be a nuisance at common law.[131]

Plaintiffs can point to two further matters in this regard. First, as discussed in Chapter 2, the GTR does not consider socio-economic harm to other farmers or their forms of agriculture when making decisions regarding GMO releases. Plaintiffs may argue that accordingly the legislative standard set by the *GT Act* is not a thorough threshold of reasonableness for the court's purposes.[132] This is a particularly strong argument given that Parliament intended that questions of common law liability following GMO releases be determined by common law principles rather than by mere compliance with the legislation.[133] Secondly, plaintiffs can point to other relevant legislation that in effect provides for thresholds with respect to contamination. As described in Chapter 2, food labelling regulations require vendors to label their products as GM if a certain level of GM presence occurs. Following contamination of the plaintiff's property, the plaintiff may

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[128] See, for eg, *Hunter v Canary Wharf Ltd* [1997] AC 655 at 721 (HL).
[129] Just as compliance with motor vehicle speed regulations is not an automatic defence to a claim in nuisance arising because of the dust thrown up at that speed. *Kidman v Page* [1959] Qd R 53 at 61. See also *Munro v Southern Dairies Ltd* [1955] VLR 332 at 335.
[130] *Gillingham Borough Council v Medway (Chatham) Dock Co Ltd* [1993] QB 343 at 357.
[131] Eg, *Feiner v Domachuk* (1994) 35 NSWLR 485 aff'd on appeal *Domachuk v Feiner* [1996](CA(NSW)) BC9606851 (Unreported, Sheller JA, Giles and Simos AJJA, 28 November 1996).
[132] Although interference with the plaintiff's business is not sufficient in itself to be an interference for the purposes of nuisance, it may still be relevant when assessing the reasonableness of any other interference.
[133] See Part 5.1.

become obliged to label where they otherwise would not. Lee and Burrell have claimed that UK courts, when presented with evidence that regulatory standards have been breached, assume the sufficiency of harm to the plaintiff without much further consideration.[134]

However, as Lee and Burrell note, the regulatory thresholds considered in the decided cases were clearer than in the case of GMO releases. Crossing the relevant thresholds in the decided cases caused the plaintiffs to be unable to use their property at all for the desired purpose. For example, in *Cambridge Water*[135] the plaintiffs used their property to obtain drinking water. Past contamination from the defendant's property meant that new drinking water standards were breached and all such use had to cease. In the case of GMO releases, agriculture, although non-organic for example, would still be possible;[136] products could still be sold although they may have to be labelled differently. Accordingly, particularly given that the release will have been approved by both national and state regulatory schemes created specifically to control GMO releases, commercialisers could submit that the Australian courts should not assume sufficiency of harm to the plaintiff in such cases. Instead the other factors identified above as being generally relevant to the determination of reasonableness, such as locality, should be important in any final decision.

Finally, in Australia standards with respect to GM content thresholds are often voluntary standards set by associations of like minded farmers.[137] It is submitted that the desire to maintain a particular voluntary standard, such as organic or non-GM, means that the plaintiff is setting its own standard as to what is reasonable or not. Australian courts should not accept that standard as determining reasonableness for two reasons. First, because the standard used by a court when determining whether an interference is a nuisance is that of the ordinary reasonable and responsible person who lives in the particular locality in which the plaintiff resides.[138] As Veale J observed '[t]his is not necessarily the same as the standard which the plaintiff chooses to set up for himself. It is

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[134] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 533.
[135] *Cambridge Water Co v Eastern Counties Leather plc* [1994] 2 AC 264.
[136] Although in the ACT and NSW, certain future uses of properties contaminated by GMOs can be prohibited. See section 3.3 above.
[137] See, for eg, organic certification rules. See subsection 5.2.3(b) above.
[138] As Lord Selborne LC observed, 'Neighbours everywhere ... ought not to be extreme or unreasonable either in the exercise of their own rights or in the restriction of the rights of each other'. *Gaunt v Fynney* (1872) 8 Ch App 8 at 11.

the standard of the ordinary man.'[139] Secondly, the adoption of such standards may mean that the plaintiff is peculiarly susceptible or abnormally sensitive to interference. This is considered next.

(c) Plaintiff's abnormal sensitivity

Case law establishes that interferences are not unreasonable where they occur only because the plaintiff is unduly sensitive.[140] Persons carrying on exceptionally delicate trades cannot complain because they are injured by a neighbour doing something lawful on their property, if the neighbour's activity would not injure anything but the exceptionally delicate trade.[141] However, if any person may be affected, judged 'according to plain and sober and simple notions',[142] the plaintiff may recover additional damages if the plaintiff suffers more because of their particular circumstances.[143]

In *R v Secretary of State for the Environment and MAFF, ex parte Watson* an application for judicial review in the UK was brought by an organic farmer concerned about a field trial of GM maize on a neighbouring farm.[144] Buxton LJ observed that if the applicant had brought an action in private nuisance 'difficult questions would arise as to the extent to which the Applicant was seeking to impose limitations..., in a farming area, by the introduction of special or specially sensitive crops'.[145] Lee and Burrell submit that whether the courts will find organic agriculture to be an 'ordinary' use or 'normal trade' rather than a sensitive use is probably not capable of purely doctrinal prediction.[146] They note though

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[139] *Halsey v Esso Petroleum Co, Ltd* [1961] 2 All ER 145 at 151.
[140] *Robinson v Kilvert* (1889) 41 Ch D 88 (CA); *Eastern and South African Telegraph Co, Ltd v Capetown Tramways Companies, Ltd* [1902] AC 381 (PC); *Phillippay v Pacific Power & Light Co* 207 P 957 (1922); *Noyes v Huron & Erie Mortgage Corp* [1932] 3 DLR 143 (Ont SC); *Amphitheaters, Inc v Portland Meadows* 198 P 2d 847 (1948); *Bridlington Relay Ltd v Yorkshire Electricity Board* [1965] Ch 436. Cf *McMahon v Catanzaro* [1961] QWN 22 (poultry owner got injunction to prevent defendant neighbour using explosives to clear stumps off property which upset the fowls plaintiff trying to coax into laying during period normally wouldn't lay. But there is no discussion of whether the plaintiff's actions were unduly sensitive or not and the Court noted the defendant had other means (although more expensive) to remove stumps).
[141] *Robinson v Kilvert* (1889) 41 Ch D 88 (CA); *Eastern and South African Telegraph Co, Ltd v Capetown Tramways Companies, Ltd* [1902] AC 381 (PC); *Bridlington Relay Ltd v Yorkshire Electricity Board* [1965] Ch 436.
[142] *Walter v Selfe* (1851) 4 De G & Sm 315 at 322; 64 ER 849 at 852.
[143] *McKinnon Industries Ltd v Walker* (1951) 3 DLR 577.
[144] [1998] EWCA Civ 1250 (21 July 1998).
[145] [1998] EWCA Civ 1250 (21 July 1998).
[146] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 532. Lee and Burrell also note that claims of abnormal sensitivity of the plaintiff are a possible obstacle to success in a nuisance claim. M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 531.

that if GM farming is found to affect non-organic as well as organic farming, the defendant's sensitive use point is considerably weakened.[147]

The rule with respect to hypersensitivity operates not only in relation to extra-sensitivity of the plaintiff's property, but also as to undue sensitivity on the part of the plaintiff.[148] Therefore in cases based on the social impacts of GMO releases such as distress caused by seeing the GMO on the commercialiser's land, commercialisers could argue that the plaintiff's reaction is due to their undue sensitivity. For example, case law establishes that the keeping of bees which on occasion sting neighbours is not usually a nuisance.[149] This is the case even though it is known that bee stings can be fatal to some people and that such people might be frightened of bees. By analogy it is submitted that the causing of distress to GM opponents/neighbours should also not be a nuisance on the basis that those who are so opposed to GM as to be significantly distressed by the release of GMOs are extra-sensitive.

Similarly where distress is claimed on the basis of fear of harm to the health of themselves, their family or other organisms[150] it could be asserted that the plaintiff is hypersensitive. In the case of GMO releases, neighbours will have been notified of the proposed release, of the GTR's assessment of risks and approval of the release. Similarly, information concerning moratoriums and exemptions/permits under State moratorium legislation is publicly available.[151] Information concerning the GMO's safety would, at the very least, be available from the GTR. Any remaining fears for human, animal and plant safety held by a plaintiff could therefore be said to be unreasonable by commercialisers. However, the court's decision on this depends upon whether it agrees that it is reasonable for someone to be sceptical of the ability of science, the GTR and State regulators to determine the

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[147] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 532.

[148] C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-8. See, for eg, *Pelmothe v Phillips* (1899) 20 LR (NSW) 58.

[149] Nuisance only occurs in such cases if an excessive number of bees are kept or bees are kept in such a place as to cause discomfort to neighbours through their escape. P M North, *The Modern Law of Animals* (Butterworths, London, 1972), p 173. See *O'Gorman v O'Gorman* [1903] 2 IR 573; *Lucas v Petit* (1906) 12 OLR 448 at 451-2.

[150] For eg, a person may suffer distress because of fear of the long term effects of exposure to a GMO. See, for eg, *Mink v University of Chicago* (1978) 460 F Supp 713 (US District Court, N D Illinois) concerning fear of long term effects of exposure to a drug where the court held that there was no liability in negligence because there was no harm for these purposes.

[151] Gene Technology (GM Crop Moratorium) Bill 2004 (ACT) cls 7(2) and 8(2); *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) ss 6, 8(1) and 9(1); *Genetically Modified Crops Management Act 2004* (SA) ss 5(1) and 6(1); *Plant Quarantine Act 1997* (Tas) ss 8(1) and 12(1) (information re permits does not have to be made available. See s 38); Genetically Modified Organisms Control Bill 2004 (Tas) cl 5(1) (no requirement regarding permits); *Control of Genetically Modified Crops Act 2004* (Vic) ss 5(3) and 6(1); *Genetically Modified Crops Free Areas Act 2003* (WA) ss 4(1) and 6(1).

possible consequences of GMO releases. It is submitted that a court should not find it reasonable because such a decision would render activities under many regulatory schemes vulnerable to the same complaint.

Sensitivity is a relative thing.[152] '[S]ome judgment must be made about how great the plaintiff's deviation from the norm must be to justify denial of recovery.'[153] Judgments of hypersensitivity 'involve an evaluation of the social desirability of the plaintiff's activity, and such evaluations can change over time and may vary from place to place.'[154] Non-GM agriculture is arguably socially desirable because it creates choice for consumers and may have other advantages such as the maintenance of genetic diversity in particular species. But it is occurring in a country whose elected representatives have decided that GMO releases are also worthwhile or at least lawful.

There is some case law support for the view that lawful activities, the curtailment of which would have potentially serious consequences for development and the economy, are not nuisances.[155] Nevertheless, the public interest in the commission of the alleged nuisance is generally an irrelevant factor in the assessment of reasonableness of interferences.[156] The courts neither allow it to determine whether a nuisance has been committed or whether an injunction should be granted. This does not mean, however, that public interest is irrelevant to the linked but separate assessment of hypersensitivity. It is submitted that just as public interest is relevant in determining the nature of a locality, as discussed in

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[152] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 630.
[153] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 630.
[154] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 630.
[155] In *Hunter v Canary Wharf Ltd* [1997] AC 655 (HL), the alleged cause of the interference with the plaintiffs' television reception was the mere presence of the defendant's building. The building had planning approval and was otherwise lawful. The House of Lords found there was no wrongful interference. Baker suggests that this was because otherwise the freedom to build would be curtailed with potentially serious consequences for development and the economy. C Baker, 'Canary Wharf: the boundaries of private nuisance' (1997) 141 *Solicitors Journal* 524, 525.
[156] *The Attorney-General v The Council of the Borough of Birmingham* (1858) 4 K & J 528; 70 ER 220; *Pennington v Brinsop Hall Coal Company* (1877) 5 Ch D 769; *Shelfer v City of London Electric Lighting Co* [1895] 1 Ch 287; *Munro v Southern Dairies Ltd* [1955] VLR 332; *Lester-Travers v City of Frankston* [1970] VR 2; *Miller v Jackson* [1977] 1 QB 966. See also F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 634; C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-6; R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 484.

subsection (d) below, it is relevant to the evaluation of the social desirability of the plaintiff's activity.[157]

In claiming that non-GM farmers are hypersensitive, commercialisers should therefore argue that the social desirability of the plaintiff's activity is not so great as to justify a finding that such activity is not hypersensitive. In areas not designated GM-free under State legislation it is submitted that a court should agree with this view. However, in or near areas designated GM-free under State law an argument that non-GM or even organic agriculture is a 'sensitive use' is less likely to be successful. This factor begins to merge with the factor of locality, which is discussed in the next subsection.

(d) Locality

A crucial factor in determining whether interferences caused by GMO releases are unreasonable is the locality where the interference occurs.[158] What may be a nuisance in one locality might not be so in another.[159]

The nature of activities in a particular area often suggests the degree of use and enjoyment that can be reasonably expected by people in that area. Prima facie people would expect some contamination from neighbours' properties in agricultural areas.[160] Provided the neighbours carry on their agriculture in a reasonable and proper manner, there should be no nuisance.[161] As noted above, the keeper of animals infected with a contagious disease will not be liable in nuisance if the disease is communicated to other animals on adjoining lands.[162] Such an outbreak would be 'a misfortune incidental to the natural user of the land'.[163] However, the keeper of such animals must keep the animals on their land and

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[157] Cardwell suggests that a court may baulk at weighing up the respective interests of GM farmers and other farmers. M Cardwell, 'The release of genetically modified organisms into the environment: public concerns and regulatory responses' (2002) 4 *Environmental Law Review* 156, 163.

[158] *Sturges v Bridgman* (1879) 11 Ch D 852 at 865; *Polsue & Alfieri Ltd v Rushmer* [1907] AC 121 (HL); *Pittar v Alvarez* (1916) 16 SR (NSW) 618 at 627-8; *Clark v Sloane* [1923] NZLR 1129 at 1132-3; *Vanderpant v Mayfair Hotel Co Ltd* [1930] 1 Ch 138 at 166; *Dunstan v King* [1948] VLR 269 at 272; *Bloodworth v Cormack* [1949] NZLR 1058 at 1062; *Field v South Australian Soccer Association* [1953] SASR 224 at 231; *Munro v Southern Dairies Ltd* [1955] VLR 332 at 337; *Kidman v Page* [1959] Qd R 53 at 65-6.

[159] *Sturges v Bridgman* (1879) 11 Ch D 852 at 865.

[160] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 531; D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 147.

[161] *Clark v Sloane* [1923] NZLR 1129 at 1132 (with respect to noise from a hall).

[162] *Ruhan v The Water Conservation and Irrigation Commission (NSW)* (1920) 20 SR (NSW) 439 at 444. Action brought in nuisance and negligence and the two are not clearly distinguishable in the decision.

[163] *Ruhan v The Water Conservation and Irrigation Commission (NSW)* (1920) 20 SR (NSW) 439 at 444.

there must be no negligence in the keeping of them.[164] By analogy it could be argued that at the very least, provided commercialisers keep their organisms on their property, the spread of pollen or seeds should be treated the same way as the spread of disease-causing organisms from one property to another – part of the reasonable use of land. There is no relevant difference between contamination caused by GMOs compared with that caused by other organisms, disease-causing or otherwise. Both could cause damage to other organisms. The success of this analogy though depends upon commercialisers establishing that compliance with the GTR's licence conditions and State moratorium legislation is all that is required for there to be no negligence in releasing the GMOs onto their land. As discussed in Part 5.3 below, it is possible that a court may still find there has been negligence in such cases.

Furthermore, if the defendant's activities are common to the area that can indicate that those activities are a reasonable use by the defendant. As more GMOs are raised in any particular locality, the more likely it becomes that that form of agriculture and the possible effects of it will be considered common and therefore reasonable.[165] However, GM is a new technology. Its widespread use cannot be expected at this early stage. The issue for commercialisers is whether GM agriculture is nevertheless just a part of 'agriculture' in which contamination is to be expected and is reasonable. Many of the same issues relevant to whether a non-GM farmer is hypersensitive for the purposes of nuisance are relevant to this factor. With respect to locality though, the public interest in the defendant's activity is more clearly relevant.[166] Therefore commercialisers should show that their industry is an economically worthwhile one. That the law must keep up with changes in the nature of localities is also in favour of a new technology.[167] Nevertheless, the 'newness' of the technology makes it difficult to predict what a court will assess as reasonable. Commercialisers in or near GM-free areas are in a particularly precarious situation even when acting lawfully. GM agriculture will not, or will not usually, occur in GM-free areas. Generally, the more exclusively a locality is devoted to a particular land usage, the greater the presumption that a different form of land usage is unreasonable if it interferes with the

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[164] *Ruhan v The Water Conservation and Irrigation Commission (NSW)* (1920) 20 SR (NSW) 439 at 444-5. In that case there was negligence because defendant allowed excreta from pigs infected with swine fever to build up along the fence with the plaintiff's property, and the excreta was pushed through the fence by defendant's pigs. The plaintiff's pigs caught the disease from the excreta.

[165] This has also been suggested by M Cardwell, 'The release of genetically modified organisms into the environment: public concerns and regulatory responses' (2002) 4 *Environmental Law Review* 156, 163.

[166] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 634.

[167] *Field v South Australian Soccer Association* [1953] SASR 224 at 231. See also *Munro v Southern Dairies Ltd* [1955] VLR 332 at 338.

use and enjoyment of others.[168] Additionally, the 'ordinary' person in such areas may be more likely to be one to whom the GM status of their property is important. Such people may be more likely to object to GM invasion although this is not certain. It is relevant here that the States differ in how they create 'GM-free' areas. As discussed in Chapter 3, in SA, WA and Tasmania,[169] the entire jurisdiction has been designated a 'GM-free area'. However, in the ACT, NSW and Victoria, the State is designated as one where only the cultivation of certain GMOs is prohibited. It is arguable that in these later States it is no more likely that residents will complain about GM contamination by non-prohibited GMOs than in States without moratorium legislation.

Finally, commercialisers can point to the courts' deference to planning legislation as providing a useful analogy in their defence.[170] Compliance with relevant planning legislation weighs heavily in favour of a finding that a particular use is reasonable in a particular locality.[171] Planning decisions are clearly relevant to characterising the locality in which the interference occurs and can change the character of the neighbourhood concerned.[172] Approvals by the GTR or State authorities may do the same. Courts concede that local planning authorities are generally better equipped than the courts to balance the conflicting interests of the parties, the locality and, in some cases, the nation.[173] By analogy, compliance with the *GT Act*, particularly if the GTR has approved the GMO concerned for release in a particular area, should also be of considerable weight in favour of the commercialiser. As in planning schemes, individuals have the right to make submissions with respect to the GTR's decision.[174] Further, as with planning disputes, if an action in nuisance is successful in such a case, then GM opponents will be able to defeat

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[168] J G Fleming, *The Law of Torts* (9th ed, LBC Information Services, Sydney, 1998), p 469.
[169] The proposed Genetically Modified Organisms Control Bill 2004 (Tas) will, if enacted, also mean that all of Tasmania could be declared GM-free. See section 3.3.3 above.
[170] See, eg, *Gillingham Borough Council v Medway (Chatham) Dock Co Ltd* [1993] QB 343 (public nuisance case).
[171] *Allen v Gulf Oil Refining Ltd* [1981] AC 1001 at 1013-4 (HL) although it is noted that compliance with zoning requirements cannot be conclusive because a defendant might carry out permitted activities in an unreasonable way. See also *Wheeler v JJ Saunders Ltd* [1996] Ch 19 (CA). Cf *Feiner v Domachuk* (1994) 35 NSWLR 485 aff'd *Domachuk v Feiner* [1996] CA(NSW) BC9606851 (Unreported, Sheller JA, Giles and Simos AJJA, 28 November 1996). See also G Murphy and L Rutherford, 'Planning decisions and nuisance' (1995) 139 *Solicitors Journal* 388 (re danger of allowing planning legislation to determine the result of an action in nuisance).
[172] *Gillingham Borough Council v Medway (Chatham) Dock Co Ltd* [1993] QB 343 (a public nuisance case) where a planning approval in effect changed the character of the area concerned and meant that the defendant's activities were not a nuisance whereas in another locality they may have been.
[173] E McKendrick, 'Public Nuisance and the Environment' (1993) 1 *Tort Law Review* 14, 15. See also *Gillingham Borough Council v Medway (Chatham) Dock Ltd* [1993] QB 343 at 359 and 361.
[174] In respect of some decisions anyway. See Chapter 2.

a scheme deliberately created by Parliament. The courts seek to avoid this in the case of planning disputes.[175]

However, unlike in planning scheme decisions, the GTR does not have to balance the interests of the community against those of individuals likely to be adversely affected by the release being considered.[176] Individuals also have no right to appeal against the final decision of the GTR.[177] Accordingly, the courts' deference to the GTR's decisions will in effect create a statutory authority defence in a factual situation in which it would otherwise not be available.[178] The courts will be slow to do this.[179] The introduction of the State moratorium legislation though may improve commercialisers' position in those jurisdictions where the State has not been declared GM-free. Although it is uncertain what are the relevant considerations under the legislation, there will have been some assessment by the relevant Minister of the economic acceptability of GMO releases and a decision not to prohibit the particular release and also, in Victoria's case, not to declare the State GM-free. It is submitted that a court is as likely to defer to such decisions as to planning decisions.

(e) Precautions taken by defendant

It is also material to the assessment of reasonableness whether the defendant could have carried out their activities but, by taking reasonably practical steps, could have prevented an undue interference with the use by the plaintiff of their land.[180] If the defendant could have taken such steps but did not, that may be almost conclusive evidence that the activity was unreasonable.[181] On the other hand, provided the locality is appropriate for the

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[175] See, for eg, *Allen v Gulf Oil Refining Ltd* [1981] AC 1001.

[176] But query how much of the public interest the planning authority actually takes into account. As Rook points out, it is unlikely, for eg, that they actually consider the effect on television reception when giving approvals to construct high rise buildings. D Rook, 'Private Nuisance – A Proprietary Interest' (1996) 4 *Tort Law Review* 181, 183. Yet planning approval was very influential in the decision in *Hunter v Canary Wharf Ltd* [1997] AC 655 (HL).

[177] A Senate Committee recommended that such a right be included in the legislation but this was not done. *Cautionary Tale* Report, p xvi. There are some limited rights of appeal in *GT Act*. See Chapter 2.

[178] See section 5.2.5 below.

[179] In *Wheeler v JJ Saunders Ltd* [1996] Ch 19 at 35.

[180] Expense and effectiveness are taken into account in assessing practicality. See *Lester-Travers v City of Frankston* [1970] VR 2.

[181] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 488. See *Painter v Reed* [1930] SASR 295 at 304; *McMahon v Catanzaro* [1961] QWN 22; *Bayliss v Lea* [1961] SR (NSW) 247 at 271-2, aff'd [1962] SR (NSW) 521 (FC).

activity, the exercise of proper care in the selection of methods used to carry out the activity should generally exonerate the defendant from liability.[182]

With respect to most GM animals therefore, the relative ease with which the defendant could prevent contamination, for example, by adequate fencing, means that contamination will in most cases be a nuisance.[183] However, in the case of GM plants, such as canola, prevention of contamination is not straightforward. One concern for commercialisers is whether compliance with the GTR's licence conditions and relevant State legislation would be 'proper care' for these purposes or whether commercialisers need to go beyond those conditions. Commercialisers are, of course, free under the *GT Act* to observe stricter conditions than those imposed by the GTR, including not proceeding with releases.

Given that the GTR's conditions are imposed for purposes other than avoiding causing an unreasonable interference with the defendant's neighbours a court is unlikely to find that compliance with such conditions per se is sufficient. However, practically, whether reasonable precautions to avoid such interference requires anything more than the GTR's conditions depends upon the particular circumstances and cannot be answered in the abstract. It is possible though that more stringent precautions than those imposed by the GTR may need to be taken to prevent commercialisers' activities being a nuisance. Further, because nuisance is a continuing tort and every new substantial interference creates a fresh cause of action,[184] a defendant may be liable for failure to incorporate new precautions regarding GMO releases when they become available. Finally, a court may find that because of the lack of clarity about the risks and possible precautions necessary it was unreasonable to release the organism at all.[185]

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[182] R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 488. See *Andreae v Selfridge & Co Ltd* [1938] Ch 1 at 5-6; *Wherry v KB Hutcherson Pty Ltd* (1987) Aust Torts Reports 80-107 at 68,748. *Contra* M Davies and I Malkin, *Torts* (4th ed, LexisNexis Butterworths, Sydney, 2003), p 324 where it is noted that private nuisance may still be, at least in some respects additional to cases of material damage, one of strict liability. This is on the basis of *Feiner v Domachuk* (1994) 35 NSWLR 485 at 493 (Aff'd on appeal but Court did not comment on that point. See *Domachuk v Feiner* [1996] (CA(NSW)) BC9606851 (Unreported, Sheller JA, Giles and Simos AJJA, 28 November 1996)) and *Bonnici v Ku-Ring-Gai Municipal Council* (2002) Aust Torts Reps 81-631 at [187]. However, it is submitted that in the first case the locality was inappropriate and, in respect of the later, the statement is obiter and only one of a very general nature.

[183] An exception may be if the defendant keeps bees and it can be established that it is the bees which are spreading GM pollen to the plaintiff's property. In that case, the defendant would not be a commercialiser of GMOs (unless the bees were GM) and the scenario is outside the scope of this study.

[184] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 633.

[185] G M F Snijders, 'Biotechnology, Property Rights and the Environment: Towards a New Legal Order?' (2002) 6 *Electronic Journal of Comparative Law* (http://www.ejcl.org/64/art64-9.html accessed 5/2/2004).

The introduction of State legislation though affects such conclusions. The State moratorium legislation generally does not set down the considerations relevant in deciding whether to declare GM-free areas, prohibit certain GMOs or to grant exemptions/permits to release in GM-free areas. Nevertheless, the legislation purports to be for the purpose of protecting agricultural markets. The relevant decision-maker should therefore have considered many of the same concerns as will be relevant to a court in nuisance proceed . Compliance with the conditions imposed under such legislation together with the G conditions would therefore be better evidence of reasonableness than compliance only with the GTR's conditions.

(f) Frequency, duration and time of interference

Frequency, duration and time of the interference are further factors considered in the determination of reasonableness. The low frequency at which many GM contaminations could be expected to occur[186] favour claims that the release is reasonable.[187] The duration of the interference is also relevant.[188] Temporary, short-lived interferences causing only amenity damage, such as where the complaint concerns overlooking a GMO or where GM animals wander across the plaintiff's land,[189] are less likely to amount to nuisance than ones causing physical damage.[190] However, in many GM contaminations, once contamination has occurred the consequences for the plaintiff will be ongoing. For example, once a crop has been contaminated it may be difficult for the plaintiff to remove the GMO and the particular harm claimed by the plaintiff avoided. This factor points to the unreasonableness of such interferences.

Related is the time when the interference occurs. Although this generally applies to the particular time in any 24 hours,[191] it could also refer to the time of the year. If contamination occurs at a time when the plaintiff's organisms will not be affected then the interference is less likely to be unreasonable. For example, the plaintiff's organisms may

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[186] Particularly given that the GTR will have assessed risks of contamination to the environment generally and imposed necessary controls.
[187] Eg, *Andreae v Selfridge & Co Ltd* [1938] Ch 1.
[188] *St Helen's Smelting Co v Tipping* (1865) 11 HLC 642; *Halsey v Esso Petroleum Co. Ltd* [1961] 2 All ER 145.
[189] Note though, that there has been only one escape of the organism from the commercialiser's land does not necessarily prevent an action in nuisance. See *British Celanese Ltd v A H Hunt (Capacitors) Ltd* [1969] 2 All ER 1252. Further, interference for a short time can be a nuisance if it is unreasonable. See *Matania v The National Provincial Bank Ltd* [1936] 2 All ER 633 at 642-5.
[190] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 632. See *Crown River Cruises Ltd v Kimbolton Fireworks Ltd* [1996] 2 Lloyd's Rep 533.
[191] Eg, *Daily Telegraph Co Ltd v Stuart* (1928) 28 SR (NSW) 291.

have a different flowering period to that of the defendant's. Therefore cross-pollination would be unlikely. In such cases, the interference is less likely to be unreasonable.

(g) Defendant's motive

Finally, the defendant's motive for the activity, if any, is relevant. If a commercialiser acts with malice in releasing their GMO that can cause what would otherwise have been a reasonable interference, to be an unreasonable one and therefore a nuisance.[192] But simply knowing a particular thing, such as GM contamination, could happen or has happened is not enough for malice to be found. This factor is therefore unlikely to be relevant in most cases under consideration.

(h) Whether GMO releases cause substantial and unreasonable interference

The introduction of the State moratorium legislation is of crucial significance in determining the substantiality and unreasonableness of interferences arising from GMO releases. GTR authorisation will also be of significance.

With respect to claims arising from social impacts which are a protected interest for the purposes of nuisance, it has been submitted that there will be no unreasonable interference. Plaintiffs claiming to suffer significant distress because of fear that GMO releases could harm their health or that of their animals and plants should be considered hypersensitive. In particular, that the GTR considers risks to human health and the toxicity of GMOs for other organisms means, it has been submitted, fear of harm is unreasonable. To find otherwise would expose many regulated activities to the same claims.

Claims arising from economic impacts can be divided into three groups depending upon the release site's classification under State moratorium legislation.

The first group are GMO releases in areas designated GM-free under State law without an exemption/permit. In SA, WA and Tasmania, the entire jurisdiction has been designated a 'GM-free area'. It is submitted that such releases will generally be substantial and unreasonable interferences. First, such releases are contrary to regulation. There will therefore be a strong presumption that interferences caused by such releases are unreasonable and substantial. Secondly, GM status could be expected to be significant to

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[192] *Christie v Davey* [1893] 1 Ch 316; *Hollywood Silver Fox Farm Ltd v Emmett* [1936] 2 KB 468. But see *Mayor of Bradford v Pickles* [1895] AC 587 at 601. See also J G Fleming, *The Law of Torts* (9th ed, Law Book Company, Sydney, 1998), pp 472-3 with respect to that decision.

farmers in such areas. Arguments that a plaintiff is abnormally sensitive in objecting to GMO releases or GM contamination are therefore unlikely to succeed in such areas. Finally, finding nuisance in such cases would not undermine existing regulatory schemes.

Where a release occurs pursuant to an exemption/permit in a GM-free State or because the GMO is not prohibited under the legislation of the relevant State, the outcome is less certain.[193] However, it is submitted that in light of the commercialiser having regulatory approval to release, and assuming compliance with any conditions imposed, a court would not and should not find there has been an unreasonable interference in such cases unless there has been material damage. Importantly, the release is for the purposes of agriculture rather than leisure. Such releases will also not be contrary to regulation. Further, the GTR and State regulator together will have assessed most if not all considerations relevant to the court in nuisance proceedings. In particular, the GTR will have considered safety and environmental concerns; the State regulator will have considered the economic impact and possibly other social objections to GMOs. A finding of nuisance would conflict with a regulatory decision not to prohibit the release of that GMO. The release though could still be in a locality where, depending upon the number and extent of exemptions/permits granted and the number of GMOs not covered by the legislation, such releases are uncommon. GM status may therefore be significant to farmers in the area.

Finally, liability for releases in those States without moratorium legislation, namely Queensland and NT, is the most uncertain of the scenarios. There is no legislation demonstrating the State's conclusions on the acceptability or otherwise of the socio-economic consequences of GMO releases.[194] Because the relevant State is not 'GM-free' it should be easier for commercialisers to successfully assert that plaintiffs are hypersensitive than in GM-free States.[195] Nevertheless, it is submitted that interferences will be found unreasonable by a court even if there has been no material damage. A finding of liability would not be contrary to a State regulatory decision although it may conflict with a GTR decision. Whether or not an interference is unreasonable will

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[193] There is also the theoretical possibility of a release in a non-GM-free area in a State with GM moratorium legislation. However, no State has so far divided itself into different parts with respect to GM or GM-free designations. It is submitted that if this should occur, commercialisers releasing GMOs in such areas would be in the same position as this second group.

[194] There is some extra-legislative evidence although it is inconclusive on the issue of liability. See, for eg, statement by the Queensland Minster for Innovation and Information Economy: 'In relation to [GM], government policy is that we do not tell farmers what they should grow on their land.' Qld, *Parliamentary Debates*, Legislative Assembly, 7 October 2003, (Lucas, Minister for Innovation and Information Economy).

[195] Although releases may be uncommon in the particular area that may be because of the newness of the technology rather than the attitude of the neighbouring community.

ultimately depend upon the courts' deference to GTR risk assessments. Given that the GTR does not take into account socio-economic considerations, it is unlikely that a court will feel constrained by the existence of a DIR licence in making decisions regarding commercialisers' liability in nuisance.

5.2.5 *Defences to Nuisance*

Four defences may be relevant to commercialisers. These are the defences of 'coming to the nuisance', consent, statutory authorisation and the defence of 'act of god'.[196] These are considered in this section. In SA, the *Genetically Modified Crops Management Act 2004* creates a new legislative defence to tort actions brought against innocent third parties whose land is contaminated by a GM plant.[197] It would not protect commercialisers.

Commercialisers may seek to use in their defence the fact that there are others near the plaintiff's land also releasing GMOs. However, it is no defence to a nuisance action to prove that the environment was already polluted from another source[198] or that the defendant's actions were not the sole cause of the nuisance.[199] Where no individual GMO release would be a nuisance but the cumulative effect of many releases is that a nuisance arises, the court may still allow an action against all 'releasors' although the plaintiff cannot successfully sue any individual commercialiser.[200] Commercialisers would then need to negotiate between themselves to reduce the GMO threat to acceptable levels.[201]

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[196] Contributory negligence is legally available in nuisance actions provided the interference was due to negligent conduct rather than an intentional result of the defendant's act. C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-17; R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 500. See also F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 654. However, it is considered generally unlikely to succeed. C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-17. For problems in applying the defence see, eg, *Mitchell v Tsiros (No 2)* [1982] VR 301 at 303.

[197] *Genetically Modified Crops Management Act 2004* (SA) s 27(2).

[198] *Wood v Sutcliffe* (1851) 2 Sim NS 163; 61 ER 303; *Attorney-General v Leeds Corporation* (1870) 5 Ch App 583.

[199] G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), p 31. See *City of Footscray v Maize Products Pty Ltd* (1942) 67 CLR 301 at 312.

[200] G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), p 31. See *Pride of Derby and Derbyshire Angling Association Ld v British Celanese Ld* [1953] 1 Ch 149 at 154 which did not go quite so far as to determine this.

[201] G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), p 31.

(a) 'Coming to the nuisance' and consent

That the plaintiff is in a locality with GMOs present is relevant to the question of whether there has been a nuisance as discussed above. However, that a plaintiff moved to an area knowing there were or would be GM crops or animals nearby (that is, 'came to the nuisance') is no defence.[202] Nor does the plaintiff's tolerance of the growing of GMOs on a neighbouring property establish the defence of consent.

(b) Statutory authorisation

Approval by the GTR and the State regulators' of the GMO release pursuant to legislation will not be sufficient in itself for the defence of statutory authorisation.[203] For this defence to succeed, the creation of the nuisance in the performance of the authorised activity must be expressly or impliedly authorised by statute.[204] That is, any nuisance created must be the inevitable consequence of the authorised activity. The criterion of inevitability is measured according to the state of scientific knowledge at the time and what is practically feasible in view of the situation and expense.[205] With respect to GMO commercialisers, although they may have regulatory approval to release the organism and conditions may be imposed as to how that release occurs, they may still choose not to proceed with the release or to take precautions additional to any required by the regulators.[206] Nuisance is thus not inevitable. Further, the GTR and regulators' decisions are mere administrative decisions. They are, as Bates suggests with respect to other administrative decisions, unlikely to be interpreted as conferring the ability to remove a legal right to bring a nuisance action.[207] The defence is therefore unlikely to be of practical significance for commercialisers.[208]

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[202] *Bliss v Hall* (1838) 4 Bing NC 183; 132 ER 758; *R v McMeikan* (1869) 6 WW & a'B (L) 68; *Sturges v Bridgman* (1879) 11 Ch D 852 at 865; *Miller v Jackson* [1977] 1 QB 966.

[203] See generally S Kneebone, 'Nuisance and the Defence of Statutory Authority: Inferring the Intention of Parliament' (1986) 10 *Adelaide Law Review* 472; G Kodilinye, 'The Statutory Authority Defence in Nuisance Actions' (1990) 19 *Anglo-American Law Review* 72.

[204] *Attorney-General v Lane Cove Municipal Council* [1976] 2 NSWLR 1 (defence successful). See also *Edwards v Blue Mountains City Council* (1961) 78 WN (NSW) 864; *Lester-Travers v City of Frankston* [1970] VR 2; *Symons Nominees Pty Ltd v Road and Traffic Authority of NSW* (1991) Aust Torts Reports 81-081 (NSW SC); *Lawrence v Kempsey Shire Council* (1995) 87 LGERA 49 (NSW SC); *Van Son v Forestry Commission of NSW* (1995) 86 LGERA 103 (where defence failed).

[205] *Manchester Corporation v Farnworth* [1930] AC 171 at 183. See also *Nielsen v Brisbane Tramways Co Ltd* (1912) 14 CLR 354 at 369; *Tock v St John's Metropolitan Area Board* (1989) 64 DLR (4th) 620 (SCC).

[206] For eg, wider buffer zones than any imposed by the GTR could be used by the commercialiser .

[207] G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), p 32.

[208] The general rule is that common law rights may only be taken away expressly or by clear implication. See *Bathurst City Council v Saban* [1985] 2 NSWLR 704; *Rushcutters Investments Pty Ltd v Water Board of NSW* (1989) 68 LGRA 128; *Flynn v Whitehouse* (1989) 68 LGRA 275.

Nor, if the release is regulated under environmental legislation (a matter considered in Chapter 6), will authorisation under environmental legislation be an automatic defence. The rights of individuals to bring common law actions in respect of pollution of the environment are specifically preserved in the environmental protection legislation in all jurisdictions except WA.[209] The grant of an environmental approval in most jurisdictions therefore does not imply statutory authorisation for these purposes.[210]

(c) Act of god

The defence of 'act of god' is available in nuisance. It is available if, for example, wind blows GM pollen onto the plaintiff's land, such wind being so exceptional that it would not be reasonably anticipated.[211] This defence, by its very nature, is unlikely to arise in the usual case.

5.2.6 *Remedies*

The judicial remedies for nuisance are an injunction to prevent the continuation of the nuisance and damages provided the loss is not too remote. The remoteness test for nuisance is the same as that for negligence.[212] Harm must be of a kind that is reasonably foreseeable as a result of the defendant's conduct at the time of creating the state of affairs.[213] The same issues arise here as discussed below with respect to negligence and won't be repeated here.[214] Where damages are awarded, they will cover both past and future loss. However, where an injunction is awarded only past loss will be compensated.[215]

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[209] *Environment Protection Act 1997* (ACT) s 9; *Waste Management and Pollution Control Act 1998* (NT) s 7(1); *Protection of the Environment Operations Act 1997* (NSW) s 322; *Environmental Protection Act 1994* (Qld) s 24(1); *Environment Protection Act 1993* (SA) s 8; *Environmental Management and Pollution Control Act 1994* (Tas) s 10; *Environment Protection Act 1970* (Vic) s 65(1). Cf *Environmental Protection Act 1986* (WA).

[210] However, the NT legislation creates a statutory defence to common law actions for water pollution for pollution licence holders. See *Water Act 1992* (NT) s 17(2).

[211] See *Nitro-Phosphate and Odam's Chemical Manure Co v London and St Katharine Docks Co* (1878) 9 Ch D 503; *Greenock Corporation v Caledonian Railway Co* [1917] AC 556.

[212] *Overseas Tankship (UK) Ltd v The Miller Steamship Co Pty Ltd (The Wagon Mound (No 2))* [1967] 1 AC 617. See also *Cambridge Water Company v Eastern Counties Leather plc* [1994] 2 AC 264. Therefore there is no liability for damage where it could not have been reasonably foreseen that damage of that kind would have been caused. See also G Cross, 'Does Only The Careless Polluter Pay? A Fresh Examination of the Nature of Private Nuisance' (1995) 111 *Law Quarterly Review* 445. The position in Aust is expected to be the same. C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-19.

[213] See *McKinnon Industries Ltd v Walker* [1951] 3 DLR 577 at 581 (PC) where the Judicial Committee of the Privy Council decided that damage to sensitive and delicate orchids was a non-remote consequence of what had already been proved to be a nuisance.

[214] See subsection 5.3.5(c).

[215] C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-19.

Where a plaintiff has suffered material damage, damages in respect of property damage are assessed in the same way as for negligence.[216] Where there has been no material damage, damages are awarded to remedy the diminution in enjoyment of the use or enjoyment of the plaintiff's land or its fixtures. Once a plaintiff has established interference with a property right in order to establish the tort, there is no reason in principle why they cannot then recover for consequential damage such as damage to chattels[217] or personal injury[218] or economic loss from disruption by nuisance of business activities.[219] Therefore plaintiffs can receive damages for damage to their crops and/or livestock even if there has been no material damage. Damages can also be awarded for loss of profits that would otherwise have been earned from use of the land. Accordingly if the plaintiff has lost a premium that would otherwise have been paid for their product they can be compensated.[220]

Injunction is the primary remedy in the case of a continuing nuisance.[221] That the defendant must cease its activity in order to comply with an injunction is no answer to a claim for one.[222] Damages may be awarded in lieu of an injunction with respect to an ongoing nuisance although the courts are generally reluctant to do this.[223] A *quia timet* injunction, to restrain a threatened nuisance, is also possible but rarely given. A neighbour may argue in advance of a GMO release, that there is a risk of contamination and therefore seek such a remedy. To obtain one the plaintiff must prove there is a real probability that the defendant's activities are imminent and if performed will cause the plaintiff substantial

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[216] See subsection 5.3.5(e).

[217] *Harris v Carnegie's Pty Ltd* [1917] VLR 95; *Howard Electric Ltd v A J Mooney Ltd* [1974] 2 NZLR 762. Also *Crowhurst v Amersham Burial Board* (1878) LR 4 ExD 5; *British Celanese Ltd v A H Hunt (Capacitors) Ltd* [1969] 2 All ER 125.

[218] *Pelmothe v Phillips* (1899) 20 LR (NSW) 58 (FC) and dictum of Windeyer J in *Benning v Wong* (1969) 122 CLR 249 at 318. *Contra Evans v Finn* (1904) 4 SR (NSW) 297 (FC). See also F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 649. But cf C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-9 who conclude that the tort is not available for recovery re personal injury, although they do not necessarily agree with the legal position.

[219] See *Andreae v Selfridge & Co Ltd* [1938] Ch 1; *Dodd Properties (Kent) Ltd v Canterbury City Council* [1980] 1 All ER 928 (CA) (where court supported claim for loss of profits by tenant in possession); *Hunter v Canary Wharf Ltd* [1997] AC 655 at 706 (HL)(Lord Hoffmann). See also F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 649.

[220] *Campbell v Paddington Corporation* [1911] 1 KB 869.

[221] Lee and Burrell point out that the fact an injunction is the primary remedy may discourage courts from finding nuisance in GM contamination cases because it effectively overrides the regulatory scheme. M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 534.

[222] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 645.

[223] The fear is that, with respect to ongoing nuisances, this would allow the defendant to effectively buy the right to interfere with the plaintiff's rights. But it may be the courts are becoming more willing to do this. See, eg, *Marcic v Thames Water Utilities Ltd* [2002] 2 All ER 55. See further R A Buckley, 'Nuisance and the Public Interest' (2002) 118 *Law Quarterly Review* 508. Also F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 646.

damage. The degree of probability is not fixed and it depends upon the circumstances how certain it must be that the damage will happen. However, the greater the threatened injury, the more readily the court will intervene.[224] Evidence that the plaintiff has had to move a crop that could be pollinated by the GMO or plant crops sexually incompatible with the commercialiser's crops could be led to show that the plaintiff believed there was such a risk.[225] However, it is far from certain that a court would be prepared to find that the risk of harm is real, particularly with respect to a lawful release.[226]

Plaintiffs also have a remedy of self-help, or abatement, whereby they can take steps to end the nuisance. For example, the plaintiff may enter the defendant's land and remove the source of the nuisance.[227] However, abatement is not favoured by the law.[228] It is unlikely that a plaintiff could wipe out or significantly harm another's livelihood in the form of organisms they are raising and successfully rely upon abatement.[229]

5.2.7 *Conclusion with respect to Case Studies*

Possible nuisance proceedings are of concern for commercialisers. Otherwise lawful acts can be nuisances and compliance with the *GT Act* and State moratorium legislation is unlikely to be a defence on the grounds of statutory authorisation. Commonwealth and State Governments, by establishing the regulatory scheme under the *GT Act*, have arguably decided that GMO releases are in the community's interests and can therefore proceed subject to the requirements of that legislation. But it is the courts that will decide the extent to which the interests of individuals, such as neighbours of commercialisers, are to be subordinated to those of the community. Regulatory approval of a release may make a

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[224] For more regarding such injunctions see F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), pp 647-8.
[225] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 531.
[226] See M L Wilde, 'The Law of Tort and the 'Precautionary Principle': Civil Liability Issues Arising from Trial Plantings of Genetically Modified (GM) Crops' (1998) 6 *Environment Liability* 163.
[227] If the plaintiff needs to go onto their neighbour's land to abate the nuisance, the plaintiff must notify the defendant before entering the land and only use such reasonable force as necessary.
[228] *Lagan Navigation Co v Lambeg Bleaching, Dyeing and Finishing Co Ltd* [1927] AC 226 at 244-5 (HL). See also F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 644.
[229] See *Monsanto plc v Tilly* [2000] Env LR 313 where the UK Court of Appeal rejected the defence of necessity to protect third parties and the public on the facts of the case. In that case, a trespasser entered the land of a company licensed to execute research and development in trials of GM plants. The trespasser uprooted plants on the property to gain publicity. The Court said in exceptional cases, not occurring on the facts before them, a trespasser could protect those in immediate and serious danger by uprooting the whole crop. But they noted that even in an emergency, trespass was not justified where a public authority was responsible for the protection of the relevant public interest. See also, with respect to real and imminent danger, *Cresswell v Sirl* [1948] 1 KB 241 and *Workman v Cowper* [1961] 2 QB 143.

court reluctant to find private nuisance if the result is effectively to override a public authorisation by injunction.[230] However, if courts become more willing to award damages (as they may do) in place of injunctions, this may be less of a problem. It may also help balance the disparity that may otherwise arise because of the economic consequences of the nuisance and of the injunction.[231]

(a) Will there have been an interference with an interest in property?

As discussed in Chapter 1, there is little chance of the GM carnation or pig contaminating another's land, crops or animals. The harm most likely to be claimed following their release is a claim on the basis of social impact. Even where such claims arise from releases of GMOs likely to invade another's land, such as GM canola, they are unlikely to be successful in nuisance.

Two kinds of social impact claims are likely: distress arising because of the plaintiff's opposition to GMOs because of the social impacts of GMOs' release and distress because of fear of harm to person, property or business. It has been submitted that the first type of claim and claims based on fear of harm to business in the second group are not interferences with the use or enjoyment of the plaintiff's land. Claims based on fear to other interests, such as harm to the plaintiff, their family or property, would be interferences with the use or enjoyment of the plaintiff's land.

In relation to the first kind of social impact claim, it has been submitted that GMO releases are not sufficiently offensive to be an interference with the use or enjoyment of the plaintiff's land for three reasons. First, on the basis of case law. The offensive acts in the decided cases were often of a nature generally considered immoral. Whilst some GM opponents may consider the technology to be immoral, it is unlikely that general community standards place it in the same class as prostitution or sex shops. It is even less likely that a court would agree that GMO releases are capable of corrupting or depraving ordinary members of the public as pornography sold in sex shops was found to be. Secondly, in assessing what is offensive, the locality where the release occurs is relevant. Commonwealth and State Parliaments control where releases occur. Approvals to release under the *GT Act* can specify the localities in which releases may, or may not, occur. In

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[230] M Lee and R Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65 *Modern Law Review* 517, 534.
[231] R A Repp, 'Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift' (2000) 36 *Idaho Law Review* 585, 611.

addition, the States have the power to prevent releases in particular areas. Provided commercialisers comply with such legislation, courts should be reluctant to interfere particularly as there will be genuine conflict of opinion over whether such releases are offensive. Finally, it is difficult to justify claims of interference for the purposes of nuisance succeeding on the basis of objection to GM, if claims of nuisance on the basis of objection to other types of agricultural production are not also permitted to succeed. That could, however, render agriculture unworkable. In respect of the second kind of social impact claim, it has been submitted that fear of harm to the plaintiff's business should not be treated as an interference for the purposes of nuisance on the basis of *Victoria Park.*

Interference may also be claimed on the basis of economic impacts of releases. Such claims may in some cases be considered claims with respect to material damage. Commercialisers will then be prima facie liable in nuisance. For material damage, a significant amount of the invading organism or its material needs to be on the plaintiff's property and that presence must cause a diminution in property value. It has been submitted that if there is a visually discernable adverse consequence of the invasion, such as where a crop dies, there will be a significant amount of material present. However, if there is no visually discernible consequence it has been submitted that whether a significant amount of contamination is present should be determined by the relevant legislative or regulatory requirements in respect of the characteristic claimed to have been adversely affected. Contamination in sufficient levels, for example, to result in the plaintiff having to comply with legislative requirements should be material damage. In this regard, the new State moratorium legislation regulating GMOs is important. It creates a further regulatory regime that those inadvertently contaminated may need to comply with and therefore expands the class of people who may suffer material damage.

Where, however, the consequence is not due to a legislative or regulatory threshold being crossed it has been submitted that there is no significant contamination and therefore no material damage. For example, loss of organic status is due to the crossing of a voluntary rather than legislative threshold. The subjective nature of the thresholds leading to these types of adverse consequences should mean, it has been submitted, that they should not be used to judge whether there is material damage. Instead, whether there is nuisance in such cases should be determined on the basis of whether there has been a substantial and unreasonable interference with the plaintiff's interests despite no material damage having occurred. The interference complained of in such cases is one with the plaintiff's use or

enjoyment of land. The advantage of this approach for commercialisers is the burden of proof is then on the plaintiff to prove that there has been a substantial and unreasonable interference. The advantage for the community is that it gives the court the opportunity to better balance the interests of both parties. It is relevant here that the States had the opportunity to clarify GM thresholds in the moratorium legislation. Only Victoria and SA did so.[232] However, even they have only provided for the setting of thresholds establishing how much GM contamination causes a crop to be 'GM'. Thresholds have not actually been set nor is it clear on what basis they will be determined. Further, such thresholds will be relevant only for the purposes of the moratorium legislation.

With respect to the less immediate consequences of contamination, such as liability to patent holders, the need to take precautions or the need to comply with a regulatory scheme previously inapplicable, most of these are likely to be considered interferences with the plaintiff's use or enjoyment of land protected by nuisance. Accordingly even if they are the only claims made, there may be a nuisance. The exceptional group are those claims arising because of a need to pay patent licence fees. Such claims, it has been submitted, are not interferences with the use or enjoyment of land protected by nuisance. However, it is unlikely that such claims would be the only harm relied upon by a plaintiff. To have suffered such consequences there will in most cases have been an invasion and, as described above, in that case there may be material damage or an interference with the use or enjoyment of the plaintiff's land protected by nuisance. The issue will then again be whether the interference is substantial and unreasonable.

(b) Will the interference be substantial and unreasonable?

Given that some of the claims described in Chapter 1 may be an interference for the purposes of nuisance, commercialisers' liability will largely depend upon the court's assessment of the substantiality and reasonableness of the interference. The court determines reasonableness by examining all relevant factors. This need to assess reasonableness in each case means an assessment needs to be made in respect of each GMO and each new circumstance of release. Different organisms and different localities of release in particular will mean different levels of risks of contamination. Different farming practices followed by the parties will also be relevant. Compliance with the *GT Act* and any other relevant regulations will not, however, of itself prevent a successful

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[232] *Genetically Modified Crops Management Act 2004* (SA) s 4(1); *Control of Genetically Modified Crops Act 2004* (Vic) s 7(1). See further section 3.3 above.

claim in nuisance. Nor, as discussed in section 5.2.4 above, will the fact that the defendant's activity is arguably of public benefit be enough of its own to prevent a finding of nuisance.

In cases of material damage caused by GMOs, it is submitted that nuisance will usually be made out because the courts' tendency is to view activities causing material damage as unreasonable.[233] It has been submitted though that in respect of social impact claims, fear for human, animal or plants' safety is unreasonable because of the GTR's assessment of the risks to such safety. Significant distress despite such assessment could be asserted to arise only in those who are extra-sensitive. Further, a finding of nuisance in such cases could give rise to a proliferation of nuisance claims.

It would have been preferable for commercialisers if the *GT Act* required the GTR to take into account socio-economic consequences in making licensing decisions. GTR approval may then have been more influential in nuisance cases in showing the reasonableness of the release. However, the recent introduction of the Designated Areas Policy Principle, prohibiting the GTR from issuing licences to release GMOs in designated areas, and the even more recent introduction of State moratorium legislation goes some way in assisting commercialisers in this matter. State legislation in particular strengthens the position of commercialisers releasing GMOs with appropriate exemptions/permits or because the GMO release concerned is not prohibited. Regulatory decisions will have taken into account, in effect, the economic interests of other farmers and their rights to undertake different farming practices. The States can and should have determined whether a person or their farming practices is to be protected from interference by GMO releases when deciding whether and where to declare designated areas or prohibit/allow certain GMO releases. If a GM-free area is declared, the Minister has effectively decided that economic interference with non-GM agriculture is unacceptable. Conversely, it has been submitted that where an area is not declared GM-free, an exemption/permit is granted or a GMO is not prohibited by the legislation, courts should be less willing to intervene and declare an authorised release a nuisance where there has been no material damage. In those States without moratorium legislation though, it has been submitted that interferences not causing material damage may still be found to be unreasonable.

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[233] D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 151.

In all cases, commercialisers should consider whether there are precautions additional to compliance with the *GT Act* and State legislation and any conditions imposed by the regulators that could reasonably be taken to prevent contamination or fear of contamination.[234] The taking of precautions is likely to be extremely influential on courts deciding whether or not commercialisers have made reasonable use of their land and are therefore liable in nuisance. For example, commercialisers should ascertain which varieties their neighbours are growing within outcrossing range of their GMO and where they intend to market their crops.[235] Commercialisers should then consider planting distances between their organisms and those of their neighbours. These depend to some extent on the tolerance levels for GMOs set by domestic and overseas regulatory authorities.[236] Commercialisers may also need to clean out bins and trucks and other equipment after use to prevent contamination.[237] Commercialisers or their industry association should also ensure that S&IP systems are developed thereby decreasing the threat to neighbours and the corresponding threat of nuisance liability.[238]

5.3 NEGLIGENCE

5.3.1 *Introduction*

Negligence is the breach of a duty to take reasonable care. The plaintiff must prove that a duty of care was owed by the defendant to them, that the defendant breached that duty, that the breach caused the plaintiff damage and that the damage suffered is not too remote.

Damage is the gist of negligence.[239] If the plaintiff suffers damage for the purposes of negligence, the type of damage to a great extent determines the principles used to decide liability. Accordingly, as in nuisance, how the impacts described in Chapter 1 are classified for the purposes of negligence will be critical. The next section, 5.3.2, considers

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[234] See T P Redick and C G Bernstein, 'Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date With Damocles' (2000) 30 *Environmental Law Reporter* 10328 with respect to further precautions.
[235] T P Redick and C G Bernstein, 'Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date With Damocles' (2000) 30 *Environmental Law Reporter* 10328 text accompanying fn 50, citing W Vogt, 'Know Your Neighbors: Best Bet to Avoid Challenges With Pollen From Adjacent Corn Fields Is to Understand What's Been Planted' (February 2000) *Prairie Farmer* 20 (not seen).
[236] T P Redick and C G Bernstein, 'Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles' (2000) 30 *Environmental Law Reporter* 10328 text accompanying fn 14.
[237] T P Redick and C G Bernstein, 'Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles' (2000) 30 *Environmental Law Reporter* 10328 text accompanying fn 135.
[238] T P Redick and C G Bernstein, 'Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles' (2000) 30 *Environmental Law Reporter* 10328 text accompanying fn 13 although they only consider nuisance through loss of export market.
[239] *Williams v Milotin* (1957) 97 CLR 465 at 474.

the meaning of damage for these purposes. The first part of that section, 5.3.2(a), describes the types of 'damage' compensable under the law of negligence. Subsections 5.3.2(b), (c) and (d) outline the facts of three recent decisions as illustrations of those types of damage. Two are recent High Court decisions and the third is a decision of the Victorian Supreme Court. The final subsection, 5.3.2(e), considers whether all or some of the impacts described in Chapter 1 is compensable damage for the purposes of negligence.

If all or some of the impacts following GMO releases is compensable damage, the next concern is whether a duty of care is owed by commercialisers to others in respect of that damage. Sections 5.3.3 and 5.3.4 consider duty of care. Section 5.3.3 summarises the legal requirements for a duty of care. These requirements are then applied in section 5.3.4 to those impacts described in Chapter 1 for which compensation in negligence is possible. The relevance, if any, of compliance with the *GT Act* and State moratorium legislation in the establishment of a duty of care is also considered in this section.

The remaining elements of negligence are examined in section 5.3.5. Once again the relevance, if any, of compliance with the *GT Act* and State legislation in satisfying those elements is considered. Section 5.3.6 contains the conclusions.

5.3.2 *Damage*

(a) Types of damage

Actual harm must be suffered by the plaintiff for a successful cause of action in negligence. What qualifies as actionable damage in negligence is a question of policy.[240] Simply because something is unwanted does not make it 'damage'. Once damage sufficient to form the basis of a negligence action is established though, other losses may be recoverable although such losses alone would not be sufficient to found an action.[241] Personal injuries, that is bodily harm, are actionable damage. Distress or other emotional reaction, on the other hand, is not compensable in negligence if that is the only 'harm' suffered by the plaintiff.[242] Fear by itself, even of impending death, is an emotional reaction for which no damages will be awarded.[243]

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[240] J G Fleming, *The Law of Torts* (9th ed, Law Book Company, Sydney, 1998), p 216.
[241] J Stapleton, 'The Gist of Negligence: Part I' (1988) 104 *Law Quarterly Review* 213, 215-7.
[242] *Caveley v Chief Constable of the Merseyside Police* [1989] AC 1228 (H of L); *APQ v Commonwealth Serum Laboratories Ltd* [1999] 3 VR 633, 641; *van Soest v Residual Health Management Unit* [2000] 1 NZLR 179 (NZ CA). In a recent decision of the High Court, many members of the Court note without disapproval, in obiter, that emotional upset alone is not compensable. See *Tame v NSW* (2002) 211 CLR 317

Distress or anxiety suffered by a person may cause them to vomit or have some other relatively minor physical expression. There is uncertainty as to what is the minimum damage recognised in a negligence claim. Nevertheless, such physical injuries are unlikely to be sufficient.[244] Should the anxiety or distress be sufficiently serious, however, to be or lead to a pathological condition such as a recognisable psychiatric[245] or physical injury a person may have a successful cause of action in negligence. It should be noted though that it has traditionally been more difficult to establish that a defendant owes a plaintiff a duty of care in cases where the plaintiff suffers mental rather than physical harm.[246]

'Property damage' is physical damage to or destruction of tangible property.[247] It is harm of an actionable nature in negligence. As a result of damage to their property, plaintiffs may suffer 'consequential economic loss', that is, economic loss that is the immediate consequence of the property damage they incurred.[248] That harm is also compensable. 'Pure economic loss' is 'economic loss suffered by the plaintiff that is not consequential upon injury to the plaintiff or damage to the plaintiff's property.'[249] Such loss is also, in limited circumstances, recoverable.

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at [7] (Gleeson CJ) (although expressed as 'save in exceptional cases' which may indicate there may be exceptions), [44] (Gaudron J), [193] (Gummow and Kirby JJ), [285]-[298] (Hayne J).

[243] *Hicks v Chief Constable of the South Yorkshire Police* [1992] 2 All ER 65 at 69. Note also *Sutherland Shire Council v Heyman* (1985) 157 CLR 424 at 490 where Brennan J said 'damages in respect of personal injury cannot be awarded for the risk of personal injury even though the prospect of such injury is present and immediate.' See also N J Mullany, 'Fear for the Future: Liability for Infliction of Psychiatric Disorder' in N J Mullany (ed), *Torts in the Nineties* (LBC Information Services, Sydney, 1997), p 101.

[244] J Stapleton, 'The Gist of Negligence: Parts I and II' (1988) 104 *Law Quarterly Review* 213 and 389 respectively. In practical terms, the cost of litigation is likely to outweigh the compensable value of the 'injury' although the availability of class actions lessens the importance of this factor.

[245] If the damage is too vague it is incapable of recognition. *Roberts v Roberts* (1864) 5 B & S 384; 122 ER 874.

[246] Eg, *Mt Isa Mines v Pusey* (1970) 125 CLR 383; *Jaensch v Coffey* (1983-4) 155 CLR 549; *Tame v NSW* (2002) 211 CLR 317. See also *Civil Law (Wrongs) Act 2002* (ACT) ss 32-36; *Civil Liability Act 2002* (NSW) ss 27-33; *Civil Liability Act 1936* (SA) s 33; *Civil Liability Act 2002* (Tas) Part 8; *Wrongs Act 1958* (Vic) s 23; *Civil Liability Act 2002* (WA) Part 1B.

[247] The damage must be caused by a force external to the property. If a person buys a defective building or product but discovers the defect before it causes physical damage to the building or product itself or to any person or other property, the plaintiff suffers only pure economic loss in Australian law. F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 370.

[248] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 369.

[249] C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 8-10. Pure economic loss can itself be divided into groups. See, for eg, the categories described in B Feldthusen, *Economic Negligence. The Recovery of Pure Economic Loss* (3rd ed, Carswell Thompson Professional Publishing, Ontario, Canada, 1994), p 2. The group most relevant to this study is relational economic loss, sometimes referred to as loss through 'the ripple effect'. Relational pure economic loss arises from damage to a person or property on which the plaintiff's business is economically dependent. C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 8-34. The division of pure economic loss cases into groups has been rejected in Aust. See P Cane, 'The Blight of Economic Loss: Is There Life After *Perre v Apand*?' (2000) 8 *Torts Law Journal* 246, 254; J Stapleton, 'Comparative Economic Loss: Lessons from Case-Law-Focused "Middle Theory"' (2002) 50 *UCLA Law Review* 531, 542 fn 45.

The fact situations in *Perre v Apand Pty Ltd*[250] ('*Perre*'), *Johnson Tiles Pty Ltd v Esso Australia Pty Ltd*[251] ('*Johnson Tiles*') and *Dovuro Pty Ltd v Wilkins*[252] ('*Dovuro*') discussed immediately below provide useful illustrations of the types of damage for the purposes of negligence actions.

(a) *Perre*

In *Perre* a farm owned by the Sparnons was contaminated by the potato disease, bacterial wilt.[253] Contamination followed the supply of infected seed potatoes to the Sparnons by the respondent. The Sparnons were commercial potato growers in SA. The respondent was a potato crisp manufacturer. The importation of the infected seed potatoes into SA by the respondent was illegal.[254] The disease caused physical damage to the Sparnons' potatoes. The Sparnons therefore suffered property damage because their tangible property, the potatoes, was damaged by the disease introduced by the respondents. The Sparnons also suffered consequential economic loss, such as lost profits they would otherwise have received upon the sale of vegetables grown on their property and the costs of eliminating the disease from their land. The Full Court of the Federal Court found the respondent liable in negligence to the Sparnons for all such damage.[255] The respondent did not appeal to the High Court from that decision.

The Perres were a group of potato producers on properties between about 2 to 3 1/2 kms around the Sparnons' farm. Some of them grew potatoes while others processed and packed them. The disease did not spread to their properties and they had no contractual relationship with the respondent. However, their businesses were affected by the damage to the Sparnons' property. Most of the Perres' potatoes were sold in WA where they received twice as much as they did in SA. Upon the outbreak of the disease on the Sparnons' property, the Perres lost their export market. Regulations in WA[256] prohibited the sale of potatoes in that State if grown on a property, or processed with other potatoes grown, within 20 kms of a property infected with bacterial wilt in the previous five years. Due to those regulations the entire region in which the Sparnons lived lost its export

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[250] (1999) 198 CLR 180.
[251] (2003) Aust Torts Reports 81-692.
[252] (2003) 201 ALR 139.
[253] Caused by *Pseudomonas solianacearum*.
[254] Pursuant to *Fruit and Plant Protection Act 1968* (SA).
[255] *Perre v Apand Pty Ltd* (1997) 80 FCR 19 (Full Fed Ct). The defendant was also found liable for breach of contract arising from implied warranties as to fitness of the seed potatoes.
[256] The Plant Diseases Regulations 1989 (WA) made under the *Plant Diseases Act 1914* (WA).

approved status despite the fact that the disease did not spread beyond the Sparnons' property. There was no physical damage to the potatoes owned by the Perres. Landowners also claimed that the value of their land had been reduced because it could not be used for growing potatoes for the WA market.

The High Court unanimously held that the loss suffered by the Perres was pure economic loss.[257] Such economic loss was caused by the respondent's damage to a third party's, the Sparnons, property. Two of the judges found that certain of the Perres were one step further removed from the property damage suffered by the Sparnons than the other members of the Perre group. Accordingly, although all seven judges found that those of the Perre group who grew potatoes succeeded in negligence, only five found that those who processed and packed the potatoes could succeed.[258] The reasons for the decision are discussed in the next sections, 5.3.3 and 5.3.4.

(c) ***Johnson Tiles***

Johnson Tiles[259] concerned a group proceeding brought following the cessation of gas supply to all domestic consumers and most commercial gas consumers in Victoria from 25 September to about 6 October 1998.[260] Cessation followed an explosion at the Longford gas processing plant controlled and operated by the defendant.[261] Claimants were divided into three groups: commercial consumers, workers stood down after gas supply to their employer ceased and domestic consumers.

Esso admitted it had been negligent, that is, that it had breached a duty of care if one was found to exist, in the management and operation of the Longford plant.[262] At issue was whether it owed a duty of care to consumers. Briefly, Gillard J found that Esso owed a duty of care to commercial gas consumers, but not domestic consumers, in the management and operation of its gas processing plant to avoid stoppage of gas causing

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[257] Gummow J said that the Perres' case 'is best approached on the substantial footing that they do not complain of "physical" damage to their land or the tangible assets used in their business operations there'. (1999) 198 CLR 180 at [166].

[258] McHugh and Hayne JJ held that those of the Perre group who had only a packing and processing interest could not recover for pure economic loss. (1999) 198 CLR 180 at [144]-[145] and [352]-[353] respectively.

[259] (2003) Aust Torts Reports 81-692.

[260] Some consumers were provided with gas earlier than others.

[261] There was an explosion at only one of the three gas plants at Longford but as a consequence, the other two plants were shut down. It was found that the shutting down of all plants in these circumstances and therefore cessation of all gas supply should have been reasonably foreseeable to the defendants. *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [50].

[262] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [49]-[51].

property damage.[263] It did not owe a duty of care to any group of consumers to avoid pure economic loss. No duty of care was owed to the stood down workers.[264] Esso was therefore liable for some property damage and consequential economic loss resulting from that damage caused by the negligence. It was not liable for any pure economic loss caused by its negligence.

One of the commercial consumers, Johnson Tiles Pty Ltd, produced glazed ceramic tiles. Production of tiles ceased during the gas emergency. The company claimed, amongst other things,[265] the costs of agitating the slurry of raw materials for a longer period than would have been necessary during normal production. If agitation did not occur the slurry would solidify resulting in loss of value of the slurry and damage to the vessels it was in. Gillard J found that the defendant's negligence caused this damage.[266] However, he disagreed with the plaintiff who had classified this as property damage because it was a cost incurred to avoid property damage,[267] finding instead that it was pure economic loss.[268] Gillard J noted that if the slurry had solidified then it would have been damaged to the point where it would have to be thrown out and there would be an expense in removing

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[263] Only one member of the domestic consumers group was found to have suffered property damage: an elderly woman who had to throw away food which went bad because she had no refrigeration following the gas stoppage. However, Gillard J found that although she had suffered property damage (*Johnson Tiles* (2003) Aust Torts Reports 81-692 at [661]) such loss was not reasonably foreseeable because most Melbourne houses would have at least one electrical cooking appliance or a barbecue and a refrigerator (*Johnson Tiles* (2003) Aust Torts Reports 81-692 at [838]). The woman was therefore not owed a duty of care. A second domestic consumer claimed property damage in respect of a hot water heater that had to be replaced the day after being turned back on after the gas stoppage. However, it was not proven that the need for replacement was caused by the stoppage rather than the ordinary deterioration of a heater, the unit not having been inspected by anyone before disposal (*Johnson Tiles* (2003) Aust Torts Reports 81-692 at [638]-[655]). All other domestic consumers made claims arising from [illegible]ed to buy electrical appliances for cooking and heating. That loss was found to be pure economic loss and not recoverable.

[264] In respect of those workers who took their annual leave entitlements rather than lose wages, it was found they had suffered no damage although they had used up their leave entitlements (*Johnson Tiles* (2003) Aust Torts Reports 81-692 at [665]). As to those who were stood down and therefore lost wages, His Honour found that they had suffered pure economic loss (*Johnson Tiles* (2003) Aust Torts Reports 81-692 at [669]). However, as they were 'second line victims' they were not owed a duty of care. The first line victim was their employer. See *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [937]-[949].

[265] Gillard J severely criticised the evidence presented by this party. He found that damaged tiles in one of the company's kilns when the gas restrictions were imposed, were damaged because of the party's own error and not because of the restrictions (*Johnson Tiles* (2003) Aust Torts Reports 81-692 at [472]). The plaintiff classified this as property damage but the Judge did not decide what type of loss this would have been if the damage had been caused by the defendant. The plaintiff also claimed the costs of repairing damage to a second kiln which it alleged was caused by turning the kiln off to comply with gas restrictions. Gillard J found that although the gas stoppage caused a small deterioration to the kiln (*Johnson Tiles* (2003) Aust Torts Reports 81-692 at [563]) the roof of the kiln was already in a poor condition before the stoppage and was due to be replaced anyway. Therefore the defendant did not cause that damage. There is no discussion by the Judge of the type of loss it would have been. Once again plaintiff classified it as property damage.

[266] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [567].

[267] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [567].

[268] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [574].

it from the vessels and risk of damage to the vessels. That would be property damage.[269] But here there was no damage to the slurry because it continued to be agitated.[270] That additional agitation cost more than would usually have been the case but Gillard J held that the expense involved was financial and the loss was purely economic.[271] The reasons for decision are discussed in section 5.3.4 below.

(d) *Dovuro*

In *Dovuro*,[272] the appellant Dovuro imported into Australia and distributed canola seed which it knew to be contaminated by three varieties of weed seeds.[273] The presence of the weeds in the canola crop could reduce the yield and affect the quality of the oil produced. The seed bags accurately alerted the buyer to the fact that the canola seed was contaminated by weed seed.[274] However, it did not name the contamination.[275] The seed was checked by Australian and WA Quarantine and Inspection Services upon importation. No restricted or prohibited species were detected. Wilkins purchased 40 bags of the canola seed and sowed it on his property in WA. Some two months later at the recommendation of the WA Department of Agriculture the three species of weeds in the canola seed were declared prohibited species under WA legislation.[276] As a consequence it became illegal to import or sell the weed seeds in WA. Further, the Department recommended that growers take steps to eradicate the weeds from their properties. Amongst other steps, growers were advised to spray their crops with certain chemicals to eradicate the weeds and to destroy seed derived from the affected paddocks for at least five years. Wilkins incurred expense in implementing this recommendation. He sued Dovuro in group proceedings on behalf of himself and other growers to recover their losses. Two causes of action were relied on

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[269] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [568].
[270] Another commercial consumer was Nando's Australia Pty Ltd ('Nando's'). Nando's operated a grilled chicken takeaway restaurant business. Following the cessation of gas, some stock became unfit for consumption because it could not be cooked in time and was disposed of. This was property damage. *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [629].
[271] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [574].
[272] (2003) 201 ALR 139. See also M Vranken, 'Time for the High Court of Australia to apply self-restraint? *Dovuro Pty Ltd v Wilkins*' (2004) 12 *Torts Law Journal* 33.
[273] Cleavers, redshank and field madder. The canola was modified by non-GM methods to tolerate the herbicide triazine commonly used to control spread of wild radish, a weed of canola. (2003) 201 ALR 139 at [42].
[274] Cf episode in June 2000 when it was discovered that a supply of canola seed grown in Canada and planted in a number of European Union countries was contaminated with GM material. The seed had been sold as GM-free. The planted crops were destroyed and growers compensated for the loss. N D Hamilton, 'Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms' (2001) 6 *Drake Journal of Agricultural Law* 81, 104-5.
[275] The label said in this regard 'minimum 99% purity'.
[276] *Agriculture and Related Resources Protection Act 1976* (WA).

including negligence[277] for, inter alia, failing to warn of the presence of the particular weed seeds in the canola seed.[278] No weeds were found to have grown on any property as a result of the contamination. No crop was destroyed. The declarations of two of the weed species as prohibited species were later cancelled.

In its submissions at trial, Dovuro conceded it owed a duty of care to the respondents.[279] Therefore in dispute was whether Dovuro had been negligent, that is, had breached its duty. The trial judge, Wilcox J in the Federal Court, found Dovuro had been negligent in not warning growers of the presence of the weeds.[280] That decision was upheld by a majority in the Full Court of the Federal Court.[281] On appeal to the High Court, a majority found that Dovuro had not been negligent.[282]

The trial judge and all members of the Full Court of the Federal Court and High Court proceed on the basis that the respondents suffered only pure economic loss. This was how Dovuro referred to the respondents' loss in its written submissions at trial.[283] The loss suffered by Wilkins included the cost of adoption of more costly farming practices than would otherwise have been adopted.[284] Branson J noted that the case may have been one of physical damage to land by the introduction of the exotic weeds.[285] However, as the case was argued on the basis that the loss was pure economic loss that was the basis on which she considered it. The judgments of the other two members of the Full Court of the Federal Court, Finkelstein and Gyles JJ, indicate that they would not have considered that the respondents had suffered property damage simply because of the introduction of weed seeds.[286]

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[277] The other was contravention of *Trade Practices Act 1974* (Cth) s 52. This failed at first instance.
[278] Negligence was also alleged to arise because Dovuro failed to check specifically with the WA authorities as to their reaction to the sale of canola seed with the particular contamination in question.
[279] There was some argument that the duty conceded was not clear because no differentiation was made between different kinds of injury and it was not clear to whom it was owed. Dovuro tried to reopen the question of duty and argue that it owed no duty with respect to pure economic loss but the High Court would not allow that question to be reopened. *Dovuro* (2003) 201 ALR 139 at [29] (McHugh J) and [94] (Kirby J). See also [50] (Gummow J).
[280] *Wilkins v Dovuro Pty Ltd* (1999) 169 ALR 276 (Fed Ct).
[281] Branson and Gyles JJ (Finkelstein J dissenting). *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 (Full Fed Ct).
[282] McHugh, Gummow, Hayne, Callinan and Heydon JJ; Gleeson CJ and Kirby J dissenting.
[283] *Dovuro* (2003) 201 ALR 139 at [158].
[284] (2000) 105 FCR 476 at [11]. Hayne and Callinan JJ note that in Wilkins' written submissions Wilkins said the risk of injury was to introduce a weed seed to the consumers' farms that had the potential to cause loss in eradicating it or in restricting [the consumers'] income potential in the use of [their] farm'. (2003) 201 ALR 139 at [147].
[285] (2000) 105 FCR 476 at [11].
[286] (2000) 105 FCR 476 at [124]-[125] (Finkelstein J) and [182]-[183] (Gyles J).

In the High Court, Gleeson CJ noted that Gyles J[287] had pointed out with respect to the particular weeds concerned that they 'occur naturally and are not poisonous, noxious or diseased themselves, and do not transmit disease or noxious qualities to stock or humans or even to the canola seed either as part of the seed mix or in the ground'.[288] Gleeson CJ went on to say there was:

> [n]o actual harm to the crop, or the land, of the growers who bought and sowed the seed...Their financial loss resulted from the fact that, after they bought and planted the seed, the Western Australian agricultural authorities became concerned about possible harm, and declared the weeds as prohibited species. Those declarations required the growers to take certain precautionary measures...the farmers suffered financial loss and expense which they sued to recover.[289]

Hayne and Callinan JJ in their joint judgment with which Heydon J agreed, note that 'none of the seeds was known to be dangerous'.[290] This was the case, it seems, even though Dovuro knew that contaminated canola was worth less than uncontaminated canola.[291] Kirby J refers to canola grown in WA as having a particular market advantage, specifically in Japan, because it is known as weed-free – but that the presence of more than a tiny percentage of weed seeds in canola can make it unsuitable for growers.[292] He also refers to the weed seeds as 'noxious'[293] although the basis on which he decides this is not clear. The other judgments did not consider the issue of type of harm.

(e) Impacts caused by GMOs

Social impact claims

As noted in subsection (a) above, distress or other emotional reaction to GMO releases is not compensable in negligence. Psychological injury is compensable. However, such a reaction to GMO releases seems unlikely and, because of word restrictions, is not discussed further here. Distress due to fear of harm to the plaintiff, their family, property (both land and organisms raised on it) or their business by GMO releases is similarly not recoverable.

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[287] (2000) 105 FCR 476 at [185].
[288] *Dovuro* (2003) 201 ALR 139 at [4].
[289] *Dovuro* (2003) 201 ALR 139 at [4].
[290] *Dovuro* (2003) 201 ALR 139 at [174].
[291] *Dovuro* (2003) 201 ALR 139 at [110].
[292] *Dovuro* (2003) 201 ALR 139 at [110].
[293] *Dovuro* (2003) 201 ALR 139 at [110].

Economic impact claims

Adverse physical effects to contaminated organisms, such as death, are property damage. In *Perre*, the respondent provided infected seed potatoes to the Sparnons. The Sparnons' potato tubers then began breaking down. Left to proceed, they would eventually have died. As a result of the outbreak the Sparnons also had to rigorously pursue strict hygiene practices to prevent spread. Infected paddocks could not be used for potato growing for about five years.[294] The harm to the potato was classified as property damage and the respondent held liable in negligence in respect of both it and the consequential economic loss.

Case law, discussed below, establishes that some physical change is necessary for there to be 'property damage' for the purposes of negligence. If physical change is all that is required then in many cases of GM contamination, the contamination will be sufficient for property damage. However, something more, namely an adverse consequence is also necessary. The difficulty for commercialisers is predicting the level of physical change and adverse consequences necessary for these purposes.

(i) Need for adverse consequences

In *McMullin v ICI Australia Operations Pty Ltd*[295] ('*McMullin*') cattle were contaminated by an agricultural pesticide, 'Helix', manufactured and distributed by the respondent.[296] The owners of cattle contaminated by Helix sued the respondent.[297] A maximum residue level, or MRL, had been set for Helix in domestic meat. Therefore meat with Helix levels below the MRL could be sold in Australia. However, no MRL had been set internationally. Meat with any Helix present could therefore be rejected by overseas markets. Helix is inert in cattle. As with many GM contaminations, it does not harm or endanger the life of cattle contaminated with it. On that basis, the respondent argued that the loss suffered by owners of contaminated cattle was only a physical effect that impacted

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[294] *Sparnon v Apand Pty Ltd* [1996] 1139 FCA 1 (Unreported, Fed Ct, von Doussa J, 20 December 1996).
[295] (1997) 72 FCR 1. In *McMullin v ICI Operations Pty Ltd (No 7)* (1999) 169 ALR 227, Wilcox J said that nothing in the decision in *Perre v Apand Pty Ltd* (1999) 198 CLR 180 compelled him to alter his earlier decision in any way.
[296] The chemical was used in cotton growing and cattle were sometimes fed cotton stubble.
[297] Claims were also made by cattleowners whose cattle was not contaminated but were placed in detention or tagged because of the possibility that they may have been and by companies that transported cotton gin trash, a cattle feed which was found to be a common method of the chemical making its way to cattle. Abattoirs and stock agents, amongst others, also made claims against the respondent.

on its value. That is, it was pure economic loss and not property loss. 'Harm', they argued, meant recognised veterinary harm to the well being of the animal.

In response the applicants relied on *P and S Ranicar v Frigmobile Pty Ltd* ('*Ranicar*').[298] In that case scallops were refrigerated at -6 °C rather than -18 °C, with the result they were rejected for export. The scallops were able to be sold locally but at a lower price. The consignor sued the shipping company in contract and the insurer seeking indemnity. For both actions, the Court had to decide whether there was 'damage' to the scallops. Expert evidence was that although damage due to enzyme activity and the chemical oxidation of fats in the scallops would have been greater at -6 °C than -18 °C, storage at the higher temperature would not have resulted in any significant difference in the edibility, taste, smell, texture or appearance of the scallops. Nonetheless Green J held there was 'damage' to them. He said:

> In my view, the ordinary meaning, and therefore the meaning which I should prima facie give to the phrase "damage to" when used in relation to goods, is a physical alteration or change, not necessarily permanent or irreparable, which impairs the value or usefulness of the thing said to have been damaged. It follows that not every physical change to goods would amount to damage. What amounts to damage will depend upon the nature of the goods.
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> ...the changes caused by enzymic activity and the chemical oxidation of the fats in the scallops did not constitute damage to the scallops. Although clearly physical changes, they were not such as to significantly affect the marketability, edibility, or any other material qualities of the scallops. Further, the plaintiffs' loss did not arise out of those changes. Their loss arose out of their inability to export the scallops, which was caused solely by the fact that they were stored at a temperature above -18 °C. Even had the scallops undergone no change of any kind, the mere fact that they were stored at a temperature above -18 °C would have been sufficient to prevent the plaintiffs from being able to export them. The question which remains is whether in the circumstances of this case that change in temperature amounted to damage to the scallops. In my view, it plainly did. An alteration in temperature undeniably involves a physical change to a substance and in this case that change had the effect

[298] (1983) 2 ANZ Insurance Cases 60-525 (Tas Sup Ct).

> of removing one of the primary qualities which the scallops had – their exportability. As a result, it is plain that their usefulness was impaired and their value reduced.[299]

Wilcox J in *McMullin* decided that Helix contamination was a physical change to cattle. That change caused damage in those cases where it postponed the cattle's saleability, reduced their price on sale or involved the owner in extra holding or sale expenses.[300] The type of damage was economic loss consequential on property damage.[301]

In the Federal Court decision in *Dovuro*, the need for an adverse consequence following physical change was also noted.[302] Finkelstein J noted in obiter that there would be property damage if *harmful* weed seeds were sown by Wilkins because of Dovuro's negligence.[303] However, the weed seed would have to make the land either unsuitable or less suitable for growing to 'damage' the land for these purposes.[304] There was no evidence in the case before him that the weed seeds adversely affected farming.[305] Gyles J also questioned whether planting weed seeds which have no other deleterious qualities can be regarded as physical damage to property.[306] This issue was not considered in the appeal to the High Court.

(ii) Need for physical change

Green CJ in *Ranicar* said in obiter:

> [i]t may be that under some circumstances goods could be said to have been damaged notwithstanding that they have not undergone any physical change. For example, it might be arguable that food which was handled in a way which violated the religious dietary laws of the country to which it was being exported could be regarded as having been damaged. Similarly, it might be that goods which were handled contrary to quarantine regulations so as to prevent their importation into a country could be regarded as having been damaged notwithstanding that the handling

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[299] (1983) 2 ANZ Insurance Cases 60-525 (Tas Sup Ct) at 78,000-1.
[300] See also *Losinjska Plovidba v Transco Overseas Ltd ("The Orjula")* [1995] 2 Lloyd's Rep 395 at 399 where Mance J said that whether there had been property damage was, in such a case, a matter of fact and degree. Furthermore, '[r]elevant considerations are whether there has been injury impairing value and usefulness of the property in question and the need for work and the expenditure of money to restore the property to its former useable condition is material'.
[301] For those claimants who did not own cattle at the time it was contaminated, their loss was considered to be pure economic loss.
[302] (2000) 105 FCR 476.
[303] (2000) 105 FCR 476 at [124] (emphasis added).
[304] (2000) 105 FCR 476 at [124].
[305] (2000) 105 FCR 476 at [125].
[306] (2000) 105 FCR 476 at [197].

> had no contaminating effect upon them. However, I do not need to go as far as that in this case....[307]

Witting has suggested that the UK courts' conceptualisation of physical damage in negligence has developed, shifting attention away from the examination of the actual changes in physical structures or states of property and towards a more context-specific inquiry into social perceptions of damage.[308] This, he says, allows courts to accede to social perceptions of damage and concern about standards of conduct. This is claimed to be justified on the basis that the real wrong in negligence is the failure to take care, given the context within which the failure takes place.[309] Green's CJ statement above with respect to not needing physical change seems evidence of this change.

However, that view is not borne out by more recent Australian case law. In *McMullin* Wilcox J[310] agreed with the decision of Gatehouse J in *Merlin v British Nuclear Fuels plc* ('*Merlin*').[311] In that case the plaintiffs made a claim for compensation under a statutory provision.[312] The defendant nuclear authority was required by statute to ensure that no occurrence, involving nuclear matter or ionizing radiation emitted from waste discharged from its site, caused 'damage to any property of any person'. The plaintiffs discovered their house had been contaminated by radionuclides emanating from the defendant's nuclear fuel processing plant.[313] Exposure to the radionuclides presented no immediate threat to the health of the occupants. However, there had been a change in the composition of air surrounding the house and radionuclides had settled on household surfaces. There was scientific uncertainty as to the long-term effects of this although the Court refers to the possibility it may induce cancers in some people. The plaintiffs purchased elsewhere and sold their house at a loss. An action was brought against the defendant to recover that loss.

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[307] (1983) 2 ANZ Insurance Cases 60-525 (Tas Sup Ct) at 78,001. This part of the decision was not referred to by Wilcox J in *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1. In *Hunter v Canary Wharf Ltd* [1997] AC 655 the House of Lords did not comment on the English Court of Appeal's comments (at [1997] AC 655 at 676) that counsel had submitted 'the deposit of dust, subject to the de minimis principle, amounts to damage in the ordinary sense of the word because it impairs the utility of the object onto which the dust is deposited. He equates impairment of utility with damage.' But the Court of Appeal said '[t]he damage is in the physical change which renders the article less useful or less valuable. On the assumptions we are invited to make, that rather than any general concept of loss of utility is the appropriate test.' [1997] AC 655 at 676.

[308] C Witting, 'Physical Damage in Negligence' (2002) 61 *Cambridge Law Journal* 189, 190.

[309] C Witting, 'Physical Damage in Negligence' (2002) 61 *Cambridge Law Journal* 189, 206.

[310] *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1 at 71.

[311] [1990] 2 QB 557 (QB).

[312] Although the action was under specific legislation, commentators agree that Gatehouse J's view in the case on the meaning of 'damage to property' has general application and significance. See, for example, D Rook, 'Private Nuisance – A Proprietary Interest' (1996) 4 *Tort Law Review* 181.

[313] The plaintiffs' land was contaminated by radioactive waste that overflowed from a pond on the defendant's land. The defendant removed and replaced the contaminated topsoil.

The action failed. Gatehouse J held that the relevant loss - loss of value in the house - was not 'damage to property' for the purposes of the statutory provision. He said this meant 'physical damage to tangible property'.[314] The nucleoclides had not affected any physical damage to the property itself. They had made it a.. unappealing, perhaps dangerous, place to live but did not affect the property itself. The radioactive dust in the house did not intermingle with the house so as to alter the characteristics of the house in any way so there was no property damage.[315]

In *Perre* a physical restriction was placed on the movement and sale of potatoes owned by neighbours of the infected property. Because of the contamination of a neighbour's potatoes, the Perres were prohibited by regulations from selling their potatoes in WA. There was no physical change to the potatoes owned by the Perres. The High Court held that the loss was purely economic.[316]

(iii) Whether GM contamination is property damage

Physical contamination by GMOs will in some cases be treated as property damage by Australian courts. Those cases are where there has been a physical change to the plaintiff's organisms and such changes have had adverse consequences. Where there has been physical contamination, there will usually be measurable physical change to the plaintiff's organisms. The plaintiff's organisms will no longer be purely a particular type. A foreign organism or part of it will be commingled with the plaintiff's organisms.[317]

Genetic contamination also causes a measurable physical change. However, that physical change to the plaintiff's property is, it is submitted, trifling. A tiny amount of modified DNA will be present in the reproductive parts of the contaminated organism. Only when seed or progeny are produced which contain and express that modification does the harm become significant. But that seed or progeny 'did not exist prior to the alleged affliction of damage'.[318] The limited relevant case law indicates that there is no property damage in

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[314] [1990] 2 QB 557 at 570.
[315] [1990] 2 QB 557 at 570.
[316] Cf B Feldthusen, 'Pure Economic Loss in the High Court of Australia: Reinventing the Square Wheel?' (2000) 8 *Tort Law Review* 33, 43-4 who considers such a claim to be so analogous to a claim for property damage, that he argues that aspect of the case should have been decided on principles relevant to property damage.
[317] See also *Blue Circle Industries plc v Ministry of Defence* [1998] 3 All ER 385 discussed below, where in a claim under the same legislation as in *Merlin v British Nuclear Fuels plc* [1990] 2 QB 557 (QB), the two cases were distinguished on the basis of whether there had been commingling.
[318] *Bacardi-Martini Beverages Ltd v Thomas Hardy Packaging Ltd* [2002] 1 Lloyd's Rep 62 at [25] (Eng HC) (Tomlinson J).

such cases. Rather a defective product is produced. The acquisition of defective products is pure economic loss.[319] The decision in *Port v New Zealand Dairy Board*[320] supports this conclusion. In that case, pedigree Hereford cows were artificially inseminated. Due to the defendants' negligence, the semen used was from a different breed of cattle and the resulting calves were therefore cross-bred calves of little value. Bisson J held that the plaintiff's loss was pure economic loss.[321]

To be property damage the physical changes identified above must cause an adverse consequence.[322] For example, physical contamination causing destruction of the contaminated crop to be ordered under State moratorium legislation would be property damage. The minimum damage necessary to be an adverse consequence, that is the precise consequential threshold for negligence, is not settled. Whether the law will regard physical change due to contamination as sufficient 'depends on the evidence and the circumstances'[323] and is ordinarily subject to the rule *de minimis non curat lex* (the law does not deal with trifles).[324] However, if the GMO can be practically removed there should be no adverse consequence. For example, in *Blue Circle Industries plc v Ministry of Defence*[325] ('*Blue Circle*'), a claim was made under the same legislation as in *Merlin* referred to above.[326] The claimant in *Blue Circle* was unable to sell a contaminated property and made a claim for property damage. The Judge at first instance held that there had been contamination of the claimant's property and that this amounted to property damage because 'the contamination consisted of the intermingling of plutonium, amongst other chemicals, with the soil in the marsh with the result that there was no practical process, other than excavation, which could remove it'.[327] The Court of Appeal agreed with this assessment.[328]

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[319] *Bacardi-Martini Beverages Ltd v Thomas Hardy Packaging Ltd* [2002] 1 Lloyd's Rep 62 at [25] (Eng HC) (Tomlinson J). See also *Bryan v Maloney* (1995) 182 CLR 609; *Minchillo v Ford Motor Co of Australia Ltd* [1995] 2 VR 594 (App Div); *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 concerning purchasers of defective products or structures rather than people owning such products or structures at the time they are created.

[320] [1982] 2 NZLR 282 (NZ HC).

[321] [1982] 2 NZLR 282 at 305 (NZ HC).

[322] The adverse consequence does not have to be functionally disabling. See J Stapleton, 'The Gist of Negligence: Part I' (1988) 104 *Law Quarterly Review* 213, 214.

[323] *Hunter v Canary Wharf Ltd* [1997] AC 655 at 676 (CA)(Pill LJ).

[324] C Witting, 'Physical Damage in Negligence' (2002) 61 *Cambridge Law Journal* 189, 191.

[325] [1999] Ch 289.

[326] Although a second Act, the *Radioactive Substances Act 1960* (UK), was relevant in the understanding of damage in *Blue Circle*.

[327] [1999] Ch 289 at 298-9.

[328] [1999] Ch 289 at 300.

Plaintiffs would then, though, seek to recover the costs of removing and disposing of the invading GMO and any of the plaintiff's organisms contaminated by the invasion. Lost profit in respect of the destroyed organisms and profit lost while their land is remediated may also be claimed. A plaintiff, for example, may be unable to plant a crop for a particular season because of ongoing remediation or because of an order made under State moratorium legislation. A claim may also be made with respect to the loss of some status the plaintiff previously had. For example, the plaintiff may claim that as a consequence of the invasion they have lost organic certification they previously held or can no longer use their land for GM-free farming. Where the plaintiff has suffered no property damage, the above claims would all be in respect of pure economic loss. If the plaintiff has suffered property damage, then all but one of such claims would be for economic loss consequential on that property damage. On the basis of *Johnson Tiles*, the claim for lost profits while the land was being remediated or its use restricted under State law would be pure economic loss regardless of whether property damage had lead to the need for such remediation.[329]

Loss of value is one way to satisfy the requirement for an adverse consequence.[330] Loss of value, for example, because the GM contaminated produce is no longer organic, would be sufficient. Loss of a market because of a physical change is also sufficient. In *McMullin*, cattle owners lost their overseas markets because of the presence of Helix in their cattle even though the Helix caused no physical harm to the cattle. By analogy, if GM contaminated organisms or their produce can no longer be exported or sold in particular markets, there will be property damage.

Where there has been no physical change to the plaintiff's organisms, however, such as where the level of contamination is too low to be legally relevant[331] or there has been no spread of the GMO to the plaintiff's property, any consequences suffered by the plaintiff such as the loss of value or other market advantage, would be pure economic loss. For example, where plaintiffs claim to have suffered loss of some market advantage because of a GMO release in what was previously a GM-free area, although there is no actual contamination of the plaintiff's property, the plaintiff will suffer only pure economic loss. This was the case in *Perre*. Farmers surrounding the infected property, whose own potatoes were not infected but could not be sold interstate because of legislative prohibitions, were found by the High Court to have suffered pure economic loss.

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[329] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [627].
[330] *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1.
[331] As to what level of contamination should be legally relevant see subsection 5.2.3(b) above.

The cost of precautions against invasion is also likely to be regarded as pure economic loss in Australia.[332] In *Johnson Tiles* the cost of precautions taken to avoid raw materials solidifying while gas operated kilns were not operating was treated in that way.[333] In *Dovuro*, the costs of adopting more costly farming practices than would otherwise have been adopted in order to avoid the likelihood of injury arising from planting canola seed contaminated by weed seeds were treated as pure economic loss.[334] In the taking of precautions against invasion the plaintiff may not only incur financial costs. They may have to take steps or change procedures to avoid contamination. For example, they may need to avoid using a particular transport company known to transport GMOs. Such steps or changes are inconvenient but are not harm for the purposes of negligence. However, if such steps involve financial cost to the plaintiff, such costs would be treated in the same way as the cost of any other precaution described above.

Finally, a plaintiff may claim in respect of the need following contamination to pay patent licence fees or to comply with the *GT Act* or other regulatory regime with respect to marketing that they previously did not have to comply with. Costs arising with respect to such obligations would, it is submitted be treated in the same way as the costs of cleaning up after an invasion: consequential economic loss if the plaintiff has suffered property damage and pure economic loss if they have not.

5.3.3 *Legal Requirements for Duty of Care*

(a) Establishing a duty of care where the plaintiff claims property damage

The Atkinian formula from *Donoghue v Stevenson* is applied to determine whether there is a duty of care in property damage cases.[335] Plaintiffs must establish the reasonable foreseeability of harm. Reasonable foreseeability for these purposes requires that the plaintiff be one of the class of people who a reasonable person in the defendant's shoes would reasonably foresee would be at risk of injury in some way. The foreseeable injury must be of the same general character as that which the plaintiff suffered.[336] This is a

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[332] With respect to damages for preventive action by plaintiffs generally see J G Fleming, 'Preventive Damages' in N J Mullany (ed), *Torts in the Nineties* (LBC Information Services, Sydney, 1997), p 56.
[333] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [572]. The UK Court of Appeal in *Hunter v Canary Wharf* [1997] AC 655 at 676 said it would not consider whether the cost of preventive measures could be recoverable.
[334] (2000) 105 FCR 476 at 510 et seq. See also [128] (Finklestein J). Cf [197] (Gyles J). The High Court made no comment on such an approach. *Dovuro* (2003) 201 ALR 139.
[335] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [759].
[336] The particular damage need not be foreseeable. *Mount Isa Mines Ltd v Pusey* (1970) 125 CLR 383.

question of law and is determined objectively. The reasonable person is endowed with both any knowledge the defendant actually has and knowledge that they ought to have concerning the particular activity they were engaged in.

Case law establishes that a duty of care is owed by commercialisers as owners of animals or plants or the person having control of them.[337] That duty is to take reasonable care that the organism is not put to such use as is likely to injure neighbours.[338] It extends to injury to neighbours' organisms[339] including injury caused by the spread of disease to the plaintiff's organisms.[340]

It is not settled whether anything further is required to establish a duty of care in cases of property damage. Generally it is said that nothing further is relevant.[341] Provided property damage is reasonably foreseeable, a duty of care will usually be owed.[342] However, it seems that even in such cases policy is not irrelevant and is more likely to be examined by modern courts.[343] For example, Gleeson CJ emphasised the relevance of policy in establishing a duty of care generally in the recent decision of *Tame v NSW*.[344] He said '[i]t is important that "reasonable foreseeability" should be understood and applied with due regard to the consideration that, in the context of an issue as to duty of care, it is bound up with the question of whether it is reasonable to require a person to have in contemplation the risk of injury that has eventuated.' Policy concerns in this respect involve many of the same matters as where a plaintiff claims pure economic loss. They are therefore considered together in the next section.

Provided a duty with respect to property damage is established, there will also be a duty with respect to consequential economic loss.

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[337] *Fardon v Harcourt-Rivington* (1932) 146 LT 391 (HL).
[338] *Fardon v Harcourt-Rivington* (1932) 146 LT 391 at 392 (HL).
[339] *Matheson v G Stuckey & Co Pty Ltd* [1921] VLR 637.
[340] *Earp v Faulkner* (1875) 34 LTR 284 aff'd 24 WR 774 (CA) (spread of foot and mouth disease after contact by defendant's cattle with plaintiff's cattle).
[341] See, for eg, *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1327]-[1328]. See also P Cane, 'The blight of economic loss: Is there life after *Perre v Apand*?' (2000) 8 *Torts Law Journal* 246, 256.
[342] *Jaensch v Coffey* (1983-4) 155 CLR 549 at 581-2; *Hawkins v Clayton* (1988) 164 CLR 539 at 576.
[343] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), pp 354-5. See also, eg, *Jaensch v Coffey* (1983-4) 155 CLR 549 at 581-2.
[344] (2002) 211 CLR 317; *Annetts v Australian Stations Pty Ltd* (2002) 211 CLR 317.

(b) Establishing a duty of care where the plaintiff claims pure economic loss

Although it has been said many times that the categories of negligence are never closed,[345] the courts have procceded with caution in the area of pure economic loss.[346] In 1963 recovery for pure economic loss caused by a negligent misstatement was allowed for the first time.[347] Recovery for pure economic loss not arising from a negligent misstatement was allowed for the first time by the High Court in 1976 in *Caltex Oil (Australia) Pty Ltd v The Dredge 'Willemstad'*[348] ('*Caltex*'). In that case the plaintiff transported products from a third party's refinery across the bay to the plaintiff's factory via an underwater pipeline. The pipeline was owned by the refinery. The plaintiff successfully claimed the costs of alternative means of transporting the products to their factory using ships and road transport after the defendant negligently fractured the pipeline while dredging. If the pipeline had been owned by the plaintiff, the costs claimed by the plaintiff would have been consequential economic loss. However, because it was owned by another the loss was pure economic loss. The distinction between pure economic loss and property damage was reaffirmed by the Court.[349] Nevertheless, the High Court unanimously held that the plaintiff's claim in respect of pure economic loss should be successful.[350] The reasons for the decision are discussed in section 5.3.4 below

Although *Caltex* has been criticised in other jurisdictions,[351] the High Court has affirmed the *Caltex* decision.[352] In *Perre*, which concerned pure economic loss caused by a negligent act, no member of the Court suggested that *Caltex* was wrong and two of the judges expressly approved it.[353] Australia therefore does not have a strict exclusionary rule that there is no duty of care where a plaintiff suffers pure economic loss. But there is no

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[345] See, for eg, *Donoghue v Stevenson* [1932] AC 562 at 619 (Lord Macmillan).
[346] *Perre* (1999) 198 CLR 180 at [93] (McHugh J).
[347] *Hedley Byrne & Co Ltd v Heller & Partners Ltd* [1964] AC 465. For equivalent Australian authority see *Mutual Life & Citizens Assurance Co Ltd v Evatt* (1968) 122 CLR 556.
[348] (1976) 136 CLR 529.
[349] (1976) 136 CLR 529 at 555 (Gibbs J).
[350] Finding a common line of reasoning amongst the judgments though is difficult.
[351] See, eg, *Candlewood Navigation Corp Ltd v Mitsui OSK Lines Ltd (The 'Mineral Transporter')* [1986] AC 1.
[352] For eg, in *Shaddock v Parramatta City Council* (1981) 150 CLR 225 at 251 (Mason J), 255 (Murphy J), 424 (Deane J); *San Sebastian Pty Ltd v Minister Administering the Environmental Planning and Assessment Act 1979 (NSW)* (1986) 162 CLR 340 at 353.
[353] *Perre* (1999) 198 CLR 180 at [50] and [113] (McHugh J) and [341] (Hayne J). McHugh J added (at [113]) that the only criticism he had of the reasoning in *Caltex* was that it imposed too narrow a test for determining to whom is owed a duty.

general rule that one person owes to another a duty to take care not to cause reasonably foreseeable economic loss unconnected with physical injury to person or property.[354]

To establish a duty of care in respect of pure economic loss that type of loss must be reasonably foreseeable. However, because of concerns[355] about the effect of liability in such cases, something more is required for a duty of care in such cases.[356] A duty of care is not imposed merely because a person knows that their careless act may cause economic loss to another.[357] What else is required is not settled because of changes in the High Court's approach to the restrictive criterion for the purposes of duty. For a time the criteria was expressed as the need for the requisite degree of proximity[358] in the relationship between the parties.[359] However, the High Court has retreated in recent times from referring to this additional criterion as proximity.[360] The seven Justices in *Perre* gave six separate and disparate reasons for their decision with no clear explanation of the

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[354] *Perre* (1999) 198 CLR 180 at [4] (Gleeson CJ). See also *Caltex* at 555 (Gibbs CJ), 567-8 (Stephen J), 591-2 (Mason J), 606 (Murphy J); *Bryan v Maloney* (1995) 182 CLR 609 at 617-9 and *Hill v Van Erp* (1997) 188 CLR 159 at 169 (Brennan CJ), 211(McHugh J) and 220 (Gummow J).

[355] Discussed in subsection 5.3.4(b) below.

[356] Note though that there is only one test for duty of care that applies in all cases. See, eg, Deane J in a series of cases in High Court: *Jaensch v Coffey* (1983-4) 155 CLR 549; *Hackshaw v Shaw* (1983-4) 155 CLR 614; *Sutherland Shire Council v Heyman* (1985) 157 CLR 424; *Stevens v Brodribb Sawmilling Company Pty Ltd* (1986) 160 CLR 16; *San Sebastian Pty Ltd v Minister Administering the Environmental Planning and Assessment Act 1979 (NSW)* (1986) 162 CLR 340; *Gala v Preston* (1991) 172 CLR 243.

[357] *Hill v Van Erp* (1997) 188 CLR 159 at 211 (McHugh J).

[358] Cf Brennan's J suggested approach of proceeding 'incrementally and by analogy with established categories'. *Sutherland Shire Council v Heyman* (1985) 157 CLR 424 at 481. Gummow J in *Perre* (Gleeson CJ agreed with his reasons for decision) criticised this approach. (1999) 198 CLR 180 at [199].

[359] See, eg, *Jaensch v Coffey* (1983-4) 155 CLR 549; *Hackshaw v Shaw* (1983-4) 155 CLR 614; *Sutherland Shire Council v Heyman* (1985) 157 CLR 424; *Stevens v Brodribb Sawmilling Company Pty Ltd* (1986) 160 CLR 16; *San Sebastian Pty Ltd v Minister Administering the Environmental Planning and Assessment Act 1979 (NSW)* (1986) 162 CLR 340; *Gala v Preston* (1991) 172 CLR 243; *Burnie Port Authority v General Jones Pty Ltd* (1994) 179 CLR 520; *Bryan v Maloney* (1995) 182 CLR 609; *Esanda Finance Corporation Ltd v Peat Marwick Hungerfords* (1997) 188 CLR 241; *Romeo v Conservation Commission of the Northern Territory* (1998) 192 CLR 431.

[360] *Sullivan v Moody* (2001) 207 CLR 562 at [48] (Gleeson CJ, Gaudron, McHugh, Hayne and Callinan JJ). See also *Hill v Van Erp* (1997) 188 CLR 159 at 176-9 (Dawson J), 189 (Toohey J), 210 (McHugh J), 237-9 (Gummow J); *Pyrenees Shire Council v Day* (1998) 192 CLR 330 at [76] (Toohey J), [238] (Kirby J); *Perre v Apand Pty Ltd* (1999) 198 CLR 180 at [74]-[76] (McHugh J), [281]-[282] (Kirby J), [33] (Hayne J); *Crimmins v Stevedoring Industry Finance Committee* (1999) 200 CLR 1 at [3] (Gleeson CJ), [73] and [77] (McHugh J), [149] (Gummow J), [222] (Kirby J), [270]-[274] (Hayne J); *Modbury Triangle Shopping Centre Pty Ltd v Anzil* (2000) 205 CLR 254 at [61] (Kirby J); *Brodie v Singleton Shire Council* (2001) 206 CLR 512 at [316] (Hayne J); *Tame v NSW* (2002) 211 CLR 317 at [104]-[107] (McHugh J), [268] (Hayne J); *Graham Barclay Oyster Pty Ltd v Ryan* (2002) 211 CLR 540 at [99] (McHugh J), [234]-[236] (Kirby J); *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 at [18] (Gleeson CJ, Gummow, Hayne and Heydon JJ) and [73] (McHugh J), [147]–[148] (Kirby J) and [211] (Callinan J). Re history and status of proximity in pure economic loss cases see A Baron, 'The "Mystery" of Negligence and Economic Loss: When *is* a Duty of Care Owed?' (2000) 19 *Australian Bar Review* 167, 171-9. Proximity now seems to be just a measure of 'nearness and closeness' between the parties in dispute. See *Perre* (1999) 198 CLR 180 at [281] (Kirby J).

criterion.[361] It is generally agreed that the additional duty requirement involves consideration of the relevant factors or salient features[362] of this particular category of negligence which bear on the question of duty of care.[363] Policy and factual considerations previously relevant to proximity are now considered at this step. In essence the common law imposes liability 'in situations where it is reasonable to require a person, in the position of the alleged wrongdoer and in the circumstances of the alleged wrongdoing, to be liable for the particular kind of injury suffered as a result of the alleged wrongdoing.'[364]

The following factors were described as relevant by the High Court in *Perre* in cases of pure economic loss caused by a negligent act.[365]

- Whether the imposition of a duty of care imposes liability 'in an indeterminate amount for an indeterminate time to an indeterminate class';[366]
- Concern about the opening of the floodgates;
- Whether a finding of a duty of care is inconsistent with community standards regarding what is ordinarily legitimate in the pursuit of personal advantage;

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[361] For a review of the individual judgments in *Perre* see R Rana, 'Negligence and Pure Economic Loss: The Dance of the Seven Veils' (1999) 68 *Australian Construction Law Newsletter* 50, 50; A Baron, 'The "Mystery" of Negligence and Economic Loss: When *is* a Duty of Care Owed?' (2000) 19 *Australian Bar Review* 167, 184-8; J L R Davis, 'Liability for careless acts or omissions causing purely economic loss: *Perre v Apand Pty Ltd*' (2000) 8 *Torts Law Journal* 123; M Davies and I Malkin, *Torts* (4th ed, LexisNexis Butterworths, Sydney, 2003), pp 228-9.

[362] This term was used by Gummow J in *Perre* (1999) 198 CLR 180 at [198]. See also [201]. Gleeson CJ agreed with Gummow's J conclusions at [12]. See also Callinan J at [406]. See also *Graham Barclay Oyster Pty Ltd v Ryan* (2002) 211 CLR 540 at [243] (Kirby J). With respect to criteria suggested to be relevant to liability for pure economic loss following High Court's decisions in the area see P Cane, 'The blight of economic loss: Is there life after *Perre v Apand*?' (2000) 8 *Torts Law Journal* 246.

[363] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [742]; *Sullivan v Moody* (2001) 207 CLR 562 at [50]; R Rana, 'Negligence and Pure Economic Loss: The Dance of the Seven Veils' (1999) 68 *Australian Construction Law Newsletter* 50, 50; J Stapleton, 'Comparative Economic Loss: Lessons From Case-Law-Focused "Middle Theory"' (2002) 50 *University of California Los Angeles Law Review* 531, 583.

[364] *Dowdel v Knispel Fruit Juices Pty Ltd* [2003] FCA 851 at [73] (Selway J).

[365] All of the following other than the 'control' factor are taken from the judgment of Gillard J *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [755]. For other judicial summaries of the policy factors identified as relevant in cases of pure economic loss by the High Court in *Perre* see: *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [12]-[25] (Branson J); *McKellar v Container Terminal Management Services Ltd (No 2)* [2000] FCA 1608 (Unreported, Weinberg J, 10 November 2000) [50]-[63]. See also, for eg, *Graham Barclay Oysters Pty Ltd v Ryan* (2000) 102 FCR 307 at [272]-[281] (Lindgren J); *Ilievska-Dieva v SGIO Insurance Ltd* [2000] WASCA 161 (Unreported, Kennedy, Wallwok and Murray JJ, 9 June 2000) [13]-[29] (Wallwork J); *Papadopoulos v Hristoforidis* [1999] NSWSC 1017 (Unreported, Wood CJ, 8 October 1999) [14]-[15]; *Shalhoub v Buchanan* [2002] NSWSC 622 (Unreported, Simpson J, 12 July 2002) [23]-[30].

[366] See, eg, *Ultramares Corp v Touche, Niven & Co* (1931) 174 NE 441 at 444; *Hill v Van Erp* (1997) 188 CLR 159 at 179 (Dawson J), 192-3 (Gaudron J), 215-6 (McHugh J) and 235-6 (Gummow J). See also *Perre* (1999) 198 CLR 180 (esp McHugh, Hayne and Callinan JJ).

- Whether a duty impairs the legitimate pursuit by the tortfeasor of its own commercial interest;
- Control by the defendant over the plaintiff's legal rights;
- Whether the plaintiffs are vulnerable persons unable to protect themselves from harm;
- Reliance by the plaintiff and the undertaking of responsibility by the defendant;
- A regime of contracts between various parties; and
- Existing statutory regime and common law regulating the relevant act.[367]

Factors for or against the duty of care must be considered.[368] These factors are considered in the next section.

5.3.4 *Application to GMOs*

The requirements for a duty of care are considered in this section with respect to actions arising following GMO releases. Subsection (a) considers the requirement that the damage suffered by the plaintiff be reasonably foreseeable. Subsection (b) then considers the more difficult requirement in establishing a duty of care, the examination of relevant factors or policy considerations. It will be submitted in subsection (c) that a duty of care will be owed with respect to property damage caused by a release. Furthermore, a duty is also likely to be found with respect to pure economic loss.

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[367] The following caution should be kept in mind when using such a list.

> 'While the listing of these judicial menus of sound factors relevant to the duty issue help unmask the substantive determinations being made by judges in this field, they cannot operate as some sort of mechanical guide as to how a novel case would be decided in the future... At the end of the day, even if judges agree on the relevant factors to be weighed in the individual case, different judges may well place different weight on competing factors and do so quite reasonably.'

Professor Stapleton, quoted with approval by Callinan J in *Perre* (1999) 198 CLR 180 at [404], J Stapleton, 'Duty of Care Factors: a Selection from the Judicial Menus' in Cain and Stapleton, *The Law of Obligations: Essays in Celebration of John Fleming* at p 88 (not seen). See also warning of McHugh J in *Crimmins v Stevedoring Industry Finance Committee* (1999) 200 CLR 1 at [77].

[368] *Reynolds v Katoomba RSL All Services Club Ltd* [2001] NSWCA 234 (Unreported, Giles JA, 20 September 2001) [136].

(a) Reasonable foreseeability

Whether harm caused to neighbours by GMO releases is reasonably foreseeable depends upon the facts, particularly the type of loss suffered by the neighbour.[369] Even when the facts are known, a significant difficulty in predicting the outcome of any case is forecasting the level of abstraction or particularity at which the class of persons, or neighbours, who are to be considered will be described by the court for the purposes of the test. This is particularly the case where the plaintiff suffers pure economic loss. For example, commercialisers may seek to argue that the class should be farmers generally rather than non-GM farmers. Damage to neighbours by GMO releases is arguably less foreseeable in the case of farmers generally. Not all farmers will be concerned about the GM status of their organisms. If, however, the class is treated as being non-GM farmers, concern regarding GM status may be more likely.

However, even if the relevant class is defined as farmers generally, harm is still likely to be reasonably foreseeable. As a policy, the GTR requires commercialisers to notify all neighbouring property owners of GMO field trials.[370] Commercialisers may not be aware of the type of farming neighbours engage in but they will know who their neighbours are as a result of such notification. They will, or should, also be aware from common sense, general knowledge and the media[371] that there are opponents to GMO releases in the community and that some such opponents oppose such releases because of concerns of harm to their own crops, animals or farming practices. This is particularly the case in GM-free areas, whether created statutorily or otherwise. Commercialisers would or should also be aware of the possible consequences of GMO releases for neighbouring farmers. Knowledge of the farmers around them, together with knowledge that some of them may be opposed to GMO releases and the reasons for that opposition, means a reasonable person in the shoes of commercialisers would or should foresee that if they are negligent in releasing a GMO there is a likelihood that such farmers could suffer some harm of the same general type as suffered by the plaintiff.

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[369] The loss is probably not reasonably foreseeable if an error is made in thinking that the plaintiff's organisms are contaminated when they are not, and that mistaken belief causes loss. As where cattle were mistakenly believed to have been contaminated in *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1.

[370] Aust, OGTR, *Handbook on the Regulation of Gene Technology in Australia* (2001), pp 105-6.

[371] See *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [837] where Gillard J said the court can take into account these things in assessing foreseeability at the duty stage.

The issue is then whether that risk is *reasonably* foreseeable.[372] In *Dovuro* Branson J[373] found that the pure economic loss suffered by the respondents was reasonably foreseeable because the appellant knew the dangers in introducing new weeds into areas of Australia where grain crops were commercially grown, it had actual foresight of the likelihood of harm if it allowed contaminated seed to be distributed without warning and most importantly, it knew the seed was contaminated.[374] The High Court considered the issue of reasonable foreseeability at the breach rather than the duty stage. Their comments are discussed in subsection 5.3.5(a) below.

Commercialisers may argue that there is no reasonably foreseeable harm following GMO releases. Commercialisers release only organisms approved by the GTR and allowed under State moratorium legislation. The GTR in granting that approval will, amongst other things, have assessed whether the GMO's modified genes might transfer to conventional or wild organisms of the same or related species. However, GTR authorisation does not mean that there is no, or even little, risk of all types of relevant harm. As discussed in Chapter 2, the GTR will only have assessed the release of the organism in regards to the risks it poses to the environment or public health and safety. No assessment on matters such as possible effects on the business of neighbours or their farming practices will have been made. Therefore GTR approval does not mean that possible harm to neighbours is not reasonably foreseeable. Similarly, authorisation under State legislation will not make harm caused by GMO releases no longer reasonably foreseeable. If the legislation clearly specified all considerations relevant to decisions under it, this may assist commercialisers in asserting that it is not *reasonably* foreseeable that GMO releases allowed under the legislation could harm others. However, as noted in Chapter 3, it is uncertain what considerations are relevant to decisions under that legislation. Further, the very existence of the legislation and the powers to react to harm caused by GMO releases in it, is some evidence that harm following authorised releases is still reasonably foreseeable.

Commercialisers may further assert that people who suffer harm do so only because of an unusual sensitivity, in a situation where the general public would not be injured. No duty

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[372] Dalton asserts that economic loss from GM contamination is reasonably foreseeable although he does not explain the basis for that assertion. D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 152.
[373] (2000) 105 FCR 476 at [28].
[374] Cf Gyles J who found that economic loss was not reasonably foreseeable. (2000) 105 FCR 476 at [191].

of care is owed to the injured party in such cases.[375] This is because it is not reasonably foreseeable that a person in the plaintiff's position would suffer harm.[376] Whether that assertion is successful depends on the facts. Modern courts more readily hold that even unusual conditions are, or should have been, known; that is, the trend today is for courts to find that industry should foresee that amongst the public are people who are more susceptible than normal.[377] Nevertheless, there may be cases where the plaintiff's reaction to GMO releases is so unusual that it is not reasonably foreseeable that people with such susceptibilities exist.[378] Alternatively, where it is foreseeable, a reasonable commercialiser may be justified in not taking precautions against the risk of harm to such people.[379]

It is submitted that if a commercialiser releases a GMO in a GM-free area, claims that the plaintiff is hypersensitive are unlikely to succeed. The position is less clear regarding releases in non-GM free areas, adjacent to or in GM-free areas pursuant to an exemption/permit or because the GMO is not prohibited under the State legislation. Nevertheless it is submitted that a court is likely to find that it is reasonably foreseeable that such releases done negligently could harm others, whether such harm is property damage and its consequential economic loss or pure economic loss. With respect to property damage, GM contamination is analogous to the spread of disease to other properties. Case law establishes that it is reasonably foreseeable that the spread of a contagion could cause physical harm to others.[380] Science has established that there is a risk of spread by some GMOs. Indeed the existence of the GT regulatory scheme, the State moratorium legislation and the licence conditions usually imposed by the GTR are evidence of knowledge of those risks. With respect to claims of pure economic loss, the decision in *Perre* establishes that it is reasonably foreseeable that others could be harmed even where the contagion does not spread to the plaintiff's property but nevertheless

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[375] *Chester v Waverley Municipal Council* (1939) 62 CLR 1; *Levi v Colgate-Palmolive Pty Ltd* (1941) 41 SR (NSW) 48; *Bourhill v Young* [1943] AC 92; *Cuckow v Polyester Reinforced Products Pty Ltd* (1970) 19 FLR 122 (ACT SC).

[376] It is otherwise if the defendant has actual knowledge of the extraordinary risk. *Bourhill v Young* [1943] AC 92 at 109; *Jaensch v Coffey* (1983-4) 155 CLR 549 at 568. See also *Mount Isa Mines Ltd v Pusey* (1970) 125 CLR 383 at 406.

[377] Eg, *Hayley v London Electricity Board* [1965] AC 778.

[378] *Levi v Colgate-Palmolive Pty Ltd* (1941) 41 SR (NSW) 48; *Nova Mink Ltd v Trans-Canada Airlines* [1951] 2 DLR 241.

[379] See F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 354 who assert that this position can also be explained 'in terms of an economic policy decision not to burden industry with the cost of protecting abnormally sensitive people or activities: the hypersensitive should take steps to protect themselves'.

[380] For eg, *Weller & Co v Foot and Mouth Disease Research Institute* [1966] 1 QB 569.

causes pure economic loss.[381] As to the foreseeability of the particular consequences suffered by the plaintiff, such as loss of organic status or an overseas market, that arguably is a matter for determination at the remoteness rather than duty stage. This is considered in section 5.3.5 below.[382]

(b) Relevant factors

Where the plaintiff claims pure economic loss, and possibly also where property damage is claimed, policy considerations, or salient features, relevant to the case will be the determining matter in the duty of care test. Those considerations or factors are considered below with respect to commercialisers. A significant difficulty in predicting the outcome of any particular proceeding is that the decision as to what factors are important in any particular case is subjective.[383] The nine factors described in subsection 5.3.3(b) above will be used here because they have been described as the most significant factors judicially and by commentators. Some factors are considered together rather than separately where the distinction between them blurs sufficiently to warrant it.

Indeterminate liability

The avoidance of indeterminate liability is a primary concern in pure economic loss cases.[384] Liability is indeterminate when the likely number of claims and the nature of

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[381] Although in *Perre*, there was relevant actual knowledge on the part of the respondent leading to foresight of the appellants' harm. See, eg, *Perre* (1999) 198 CLR 180 at [13] (Gleeson CJ) and [211], [213] and [409] (Gummow J). See also *Weller & Co v Foot and Mouth Disease Research Institute* [1966] 1 QB 569 where only the possibility of infection to cattle in the neighbourhood was considered foreseeable, not the indirect losses suffered by other farmers who were prohibited from moving their cattle and therefore may not have been able to sell them at the most profitable time, transport contractors who transported animals and were now out of work, dairymen short of milk and sellers of cattle feed who suffered loss of business. Therefore no duty of care was owed to those other farmers. Wilcox J in *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1 (decided before *Perre*) said that nowadays perhaps all these losses would be seen as foreseeable for the purposes of establishing a duty of care.

[382] If proximity is still relevant, then in many cases arising following a GMO release the plaintiff will be able to establish a substantial degree of directness and connection between the defendant's allegedly negligent act in releasing the organism and the harm suffered by them for there to be a proximate relationship between them. The parties will also be in the same or similar industries with each other, which was noted in *Perre* as being relevant to proximity. *Perre* (1999) 198 CLR 180 at [411] (Callinan J).

[383] As Gillard J notes '[a] consideration of the cases enables one to compile a list of relevant matters in determining the question of duty of care. However, one has to proceed with caution, as some of the matters are not necessarily relevant to a particular claim for purely economic loss and others may be relevant but may be accorded different weight depending upon the circumstances. Of course, the list is not exhaustive and other matters may be considered relevant in a particular case.' *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [735].

[384] See, for eg, *Caltex* (1976) 136 CLR 529 at 593 (Mason J). See also 555 (Gibbs J); *Perre* (1999) 198 CLR 180 at [15] and [32] (Gaudron J), [102], [106]-[113] (McHugh J), [206] (Gummow J), [297]-[299] (Kirby J), [335]-[336] (Hayne J).

them cannot be realistically calculated.[385] For liability to be determinate the defendant's knowledge need not be of individual persons; liability can be determinate when the tortfeasor *could* have ascertained the identity of the specific class of persons likely to be affected.[386]

In *Caltex*, the defendant knew a pipeline ran from a refinery on one side of the bay to a terminal on the other because it was shown on the relevant charts.[387] There was no risk of indeterminacy because the defendant knew or had means of knowing that the plaintiff would be likely to suffer economic loss if the pipeline was damaged.[388] The nature of the damages being sought by the plaintiff was also considered important by Jacobs, Mason and Stephen JJ.[389] Damages were not claimed for loss of profits and were therefore not speculative. They were for the cost of alternative transport arrangements. The importance of the nature of the damages was presumably because it provided a limit to the amount of liability and therefore determinacy. Some members of High Court in *Perre* discussed the indeterminacy factor.[390] It was noted that so long as the class of persons who may be affected is ascertainable it does not matter if the class is numerous although the size of the class can be relevant.[391] On the facts in *Perre* all the Court agreed that there was no indeterminate liability with respect to the potato growers in the Perre group. They were an ascertainable class of vulnerable persons that the defendant knew about at the time of the negligence.[392]

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[385] *Perre* (1999) 198 CLR 180 at [107]-[108] (McHugh J).
[386] *Perre* (1999) 198 CLR 180 at [111] (McHugh J) and [336] (Hayne J).
[387] It seems it was shown in the wrong spot though and the suppliers of the chart, the second defendants, were also found liable in negligence.
[388] *Caltex* (1976) 136 CLR 529 at 555 (Gibbs J). See also 576-8 (Stephen J).
[389] Gibbs and Stephen JJ also relied on as a material, although not of itself sufficient, factor that the plaintiff and the person whose property had been damaged (the refinery) were engaged in a joint venture. Jacobs J created a test which considered whether the loss arose out of a physical effect, as distinct from damage, on the person or property of the plaintiff. Here he found there had been the immobilisation of the plaintiff's oil (at 597). Murphy J merely applied the test of reasonable foreseeability. His approach has attracted no support. C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 8-36.
[390] *Perre* (1999) 198 CLR 180 at [106]-[113] (McHugh J), [335]-[336] (Hayne J) and [409] (Callinan J). All pointed out that the respondent's liability was necessarily determinate in this case because of the WA legislation. J L R Davis, 'Liability for careless acts or omissions causing pure economic loss: *Perre v Apand Pty Ltd*' (2000) 8 *Torts Law Journal* 123, 129.
[391] Eg, *Perre* (1999) 198 CLR 180 at [107] and [139] (McHugh J). Hayne J also observed that '[t]he damage suffered by persons affected by the defendant's negligence may be very large; there may be many who are affected. But neither of those considerations means that the liability is indeterminate.' *Perre* (1999) 198 CLR 180 at [336].
[392] *Perre* (1999) 198 CLR 180 at [13] (Gleeson CJ) and [50] (McHugh J). As a general rule, the issue of indeterminacy is to be determined immediately prior to the negligent act. *Perre* (1999) 198 CLR 180 at [106]-[107] and [112] (McHugh J) and [336] (Hayne J). McHugh J said '[i]f the defendant knows or has the means to know who are the members of an ascertainable class affected by its conduct and the nature of the likely losses to members of that class, its liability is not indeterminate.'

Some knowledge of the plaintiff by the defendant is therefore an important factor in determining whether there is a duty.[393] On the facts in *Johnson Tiles*, the defendant knew or should have known of the nature of likely claims and the likely number of claims. The defendant had recognised in the past the risk of liability it faced if it was negligent and there was information available to the defendant that enabled it to make some assessment of its potential liability. In *Perre* the respondent also knew there was a great risk of disease in what it was doing,[394] that the economic impact on those near a grower who had the disease on their farm could be disastrous, that the impact would be due to the provisions of the WA legislation concerned and that SA farmers sold their potatoes to WA.[395] In both cases the Courts held that there was no risk of indeterminacy, at least with respect to some of the plaintiffs/appellants.

As noted in subsection 5.3.4(a) above, the number of people who could be affected by a GMO release would often be known by the commercialiser. Further, commercialisers would or should be aware of the existence of particular markets for non-GMOs and regulatory obligations imposed on those growing GMOs. The number of people whose property may be invaded or affected is finite and ascertainable.[396] Indeterminacy in respect of those who have directly and primarily suffered harm, that is first line victims, should therefore not be a basis on which a court refuses to find a duty of care.[397]

This factor will mean though that no duty of care will be owed to second line or ripple effect victims. Such victims would, for example, be persons who handle the produce of GM contaminated neighbours of the commercialiser.[398] As a general rule those who suffer loss as a consequence of the primary or first line victim suffering loss (that is, the person who has directly suffered harm) are not owed any duty of care to avoid pure economic loss.[399] For example, Kirby J in *Perre* noted there would be no duty owed to store owners

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[393] C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 8-36.
[394] Distributing uncertified seed potatoes.
[395] With respect to some matters, the knowledge was constructive knowledge rather than actual.
[396] As the Court held in *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1.
[397] See also *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [29] (Branson J) where the vulnerable class was described to be limited and ascertainable. The class comprised the ultimate purchasers of the contaminated seed.
[398] For eg, the StarLink situation in US where GM corn approved only for sale as animal feed, entered the human food chain. Corn products, such as taco shells, then had to be withdrawn from sale. A number of companies including grain handlers, farmers, food processors and retailers then looked to the patent owner and commercialiser, Adventis CropScience, for compensation. On the StarLink matter generally see, D L Uchtmann, 'Starlink TM – A Case Study of Agricultural Biotechnology Regulation' (2002) 7 *Drake Journal of Agricultural Law* 159; R Bratspies, 'Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco' (2003) 27 *William & Mary Environmental Law & Policy Review* 591.
[399] *Perre* (1999) 198 CLR 180 at [112]; *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [939].

in the local town or truckers who carried the potatoes to WA on the facts before him even though they lost income because of the contamination.[400] McHugh J in *Perre*[401] said:

> While the defendant might reasonably foresee that the first line victims might have contractual and similar relationships with others, it would usually be stretching the concept of determinacy to hold that the defendant could have realistically calculated its liability to second line victims.

In *Johnson Tiles*, Gillard J decided that the stood down workers were not owed a duty of care because they were second line victims.[402] It was impossible for the defendant to ascertain how many may be affected by their negligent act at the time of that act. Similarly, second line victims would be an unascertainable class in the case of GMO releases because it would be impossible to say how many are likely to be in the class. Commercialisers could not realistically calculate the numbers affected or, if required, the quantum of claims as at the time of the release.

Floodgates

The floodgates factor concerns the effect of many claims upon the administration of justice: that is, the ability of the courts to cope, the difficulty of contesting them and concerns of false claims.[403] This factor will not be a reason for refusing to recognise a duty of care in cases where the plaintiff suffers property damage or pure economic loss following a GMO release for two reasons.

First, class actions will be available to assist the court.[404] This minimises the number of proceedings brought. Secondly, in claims arising because of GM contamination or threatened contamination it will not generally be necessary to establish an individual's state of mind as would be the case, for example, where it claimed that a misrepresentation by the defendant caused the plaintiff's loss. In a negligent misrepresentation case what each particular plaintiff heard and believed is crucial to whether a duty of care is owed. These circumstances with respect to each plaintiff needs to be determined and may be difficult both to prove and contest. At the least, the defendant needs the opportunity to

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[400] *Perre* (1999) 198 CLR 180 at [298].
[401] *Perre* (1999) 198 CLR 180 at [112].
[402] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [944] and [946].
[403] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [951]. See also *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 at [97] (McHugh J) and [164] (Kirby J).
[404] See *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1209].

contest such evidence in each case. In comparison, in respect of claims arising because of contamination or threatened contamination liability will largely depend upon factual proof of damage to the plaintiff. This factual matter should not be particularly difficult to prove or contest.

Unreasonable interference with economic freedom, autonomy and market competition

Reluctance to interfere with personal autonomy, competitive commercial practice, such practice even involving deliberate action causing economic loss to others, and with the right to legitimately pursue personal gain in business is another primary concern of the courts in pure economic loss claims.[405] The courts are reluctant to hamper economic competition in the marketplace by protecting or compensating resultant losses of commercial interests, opportunities or advantages.[406] Reluctance to interfere with ordinary business conduct or an individual's autonomy is of little relevance though where the defendant already owes a duty of care to do or not to do something to someone other than the plaintiff.[407] Stephen J in *Caltex* noted that community perceptions as to culpability of the defendant also had a role in determining whether there was a duty of care.[408]

These factors, it is submitted, point to there being no duty owed by commercialisers with respect to pure economic loss where neither the plaintiff nor any other person has suffered property damage because of contamination. In all of *Caltex*, *Perre* and *Johnson Tiles* the defendant/respondent already owed a duty of care to another person which required them not to act in the way in which they had acted. In *Caltex* that duty was owed to the pipeline owner; in *Perre* it was owed to the Sparnons; and in *Johnson Tiles* it was owed to the employees killed or injured by the explosion at the gas plant. In contrast, besides the duty under consideration the commercialiser will arguably owe no *other* duty of care with respect to GMO releases if no property damage has been or will be caused to the plaintiff or other third party.

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[405] All members of the *Perre* Court noted that finding the respondent liable in that case would not derogate from its pursuit of its own commercial advantage. J L R Davis, 'Liability for careless acts or omissions causing pure economic loss: *Perre v Apand Pty Ltd*' (2000) 8 *Torts Law Journal* 123, 130. See [5] (Gleeson CJ), [32]-[33] (Gaudron J), [279] (Kirby J), [114]-[117] (McHugh J) and [335] (Hayne J). See also *Bryan v Maloney* (1995) 182 CLR 609 at 618-9; *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 at [78]-[79].

[406] B McGivern, 'Tortious liability for (selected) genetic harm: Exploring the arguments' (2002) 10 *Torts Law Journal* 41, 59. See also *Jaensch v Coffey* (1983-4) 155 CLR 549 at 578 (Deane J); *Sutherland Shire Council v Heyman* (1985) 157 CLR 424 at 502-3 (Deane J); and *Hill v Van Erp* (1997) 188 CLR 159 at 179 (Dawson J), 192-3 (Gaudron J), 215-6 (McHugh J), 235-6 (Gummow J).

[407] *Perre* (1999) 198 CLR 180 at [50] and [117] (McHugh J).

[408] *Caltex* (1976) 36 CLR 529 at 574-5.

Further, imposing a duty of care on commercialisers when lawfully releasing GMOs to avoid causing pure economic loss to neighbours is arguably inconsistent with the legitimate pursuit by the commercialiser of financial gain.[409] Commercialisers, like their neighbours, have a commercial interest in producing their crops or raising livestock. The plaintiff and the commercialiser may in some cases be in economic competition with each other. For example, they may both grow canola intended for a particular overseas market. Imposing a duty could hinder competition.

Finally, it could be submitted that the plaintiff, by adopting a form of agriculture susceptible to adverse consequences if GMOs are released, should not be able to force commercialisers to cease doing something they otherwise could.[410] Imposing a duty of care on commercialisers is arguably not in accord with the community standards reflected in the *GT Act* and the State moratorium legislation.[411] In *Perre* the defendant's activity was illegal.[412] GMO releases will be prima facie lawful if there has been compliance with the *GT Act* and State legislation. Extending liability to pure economic loss in such cases may reduce the use of GT. Even if insurance is theoretically available, it may not be practically securable because the risk of liability will be difficult to estimate given the potential number of plaintiffs and amounts involved.[413] This may have the effect of decreasing the types of agriculture practised in Australia which may in itself be an adverse consequence for consumers. If the plaintiff or another person has suffered property damage though, a duty of care with respect to that damage would be owed. Causing property damage to another is not considered legitimate market competition.

Control by defendant

That the defendant has control over the enjoyment of a legal right by another, not necessarily the plaintiff, is a factor in favour of a duty with respect to pure economic loss.

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[409] Cf Dalton who concludes that the autonomy and freedom of actions of commercialisers would not be impaired by the imposition of a duty of care to neighbours because they are already under a 'statutory obligation to guard against the risks of contamination'. It is not clear what the statutory obligation is because the *GT Act* does not impose such an 'obligation'. D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 153.

[410] P Cane, 'The blight of economic loss: Is there life after *Perre v Apand*?' (2000) 8 *Torts Law Journal* 246, 260-1.

[411] See *Perre* (1999) 198 CLR 180 at [103]-[104], [101] and [117] (McHugh J). See also *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [30] (Branson J) where it was held on the facts that the defendant's behaviour was not legitimately protecting or pursuing business interests.

[412] Per *Fruit and Plant Protection Act 1968* (SA). An important factor to Kirby and Hayne JJ. See *Perre* (1999) 198 CLR 180 at [300]-[301] (Hayne J) and [349] (Kirby J).

[413] *Esanda Finance Corporation Ltd v Peat Marwick Hungerfords* (1997) 188 CLR 241 at 282 (McHugh J).

In *Hill v Van Erp*[414] a solicitor was found to control the realisation of the testatrix's intentions and the rights of any proposed beneficiaries when organising the witnessing of a will. Both Gaudron[415] and Gummow[416] JJ saw that control as a special factor warranting the imposition of a duty.[417] The testatrix and the beneficiary had to rely on the solicitor and it could not really be known that the matter had not been handled correctly until after the testatrix's death. In *Perre* Gaudron J pursued that approach. She noted that '[t]he respondent controlled the activity on the Sparnons' land'.[418] Her Honour concluded that:

> Where a person is in a position to control the exercise or enjoyment by another of a legal right, that position of control and, by corollary, the other's special dependence on the person with control are, in my view, special factors...such that the law will impose liability upon the person with control if his or her negligent act or omission results in the loss or impairment of that right and is, thereby, productive of economic loss.[419]

Neighbours may argue they have a legal right to pursue any lawful activity on their land, including GM-free agriculture. The enjoyment of that 'right' is controlled by the commercialiser because its actions determine whether GM-free agriculture remains possible. Three arguments could be made by commercialisers in response to this. First, it could be asserted that choice of method of agriculture is not a right for these purposes. Secondly, many of the consequences suffered by the plaintiff are outside the commercialiser's control. For example, the plaintiff may be unable to export their produce because of rules of international trade regarding GMO content; they may have to label their produce sold in Australia in a particular way because of Australian food or consumer protection legislation; or the plaintiff may lose their organic certification because of the rules of the voluntary certification scheme to which they belong. Finally, it could be asserted that the GTR and the States rather than the commercialiser are in control: it is their actions which determine whether the commercialiser's activities go ahead. Only the first of these is likely to be successful.

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[414] (1997) 188 CLR 159.
[415] (1997) 188 CLR 159 at 198-9. Gaudron J also noted that this was different to the factor of assumption of responsibility and reliance, control being in some respects a more stringent test (at 198-9).
[416] (1997) 188 CLR 159 at 234.
[417] Dawson J, with whom Toohey J agreed, emphasised that 'the intended beneficiary's interests [were] totally and unavoidably dependant upon the proper performance of a function within the sole province of the solicitor'. *Hill v Van Erp* (1997) 188 CLR 159 at 186.
[418] (1999) 198 CLR 180 at [14].
[419] (1999) 198 CLR 180 at [38].

With respect to the first argument, what Gaudron J intended to be included as a right is unclear. Anything that can be lawfully done could fall within the term.[420] It is submitted that choice of agricultural style should and would not be considered a right protected by a duty of care just as a 'right' to trade was considered not to be such a right by McHugh J in *Perre*.[421] More importantly for commercialisers, only Gaudron J has pursued this factor as being significant. McHugh J in *Perre* referred to it as relevant[422] but none of the other members of the High Court emphasised it. Instead they emphasised a related factor, that of the plaintiff's vulnerability, discussed next.

That many of the consequences suffered by the plaintiff are outside the control of the commercialiser is unlikely to mean commercialisers are not 'in control'. It is likely a court would instead consider this all the more reason commercialisers should ensure that they do not do something that puts others at risk of not complying with relevant regulations or requirements.[423]

In regards to the third argument, it is true that the *GT Act* and State moratorium legislation determine whether a release can lawfully occur. But it is the commercialiser who decides whether to proceed and whether to take additional precautions. In *Perre*, the respondent did not control the WA law making it illegal for the Perres to sell their potatoes in that State. Nevertheless, Gaudron J said that the respondent's relationship with the Perres was 'closely analogous to that which obtains where one person is in a position to control the exercise or enjoyment of a legal right by another person'.[424] The respondent knew, she noted, that a class of persons 'availed themselves of the right to sell potatoes in Western Australia',[425] that they would lose the right to do so if bacterial wilt was detected near them and the class were powerless to protect their own interests.[426] Commercialisers know of the risk to others and often know the magnitude of the risk.[427] It is therefore submitted that a court would find that the commercialiser is in 'control'.

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[420] See *Perre* (1999) 198 CLR 180 at [85] (McHugh J).
[421] *Perre* (1999) 198 CLR 180 at [85] (McHugh J).
[422] *Perre* (1999) 198 CLR 180 at [127] and [129] (McHugh J). See also *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 at [222] (Callinan J).
[423] *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1.
[424] (1999) 198 CLR 180 at [41].
[425] (1999) 198 CLR 180 at [41].
[426] (1999) 198 CLR 180 at [41].
[427] *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 at 33 [87] (McHugh J).

Vulnerability – reliance and assumption of responsibility

Stapleton has suggested that protecting the vulnerable is a core value of tort law.[428] If the defendant is 'in control' of a risk-producing activity the plaintiff's vulnerability to, or special dependence on, the defendant to control the risk or activity is an important policy factor in cases of pure economic loss.[429] Gleeson CJ in *Perre* said:

> Knowledge (actual, or that which a reasonable person would have) of an individual, or an ascertainable class of persons, who is or are reliant, and therefore vulnerable, is a significant factor in establishing a duty of care.[430]

Gaudron[431] and McHugh[432] JJ in *Perre* also adopt the concept of special vulnerability of a plaintiff attracting a duty of care.

McHugh J in *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* said vulnerability to risk means:

> that by reason of ignorance or social, political or economic constraints, the plaintiff was not able to protect him or herself from the risk of injury.[433]

At least two indicators are important in the context of the 'vulnerability factor'.[434] These are reliance and assumption of responsibility. They are not, however, determinative on their own in Australia.[435] As Baron explains, reliance in this context means an expectation

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[428] J Stapleton, 'Comparative Economic Loss: Lessons From Case-Law-Focused "Middle Theory"' (2002) 50 *UCLA Law Review* 531, 535.

[429] All members of the *Perre* Court considered this relevant although different interpretations were given to the term vulnerability. J L R Davis, 'Liability for careless acts or omissions causing pure economic loss: *Perre v Apand Pty Ltd*' (2000) 8 *Torts Law Journal* 123, 130. See also *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 at [23] (Gleeson CJ, Gummow, Hayne and Heydon JJ).

[430] *Perre* (1999) 198 CLR 180 at [10]. See also [215]-[216] (Gummow J).

[431] *Perre* (1999) 198 CLR 180 at [38] and [42]. See also judgment of Toohey and Gaudron JJ in *Esanda Finance Corporation Ltd v Peat Marwick Hungerfords* (1997) 188 CLR 241 at 263-4.

[432] *Perre* (1999) 198 CLR 180 at [118]-[129].

[433] [2004] HCA 16 at [80].

[434] See *Perre* (1999) 198 CLR 180 at [118], [120], [124]-[125] and [129] (McHugh J) where McHugh J says two things are important in this factor but that they are not the only indicators of vulnerability. Gleeson J in *Perre* also referred to a vulnerability factor. See [10] and Gummow J (with whom Gleeson CJ agreed) at [216]. Vulnerability was also emphasised by the High Court in *Burnie Port Authority v General Jones Pty Ltd* (1994) 179 CLR 520; *Pyrenees Shire Council v Day* (1998) 192 CLR 330; *Crimmins v Stevedoring Industry Finance Committee* (1999) 200 CLR 1.

[435] *Perre* (1999) 198 CLR 180 at [125] (McHugh J). See also his discussion at [118]-[129]; *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [975]. Cf UK where in pure economic loss cases, assumption of responsibility is emphasised.

by the plaintiff that the defendant will use due care towards them.[436] The expectation is said to arise from the fact that the defendant knows that the plaintiff is depending upon them to use such care.[437] An assumption of responsibility by the defendant to the plaintiff means that the defendant has accepted or is deemed by the law to have accepted by their conduct that the defendant will be liable to the plaintiff for the consequences of that conduct.[438] Alternatively the defendant may have assumed responsibility by generating in the plaintiff an expectation based on the defendant's conduct that such liability will result.[439]

This approach has arguably brought many considerations, such as whether the plaintiff took steps to protect themselves, previously relevant to contributory negligence into the duty of care equation. However, unlike contributory negligence where the plaintiff's fault may cause a proportionate decrease in the damages awarded, its inclusion in the duty test may cause a court to find no duty of care exists. In that case, the plaintiff recovers nothing. It puts the onus on the plaintiff to protect its own interests and to take steps to avoid or minimise a possible risk of harm to those interests.[440] The court considers whether the plaintiff was entitled to rely, and was reasonable in relying, on the defendant. If there were other steps the plaintiff could and should reasonably have taken to protect their own economic interests then the plaintiff may not be considered to be vulnerable and a duty of care may not be owed.[441] On the other hand, if a commercialiser's behaviour is risky or unreasonable they may be considered to have assumed responsibility for the consequences of their conduct and a duty may arise. This factor begins to overlap with that of the defendant's control of the relevant risks. Thus plaintiffs could argue that because commercialisers are best able to insure against harm because they have the best knowledge of the possible risks and can offset any costs by passing them onto consumers, and because

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[436] A Baron, 'The "Mystery" of Negligence and Economic Loss: When *is* a Duty of Care Owed?' (2000) 19 *Australian Bar Review* 167, 194.
[437] A Baron, 'The "Mystery" of Negligence and Economic Loss: When *is* a Duty of Care Owed?' (2000) 19 *Australian Bar Review* 167, 194.
[438] A Baron, 'The "Mystery" of Negligence and Economic Loss: When *is* a Duty of Care Owed?' (2000) 19 *Australian Bar Review* 167, 194.
[439] A Baron, 'The "Mystery" of Negligence and Economic Loss: When *is* a Duty of Care Owed?' (2000) 19 *Australian Bar Review* 167, 194.
[440] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [997]. In *Johnson Tiles* the findings of fact with respect to this factor were that there had been an uninterrupted supply in the past but all users were aware of the risk of interruption and could have taken steps to protect themselves such as by getting electric equipment, back up generators or insurance.
[441] P Cane, 'The blight of economic loss: Is there life after *Perre v Apand*?' (2000) 8 *Torts Law Journal* 246, 251.

commercialisers choose to release GMOs for commercial gain, commercialisers are in control and thus owe a duty to anyone injured by their acts.[442]

Taking the last point first, given that the release will have been authorised by the GTR and State regulator (where relevant), commercialisers may assert that their conduct is not risky or unreasonable. In granting authorisation to release the GMO, the GTR and State regulator must have assessed the risks of harm as objectively manageable and acceptable.[443] Commercialisers could therefore assert that the regulators having struck a balance between the parties' competing interests, the court should not seek to reopen the matter.[444] However, as discussed in section 5.3.5 below with respect to breach of duty (that is, fault), the GTR does not consider all of the factors relevant to a court's assessment of fault. It is unclear what factors will be relevant to the State regulators. Therefore, assessment by them that a GMO release is acceptable does not necessarily mean that a court would consider that the balance has been struck in the right place and that therefore commercialisers have not assumed responsibility for economic harm caused to others when releasing GMOs.

With respect to the first point, it is submitted that the availability of insurance to defendants should not be a determining factor. As Stapleton points out it is morally incoherent that an equally culpable but uninsurable actor should escape what an insured actor does not. Nor should the victim be denied recompense on this basis.[445]

With respect to reliance by the plaintiff on the defendant using due care, McHugh J in *Perre* said that if it was reasonably open to the plaintiff to take steps to protect themself then there is no need for a duty of care.[446] Commercialisers could point to steps that could be taken by neighbours to avoid the risk of economic harm or minimise damage to themselves. For example, plaintiffs could produce sexually incompatible crops or increase buffer zones on their property between their crops and the GMO.[447] The issue for commercialisers is whether it is reasonable to expect plaintiffs to take such steps to protect

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[442] See D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 152 who concludes surrounding farmers are vulnerable.
[443] C 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, 197.
[444] See *R v Secretary of State for the Environment and Ministry of Agriculture Fisheries and Food, ex parte Watson* [1999] Env LR 310 at 312 (Simon Brown LJ).
[445] J Stapleton, 'Tort, Insurance and Ideology' (1995) 58 *Modern Law Review* 820, 825-6.
[446] On the facts of *Perre*, he held there was nothing the plaintiffs could have done to protect themselves.
[447] These steps may not always be practically possible.

themselves. What steps are reasonably to be taken by the plaintiff varies in each case but some guidance can be gleaned from the case law.[448]

In both *Caltex* and *Perre* the plaintiff/appellants took no steps to protect themselves from the effects of the defendant's/respondent's negligence. In neither case was the plaintiff/appellants found to have acted unreasonably.[449] In *Perre* Callinan J said that the appellants were entitled to expect that a person like the respondent would act carefully and responsibly in carrying out an experimental activity that had a real and acknowledged potential to cause grave harm to the appellants.[450] Plaintiffs in GMO release cases may argue that they also should not be required to take steps to protect themselves. However, in both *Caltex* and *Perre* the plaintiff/appellants were unaware of the risk to them posed by the defendant's/respondent's act. They therefore could not be said to have been unreasonable in not taking steps to protect themselves and were instead considered vulnerable by the court. In GMO release cases, plaintiffs would or should be aware of the risk to them posed by the commercialiser's act. Plaintiffs will know of the commercialiser's activities because the commercialiser will have been required by the GTR to notify all neighbours of the field trial.[451] There is also a publicly available OGTR website which contains a list of the locations of all intentional release trial sites and in some cases a map of the relevant area. Arguably plaintiffs should if they are concerned about GMO releases, check such website. Therefore they are not as vulnerable as the parties in *Caltex* and *Perre*.

Plaintiffs may alternatively assert that although they were aware of the commercialiser's activities that the commercialiser was acting with the GTR's approval and presumably in compliance with any State moratorium legislation induced them to believe that they did not need to take steps to protect themselves, making them vulnerable to the commercialiser's acts. They may assert that accordingly a duty of care should be imposed on the commercialiser. Such an argument was raised in *Johnson Tiles*. There the plaintiffs pointed to the fact that there had never been an interruption to the gas supply to domestic consumers, due to the failure of supply, from the time natural gas was first supplied to

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[448] As McHugh J has said, '[t]he degree and the nature of vulnerability sufficient to found a duty of care will no doubt vary from category to category and from case to case.' *Perre* (1999) 198 CLR 180 at [129] (McHugh J).
[449] *Perre* (1999) 198 CLR 180 at [149] (McHugh J) and [216] (Gummow J).
[450] *Perre* (1999) 198 CLR 180 at [430]. See also generally [407]-[422].
[451] See also *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [29] (Branson J) where the respondents were described as being vulnerable to a failure by the applicant to warn of contamination rather than being vulnerable to contamination itself.

Victorian consumers in 1969 until the year of the explosion.[452] Gas was promoted as an excellent, cheap and dependable fuel. Nevertheless, Gillard J held that consumers did know that gas supply could be interrupted[453] and could have taken steps to avoid or minimise harm to themselves if it was. These factors weighed against finding a duty of care in that case to anyone who suffered pure economic loss.[454] A claim of vulnerability on the basis of being induced to rely entirely on the defendant is also unlikely to be successful in the case of GMO releases. As discussed with respect to the reasonable foreseeability part of the duty test, common knowledge means commercialisers *and* their neighbours should be aware of the risk of harm to others following GMO releases, even where regulators' approval is obtained.

Accordingly, plaintiffs will not be able to sit on their hands and not consider whether there are any reasonable steps they can take to protect themselves. If reasonable steps are open to the plaintiff and they are not taken, this should be a strong factor against a duty of care with respect to pure economic loss being imposed on commercialisers. However, if such steps are taken and harm is still suffered, a duty may arise. Further, commercialisers will probably owe a duty with respect to the costs of taking such precautions to avoid damage. In such a case, the duty would be to take reasonable care to avoid causing a situation in which it is reasonable for the plaintiff to expend money to mitigate the risk of damage.[455] If that was not the case, the court would create an illogical situation: Plaintiffs who did nothing and so suffered property damage because, for example, of GM contamination, would in most cases be owed a duty of care in respect of the property damage but plaintiffs who acted promptly to avoid such damage but spent money doing so, would not.[456] A duty with respect to the cost of preventive measures may arise even where there is in fact no threat of physical harm but the plaintiff believes on reasonable grounds that there is.[457]

However, precautions will not always be available to plaintiffs. Even if they are, it may not be reasonable to require the plaintiff to take them. How reasonableness at this stage is to be determined is not clear. Presumably it involves many of the same considerations relevant when assessing both the defendant's fault at the breach of duty stage as well as

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[452] There was one earlier disruption in supply to many commercial users on 11-12 June 1998.
[453] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1018] and [1022].
[454] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1110].
[455] *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [34]. See also *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 at [132] (Kirby J).
[456] *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [33]. See also [138]. The judgment at [32]-[37] was specifically referred to by counsel in the application for special leave to appeal to the High Court. See *Dovuro Pty Ltd v Wilkins* S29/2001 (13 September 2002) High Court of Australia Transcripts.
[457] *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [34] and [138]-[141].

when considering whether the plaintiff has been contributorily negligent.[458] In that case, the likelihood of economic harm, the gravity of any harm and the cost and difficulty of taking precautions will all be important. This will require a case by case assessment. It seems likely that a court will decide, on policy, that tort law protection should not be denied to plaintiffs who fail to take all but the most straightforward precautions.[459]

Commercialisers may assert that insuring against loss of or damage to their crops or animals is a reasonable precaution by plaintiffs. However, it is questionable whether the availability of insurance to either party is relevant or a reasonable precaution.[460] McHugh J in *Perre* expressly stated that whether the plaintiff is insured in generally irrelevant to the issue of vulnerability.[461] In any case, it seems that it will be difficult for either party to insure in respect of such harm.[462]

Contractual matrix

Direct interference or inconsistency between contractual duties and a duty of care is relevant when determining whether a defendant owes another a duty to avoid causing pure economic loss.[463] Where there are concurrent duties in contract and tort,[464] a duty of care will not be imposed on a party to the contract which has the effect of negating some

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[458] Eg, the plaintiff's lack of backup power sources was considered relevant to whether there was a duty in *Johnson Tiles* (2003) Aust Torts Reports 81-692. Cf *Heeney v Best* (1979) 108 DLR (3d) 367 (Ont CA) where the failure to install an auxiliary generator by an electricity-dependant firm was treated as contributory negligence.

[459] J G Fleming, 'Tort in a Contractual Matrix' (1995) 3 *Tort Law Review* 12, 24.

[460] See J Stapleton, 'Tort, Insurance and Ideology' (1995) 58 *Modern Law Review* 820 and cases cited therein.

[461] *Perre* (1999) 198 CLR 180 at [130] (McHugh J). Cf *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1101] and [1103] where Gillard J found that the availability of insurance to the plaintiff can negate vulnerability as a factor because it offers a reasonable way for the plaintiff to protect themself. See also *Caltex* where Caltex could have anticipated its loss and allowed for it by taking out insurance cover. The High Court did not take insurance into account in that case. Stephen J, in fact, expressly rejected the relevance of insurance. (1976) 136 CLR 529 at 580. On this aspect of *Caltex* see eg J A Smillie, 'Negligence and Economic Loss' (1982) 32 *University of Toronto Law Journal* 231.

[462] Re availability of insurance it was noted in Tas, Parliamentary Joint Select Committee, *Report on Gene Technology* (2001), p 109 that 'producers, growers and those who may suffer accidental contamination may find difficulty in obtaining adequate insurance to cover damages in the event that they are held liable another [sic] person's loss.' Whilst not clear, it seems the Committee intended to point out that it would be difficult for commercialisers (that is, those that may be liable for another's loss) to get insurance rather than how difficult it would be for plaintiffs to get the same. Query whether neighbours could actually get such insurance.

[463] As noted by Branson J in *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [13] regarding the High Court decision in *Perre*, one of the three considerations identified by Gleeson CJ in *Perre* (at [5]) as influential in restraining acceptance of a duty of care permitting the recovery of pure economic loss is 'the potential unfairness in imposing on a party to a contract a tortious liability to a third party which involves a higher duty of care than that provided for by the contract'.

[464] As there can clearly be in some cases. For eg, *Astley v Austrust Ltd* (1999) 197 CLR 1 at 20-4 (Gleeson CJ, McHugh, Gummow and Hayne JJ).

limitation or exclusion in its contract.[465] In cases where commercialisers provide GMOs to another to release, and the release causes harm to that other (the releasor) the contractual matrix in which the release occurred may be relevant.[466] Contracts between the commercialiser and the releasor may seek to limit the commercialiser's liability to the releasor or to allocate risk between the parties. Such contractual provisions can be a salient feature against finding a duty of care is owed to the releasor.[467] Finding a duty of care in relation to pure economic loss may be inconsistent with the commercialiser's contractual obligations and the expectations of the releasor. In such cases the court can find that the obligations of the various parties should be left to the contractual structures. Tort has no place to rewrite the contracts and parties should be left to their contractual remedies.[468]

With respect to an action between commercialisers and neighbours though, there will generally be no contract between them. The plaintiff therefore could not have secured protection via contract. This factor merges with the issue of vulnerability. However, at least one commentator has submitted that the lack of a contract between the parties favours recognition of a duty of care by the defendant.[469]

Existing statutory regime and common law

In *Perre* McHugh J said that where another body of law effectively deals with the economic loss, the court should be slow to use negligence law to impose a duty of care on defendants. This was particularly important he thought where to do so interferes with a coherent body of law in another field.[470] Gillard J in *Johnson Tiles* said that in determining

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[465] The idea was first voiced in *Leigh and Sillavan Ltd v Aliakmon Shipping Co Ltd* [1986] AC 785 at 819 according to J G Fleming, 'Tort in a Contractual Matrix' (1995) 3 *Tort Law Review* 12, 19.

[466] See McHugh's J comment in *Perre* that 'the courts must keep the contractual background in mind in determining whether a duty of care should be imposed on the defendant in pure economic loss cases.' *Perre* (1999) 198 CLR 180 at [122]. See also comments in *Dovuro* (2003) 201 ALR 139 at [159] (Hayne and Callinan JJ) about the ability of large scale farmers to protect themselves in dealings with seed merchants.

[467] If the parties have clearly considered and agreed to the contractual terms. For eg, as was held to be the case in *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1144]. See also *Central Trust Co v Rafuse* [1986] 2 SCR 147; *British Columbia Hydro and Power Authority v BG Checo International Ltd* (1993) 99 DLR (4th) 577.

[468] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1148]. See also *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [186] where Gyles J said that where goods are provided in the ordinary course of commerce pursuant to a contract, the court should be slow to impose tortious liability regarding quality complaints where there is a comprehensive contractual regime applying to the parties.

[469] J G Fleming, 'Tort in a Contractual Matrix' (1995) 3 *Tort Law Review* 12, 19. See *Ross v Caunters* [1980] Ch 297; *White v Jones* [1993] 3 WLR 730; *Hill v Van Erp* (1997) 188 CLR 159. Cf A Baron who submits that the existence of a contract between the parties is a factor in favour of finding that a prima facie duty of care is owed. A Baron, 'The "Mystery" of Negligence and Economic Loss: When *is* a Duty of Care Owed?' (2000) 19 *Australian Bar Review* 167, 194. But see also *Bryan v Maloney* (1995) 182 CLR 609 at 620-1.

[470] *Perre* (1999) 198 CLR 180 at [120]. See also *Hill v Van Erp* (1997) 188 CLR 159 at 184 (Dawson J).

whether or not the law of torts should recognise a duty of care to avoid economic loss in novel situations the court must not overlook its effect on relevant common law principles or statutory provisions. He noted that it is accepted that the role of tort is one of filling the 'gaps left by other causes of action where the interests of justice so required'.[471]

That there are statutory regimes regulating GMO releases is therefore relevant to whether a court should find a duty of care to avoid pure economic loss.[472] As Gillard J in *Johnson Tiles* said, the presence of a statutory regime may as a matter of policy be a factor militating against the finding of a duty of care.[473] As a general proposition, a court should not find a duty of care to avoid pure economic loss if the duty resting upon the tortfeasor would be inconsistent with a duty imposed by a statutory instrument.[474] However, the *GT Act* does not deal with commercialisers' liability to others following approved releases. Plaintiffs could therefore submit that Parliament intended the law of negligence to apply concurrently with the legislation. A court is likely to agree and conclude that finding a duty of care is owed by commercialisers is not inconsistent with the *GT Act* and does not interfere with any decision-making under the statute.

Commercialisers could make three points in response to such an argument. First, in *Dovuro* Gyles J noted that the contaminating weeds complained about in the case before him were the subject of a comprehensive system of international, national and state regulation and were not prohibited, unlike the situation in *Perre*.[475] This was a factor against finding a duty of care. Secondly, in imposing a duty of care on commercialisers in respect of pure economic loss sustained because of GMO releases, the law of negligence would arguably be undermining another body of law, that of the statutory regulation of GT. It would be intruding into an already established area of law, the statutory schemes regulating GMO releases. McHugh J in *Perre* said 'I do not think that a duty can be held to exist in any case of pure economic loss without considering the effect of the application of these general principles'.[476] Finding a duty of care was owed by commercialisers means commercialisers will need to, in effect, second guess the decisions of the GTR and State

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[471] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1141] citing Bingham LJ in *Simaan General Contracting Co v Pilkington Glass Ltd (No 2)* [1988] 1 QB 758 at 782. Referred to with approval by Gummow J in *Hill v Van Erp* (1997) 188 CLR 159 at 231.
[472] *Perre* (1999) 198 CLR 180 at [5] (Gleeson CJ) and [121] (McHugh J); *Sullivan v Moody* (2001) 207 CLR 562 at [50].
[473] *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [1171].
[474] *Sullivan v Moody* (2001) 207 CLR 562 at [60] and [62] (Gleeson CJ, Gaudron, McHugh, Hayne and Callinan JJ).
[475] In dissent. *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [187].
[476] *Perre* (1999) 198 CLR 180 at [105].

regulators and not proceed with releases that Parliament, through those regimes, decides can proceed. Finally, some State moratorium legislation provides for compensation by commercialisers to third parties.[477] It could be argued that this is intended to replace the common law rights to compensation.

Whilst it is true that GMO releases are comprehensively regulated, it is submitted that the above arguments are unlikely to succeed. Finding a duty to take reasonable care when carrying out releases authorised under the *GT Act* and State legislation is unlikely to be considered unacceptable interference with the regulatory schemes.[478] In *Sullivan v Moody*[479] the appellants were suspected of sexually abusing their respective children. Both appellants denied abusing their children and neither was ever convicted of sexual abuse. The appellants alleged that the medical practitioners, social workers and others involved in the investigation of the allegations of sexual abuse owed them a duty to exercise reasonable care in the conduct of the investigation and were negligent in the investigation. In a joint judgment,[480] a unanimous High Court held that the duty was not owed to the appellants and dismissed the appeals. Their Honours noted that the complaint really concerned what had been said about the appellants. That was a matter bordering on defamation law and if a duty of care was allowed here, negligence may give a remedy when defamation law would not.[481] The Court was concerned not to subvert other areas of law such as defamation law. More fundamentally, the Court said, imposing a duty of care would make the law in this case incoherent.[482] In this case, the allegations were investigated under a statutory scheme created for the protection of children.[483] The interests of the children were to be treated by the respondents as paramount under the scheme. The Court said imposing a duty on the respondents to take care to protect those suspected of harming children would be inconsistent with the proper discharge of their responsibilities under the scheme and with their statutory obligation to treat children's interests as paramount.[484]

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[477] *Genetically Modified Crops Management Act 2004* (SA) s 24(1)(c); *Genetically Modified Crops Free Areas Act 2003* (WA) s 10(3).

[478] See *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [35] (Branson J) where Branson J noted that finding a duty of care to warn of contamination would not interfere with the law governing the sale of goods generally.

[479] (2001) 207 CLR 562.

[480] Gleeson CJ, Gaudron, McHugh, Hayne and Callinan JJ.

[481] (2001) 207 CLR 562 at [54].

[482] (2001) 207 CLR 562 at [55].

[483] Pursuant to the *Community Welfare Act 1972* (SA).

[484] (2001) 207 CLR 562 at [62]. See also *Tame v NSW* (2002) 211 CLR 317 where High Court noted that the police would owe inconsistent duties if they were found to owe a duty of care to those they were investigating; *Hill v Van Erp* (1997) 188 CLR 159 at 187 (Dawson J) where it was noted that imposing a duty

A court is unlikely to agree that imposing a duty to take reasonable care on commercialisers when releasing GMOs into the environment would be inconsistent with commercialisers' duties under the *GT Act* and State legislation. Satisfying a duty of care does not require conduct contrary to such legislation. Nor is the court likely to agree that the State legislation that provides for compensation for harm caused by a breach of the legislation was intended to replace common law rights of the injured person.

(c) Conclusions regarding duty

Where a duty is recognised it is a duty to take reasonable care to avoid a reasonably foreseeable risk of injury to another.[485] Where plaintiffs suffer property damage because of GMO releases, with or without consequential economic loss, a court is likely to find that the commercialiser releasing the organism owes a duty of care to the plaintiffs with respect to that type of harm. Such harm is reasonably foreseeable and that is usually sufficient in property damage cases to establish a duty of care. Further, analogous case law with respect to the spreading of disease supports such a conclusion. If the case is considered a novel one rather than analogous to pre-existing case law, a duty of care is still likely because there are no significant relevant factors against finding such a duty.

With respect to claims by neighbours for pure economic loss, it is submitted that a duty of care would also be found.[486] The harm would usually be reasonably foreseeable and, if still relevant, it is likely a court would find that there is proximity between the parties. An analysis of the factors relevant in determining whether a duty of care is owed in pure economic loss cases shows sufficient justification for imposing a duty.

The following points are in favour of a duty of care with respect to pure economic loss.

- There is no real risk of indeterminacy in such cases. The potential plaintiffs are, as individuals or members of an ascertainable class, identifiable to such an extent that

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on a solicitor with respect to the beneficiary under a will was not inconsistent with the solicitor's duty to the testatrix.

[485] *Burnie Port Authority v General Jones Pty Ltd* (1994) 179 CLR 520 at 543.

[486] However, there should usually be no duty with respect to pure economic loss suffered by persons who handle the produce of contaminated plaintiffs. Such persons would be second line victims and the clear risk of indeterminacy in such cases means there will be no duty. There would be no factor in the definition of that class that adequately restricts the class of claimants. The defendant's knowledge or means of knowledge of such plaintiffs would be minimal. The situation would be like that arising following contamination with foot and mouth disease, a 'tragedy which can foreseeably affect almost all businesses in (an agricultural) area'. *Weller & Co v Foot and Mouth Disease Research Institute* [1966] 1 QB 569. Cf *Seas Sapfor Forests Pty Ltd v Electricity Trust of South Australia* (1999) SASC 5718 (Unreported, Doyle CJ, Bollen and Nyland JJ, 9 August 1996); *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1. See also *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [125].

there are probably sufficient limits on the scope of potential liability to overcome the fear of indeterminacy.[487]

- Concern about the opening of floodgates is not relevant in such cases.
- Commercialisers control whether others can exercise their legal 'right' to engage in non-GM agriculture.
- The expected lack of contract between the parties means there is no justification for a court refusing to find a duty of care on the basis of interference with contractual arrangements.

However, it has been submitted that other factors point to finding no duty of care. These are:

- There will not always be vulnerability pointing to a strong need for imposing a duty of care. Neighbours will, or should be, aware of the commercialiser's GMO release and can in some cases take precautions to avoid or minimise the risk to them. In other cases though, there will be no precautions available to the plaintiff or it may be unreasonable to expect them to take them.
- The release is part of a legitimate pursuit of commercial interests by the commercialiser in accordance with a statutory scheme established to facilitate the very releases complained of.
- Unlike in *Caltex*,[488] *Perre*[489] and *Johnson Tiles*,[490] if no property damage is caused the commercialiser will not owe a pre-existing duty of care to another person in respect of the same act. Imposing a duty of care in such circumstances will therefore be creating a new restraint on the commercialiser's legitimate business activities.

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[487] B McGivern, 'Tortious liability for (selected) genetic harm: Exploring the arguments' (2002) 10 *Torts Law Journal* 41, 60.
[488] Where duty of care was already owed to owner of damaged pipeline.
[489] Where duty of care was already owed to the farmers, the Sparnons, whose potatoes were contaminated by potato blight.
[490] Where a duty of care was already owed to the workers injured by the explosion.

- Given that the release is not illegal, unlike in *Perre*, and that plaintiffs can take steps to protect themselves, community standards with respect to culpability would not demand the imposition of a duty.

- Control over the agricultural practices of others may not be a significant factor or freedom to farm as desired may not be a 'legal right'.

- Imposing a duty of care interferes with legislative regimes, namely the GT regulatory scheme and State moratorium legislation, because it prevents commercialisers doing something Parliament has authorised in the circumstances described in the legislation. However, plaintiffs could respond here that Parliament did not intend to oust the common law.

Commercialisers could submit on the basis of the above that there is no duty with respect to pure economic loss. They could assert that this is consistent with the commercial freedom of defendants stressed by the High Court in *Perre* and later cases.

Plaintiffs may respond that recognising a duty with respect to pure economic loss in such cases prevents situations arising where plaintiffs would, for example, be able to recover in respect of crops lost because of GM contamination (property damage), the profit that would be expected from the sale of that crop (consequential economic loss) and loss of organic certification (consequential economic loss) but unable to recover in respect of the lost profits from future crops while non-GM status is regained (pure economic loss). However, the courts have not found this to be a reason to allow recovery in the past.[491]

Nevertheless, it is submitted that a court is likely to find that a duty of care arises in such cases. The court will need to reconcile two competing interests. Reluctance to unduly interfere with legitimate economic freedom strongly points to no duty being owed by commercialisers. However, the plaintiff's economic freedom to pursue particular types of agriculture incompatible with GMOs is generally vulnerable to the defendant's actions. Unless, there is a particular action the plaintiff could take to prevent harm, reconciliation is likely to require a duty being found for two reasons.

First, this is consistent with an economic analysis of where responsibility should lie. Commercialisers, by releasing GMOs, are receiving an economic benefit from the activity

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[491] See eg, *Spartan Steel & Alloys Ltd v Martin & Co (Contractors) Pty Ltd* [1973] QB 27. See also *Johnson Tiles* (2003) Aust Torts Reports 81-692 at [622] and [627].

causing the harm.[492] It is appropriate that they therefore owe a duty when taking such action. Secondly, not to find a duty was owed would create a fractured agricultural environment. Those raising and releasing conventional organisms would owe a duty whilst those raising GMOs would not. It would be extremely difficult for a court to justify protecting one type of agriculture in such a way. That GM agriculture is strictly regulated would only seem to suggest that it is all the more appropriate that a duty to take reasonable care be owed. Further, commercialisers may be concerned about their rights with respect to contamination of their organisms by non-GMOs or GMOs modified in a different way to those of the commercialiser. For example, as Branson J in *Dovuro* noted, purity of canola crops is commercially important.[493] The spread of canola that is either non-GM or modified in a different way to the canola on the commercialiser's land may therefore concern commercialisers. Many of the same consequences described as following GM contamination of an organic crop would then follow for the commercialiser. Arguably there is no justification for treating this situation differently to that which is the subject of this study.

5.3.5 *Other Elements of Negligence Actions*

To be compensated for their loss, in addition to establishing a duty of care was owed to them, plaintiffs must show the defendant has breached the duty of care. They must also show that the breach caused the plaintiff's loss and that the loss is not too remote from that breach. Finally, the defendant must be unable to make out any relevant defence. This section considers each of these requirements in turn in subsections (a) to (d). The final subsection, (e), describes the remedy available to successful plaintiffs.

(a) Breach of duty of care

A breach of a duty of care, or more colloquially negligence, occurs where the defendant does (or does not do) something that a reasonable person would not (or would as the case may be).[494] In deciding whether there has been a breach of duty the court therefore decides

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[492] A B 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 Los Angeles International & Comparative Law Review* 453, 485.

[493] Because it enhances uniformity in oil quality. *Dovuro Pty Ltd v Wilkins* (2000) 105 FCR 476 at [4]. See also P E Bilsborrow et al, 'Contamination of edible double-low oilseed rape crops via pollen transfer from high erucic cultivars' (1998) 76 *Journal of the Science of Food and Agriculture* 17.

[494] *Blyth v Birmingham Waterworks Co* (1856) 11 Exch 781 at 784. There has been recent statutory reform of the law of negligence. Statutes in all States but NT now provide for when a person has been negligent. These reforms are unlikely to affect the conclusions reached in this study although the wording of any claim

how a reasonable person would behave in the same situation. To determine that, the court first considers whether there was a reasonably foreseeable risk that the particular thing that the defendant is thought to have done wrong might cause damage of some kind to the plaintiff's property (in the case of property damage) or pure economic loss to the plaintiff (in the case of pure economic loss). If the risk of injury is reasonably foreseeable, the court then determines what a reasonable person would do about the risk. Where the defendant is found to have done something different to that which a reasonable person would have done, the defendant has fallen below the relevant standard of care and breached their duty. To determine what a reasonable person would do, that is the standard of care, the court weighs all relevant factors.[495]

Each of these steps is considered below with respect to a commercialiser's release of a GMO with GTR authority and in compliance with State moratorium legislation.

Reasonable foreseeability

In granting a licence the GTR must have concluded that the risk of harm posed by the GMO release is non-existent, low or manageable. Nevertheless, the risk of causing property damage or pure economic loss to neighbours by a GMO release is still likely to be found reasonably foreseeable by a court for similar reasons to those discussed in subsection 5.3.4(a) with respect to duty of care.[496]

In *Ellis v Johnstone* Pearson LJ said with respect to harm caused by conventional animals:[497]

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would need to reflect the legislative changes. See *Civil Law (Wrongs) Act 2002* (ACT) s 43(1); *Civil Liability Act 2002* (NSW) s 5B(1); *Civil Liability Act 2003* (Qld) s 9(1); *Civil Liability Act 1936* (SA) s 32(1); *Civil Liability Act 2002* (Tas) s 11(1); *Wrongs Act 1958* (Vic) s 48(1); *Civil Liability Act 2002* (WA) s 5B(1).

[495] *Wyong Shire Council v Shirt* (1980) 146 CLR 40 at 47. It also seems that the court may take into account aesthetic factors in the calculus of negligence. See *Phillis v Daly* (1988) 15 NSWLR 65; *Romeo v Conservation Commission of the Northern Territory* (1998) 192 CLR 431. See also Aust, Negligence Review Panel, *Review of the Law of Negligence – Final Report* (2002), pp 106-7 (Recommendation 28). The Recommendation was adopted into legislation in all jurisdictions except NT. See *Civil Law (Wrongs) Act 2002* (ACT) ss 42-43; *Civil Liability Act 2002* (NSW) s 5B(2); *Civil Liability Act 2003* (Qld) s 9; *Civil Liability Act 1936* (SA) s 32(2); *Civil Liability Act 2002* (Tas) s 11; *Wrongs Act 1958* (Vic) s 48; *Civil Liability Act 2002* (WA) s 5B.

[496] See Aust, Negligence Review Panel, *Review of the Law of Negligence – Final Report* (2002), pp 106-7 (Recommendation 28) with respect to reasonable foreseeability for these purposes. See also the statutes adopting the recommendation that risks must be 'not insignificant' rather than reasonably foreseeable. Although that change introduces a higher threshold, it is unlikely to change the conclusions reached here. See *Civil Law (Wrongs) Act 2002* (ACT) s 43; *Civil Liability Act 2002* (NSW) s 5B(1)(b); *Civil Liability Act 2003* (Qld) s 9(1)(b); *Civil Liability Act 1936* (SA) s 32; *Civil Liability Act 2002* (Tas) s 11(1)(b); *Wrongs Act 1958* (Vic) s 48(1)(b); *Civil Liability Act 2002* (WA) s 5B(1).

[497] [1963] 2 QB 8 at 29-30.

> For the action of negligence, it is sufficient if the defendant knew or ought to have known of the existence of the danger, which does not necessarily arise from a vicious propensity of the animal, although perhaps some special propensity is required.

In the case of GM animals and by analogy plants, commercialisers will be aware of the dangers posed by, and perhaps the propensity of, their animals and plants.[498] Further, they will or ought to know that the presence of a GMO on another's land may cause that person economic harm.

The lack of reasonable foreseeability with respect to the way in which harm came about was crucial to the majority's finding that there had been no negligence in the High Court decision in *Dovuro*.[499] The majority there held that a finding of breach depended upon finding that Dovuro knew or ought to have known that selling the contaminated canola seed in WA gave rise to a reasonably foreseeable risk that seed purchasers would suffer damage because of the contaminating weed seeds becoming declared plants. The Trial Judge had found that anyone in the agricultural industry would know there was a possibility that new organisms could be pests. However, the majority in the High Court[500] agreed with Finkelstein J in the Federal Court that it was still not reasonably foreseeable that plants not known or proven to be dangerous would be declared weeds, especially as such action had never been taken by an Australian government before.[501] For example, Gummow J said that the absence of any decision by federal authorities to prohibit the sale or importation of the three species of seeds, notwithstanding that approximately 90 other species of weed seed were prohibited by the Commonwealth at the time Dovuro imported the impugned canola seed into Australia, was significant.[502] It suggested that the presence of these particular plants was not understood to be a material threat to Australian agriculture. By analogy, commercialisers may seek to argue that the fact the commercialiser has been licensed to release when others have not suggests the release of their GMO is also not known to be a material threat to Australian agriculture.

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[498] For eg, 'contaminating' the DNA of any progeny created with conventional organisms.
[499] A further related matter was that the apologies made by Dovuro after the declaration of the weeds as prohibited plants were held not to be evidence of breach. *Dovuro* (2003) 201 ALR 139 at [173] (Hayne and Callinan JJ, with whom Heydon J agreed).
[500] *Dovuro* (2003) 201 ALR 139 at [35] (McHugh J), [63] (Gummow J), [163] and [168] (Hayne and Callinan JJ); cf [120] (Kirby J) and [23]-[24] (Gleeson CJ).
[501] *Dovuro* (2003) 201 ALR 139 at [64] (Gummow J)
[502] *Dovuro* (2003) 201 ALR 139 at [64].

Nevertheless, statutory[507] and industry[508] standards are strong evidence of what constitutes reasonable care in particular cases, even if not conclusive.[509] The publicly accessible database created by the *GT Act* recording all licensing conditions also provides a benchmark of precautions considered acceptable and necessary by one government authority to counter risks posed by GMO releases. The database makes it easier for commercialisers to establish evidence of a level of reasonable behaviour (although court must actually decide this) than approaching its competitors to determine what precautions are common practice. Commercialisers may assert that commercialisation after GTR approval, assuming frank disclosure by the commercialiser, on the conditions imposed by the GTR and compliance with State legislation and industry standards[510] satisfies the relevant common law standard of care.[511] Reasonableness in the case of GMO releases, it could be argued, should not require that released GMOs pose no risk at all.[512] They may also assert that courts should be reluctant to adjudicate on the acceptability of the risk assessment by the GTR in most cases.[513] Rather, commercialisers could submit that courts should generally accept the GTR's approval as evidence that the release was reasonable. As McHugh J said in *Dovuro*:[514]

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[507] *Tucker v McCann* [1948] VLR 222 at 227; *Sibley v Kais* (1967) 118 CLR 424; *Bux v Slough Metals Ltd* [1974] 1 All ER 262; *Budden v BP Oil Ltd* (1980) 124 Sol Jo 376; *Podmore v Aquatours Pty Ltd* [1984] 1 NSWLR 111. Conversely, that a commercialiser failed to comply with particular relevant regulations is not, in itself, conclusive evidence of negligence (*Powell v Phillips* [1972] 3 All ER 864) although it will be relevant (*Blamires v Lancashire and Yorkshire Railway Co* (1873) LR 8 Exch 283; *Phillips Britannia Hygienic Laundry Co Ltd* [1923] 1 KB 539 at 548, aff'd [1923] 2 KB 832; *Anglo-Newfoundland Development Co Ltd v Pacific Steam Navigation Co* [1924] AC 406 at 413.) Cf *Foundation of Econ Trends v Heckler* 756 F 2d 143, 151 n 5 (DC Cir 1985) where the Court described the US National Institutes of Health Recombinant DNA Research Revised Guidelines 43 Fed Reg 60,080 (Dec 22, 1978) as 'the yardstick of common law liability'.

[508] *Benton v Tea Tree Plaza Nominees Pty Ltd* (1995) 64 SASR 494.

[509] As suggested by one US commentator '[a] court may find it difficult to blame a defendant for exercising poor judgment if the defendant followed all applicable regulations'. A B 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 Los Angeles International & Comparative Law Review* 453, 484.

[510] Such as S&IP systems.

[511] *Budden v BP Oil Ltd* (1980) 124 Sol Jo 376 where the UK CA held that Parliament in setting a limit with respect to the lead content of petrol must be regarded as having conclusively determined in the public interest, taking into account all factors including health, that it was reasonable to sell the type of product concerned.

[512] Eg, manufacturers are not required to produce accident proof products. *Bull v Rover Mowers (Aust) Pty Ltd* [1984] 2 Qd R 489.

[513] The Court was reluctant to do this in respect of a risk assessment by the relevant UK regulator (UK Advisory Committee on Releases to the Environment) in the first judicial pronouncement on the operation of GMO provisions in UK legislation. (Commentary, [1999] Env LR 326). The decision, however, was not one in negligence but concerned an application for judicial review. *R v Secretary of State for Environment and MAFF, ex parte Watson* [1998] EWCA Civ 1250 (21 July 1998).

[514] *Dovuro* (2003) 201 ALR 139 at [34].

> If negligence law is to serve any useful social purpose, it must ordinarily reflect the foresight, reactions and conduct of ordinary members of the community, or in cases of expertise, of the experts in that particular community. To hold defendants to standards of conduct that do not reflect the common experience of the relevant community can only bring the law of negligence, and with it the administration of justice, into disrepute.

In finding that Dovuro had not been negligent, McHugh J noted that the case was analogous to one where the defendant had followed common practice.[515] Dovuro had done what seed merchants ordinarily do and McHugh J found there was no reason for it to think there was a risk the weeds would be declared prohibited weeds causing financial loss to purchasers. It is submitted that in fact there was some reason to think there was such a risk because, as noted by the Trial Judge there is always a risk with any new organism that it will be a pest. Nevertheless that risk was dismissed by McHugh J. Arguably the risk posed by authorised GMO releases should also be dismissed as one that a reasonable person would not act on.

However, it is not certain that such assertions would succeed.[516] As discussed in Chapter 2, the probability of the risk of contamination occurring to other plants or animals of the same species, domestic or wild, must have been assessed by the GTR as non-existent, low or controllable, where the GTR has granted a licence.[517] There is no reason to suggest that a court would reach a different conclusion assuming frank disclosure by the commercialiser to the GTR and proper performance of her task by the GTR. [518] The critical issue in the case of GMOs though is that the GTR will not have considered the risk of harm to the same range of interests of the plaintiff that a court may consider. Most importantly, possible economic harm to other farmers or to the agricultural industry generally is not considered by the GTR. The GTR also only considers risks additional to

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[515] *Dovuro* (2003) 201 ALR 139 at [35].

[516] Cf D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 155-6 who concludes that a finding of breach is unlikely where there has been compliance with licence conditions.

[517] See subsection 2.8.5(a) above. The low likelihood of physical harm means GMO releases are unlikely to be considered an ultra-hazardous activity. If they are ultra-hazardous, the standard of care may then be such that it is almost a guarantee that no harm will result, so that if harm does occur the standard of care has been breached. *Burnie Port Authority v General Jones Pty Ltd* (1994) 179 CLR 520.

[518] Note though, for eg, in Tas, Parliamentary Joint Select Committee, *Report on Gene Technology* (2001), p 68, reference is made to the GMAC approval of release of canola. The Committee notes that GMAC did not consider the risk of introducing GM canola into an environment where wild turnip (a wild relative of canola) was common, unlike in other parts of Aust.

those posed by conventional organisms. The obvious corollary of these omissions is that the GTR's decisions will have less relevance to negligence actions by those affected by authorised releases.

It is submitted that the introduction of the Designated Areas Policy Principle improves the position of commercialisers. States can now choose whether economic risks justify prohibiting GMO releases. In those States that have enacted moratorium legislation, commercialisers can point to the determination by the State Minister of the appropriateness of GMO releases. Courts should be reluctant to find commercialisers have behaved unreasonably where releases can lawfully occur in a particular area. In those States that have not enacted such legislation presumably it has been decided that the economic interests concerned do not justify restricting GMO releases.

However, the introduction of the State legislation is not entirely beneficial for commercialisers in this regard. Where a release occurs in or perhaps even just near areas that are GM-free at least with respect to some GMOs there may be a greater likelihood of harm. It will not matter in this regard whether the GM-free area is statutorily created or a community imposed one. Although the GTR can ignore non-statutorily created areas, the existence of such an area will be relevant in negligence proceedings provided it is reasonable to expect the commercialiser to be aware of the area. Where a release occurs in or near such an area, the risk of harm to others is likely to be greater than in other areas. This is not because GMOs are any more likely to spread from the property they are released on. It is because if it does escape, it is arguably more likely to spread to the property of someone who objects to its presence. For example, it may be expected that organic farmers would be in GM-free areas but not expected that they will be in areas designated for GMO releases. However, in those States without moratorium legislation or where only prescribed GMOs are prohibited it is submitted that the likelihood of harm is not as great as in designated GM-free areas.

The gravity of the potential injury is also significant to the negligence calculus.[519] As discussed in Chapter 1, some GMO releases will cause relatively minor harm to the plaintiff, such as the insemination a small number of the plaintiff's animals by a GMO. Not all progeny will carry the GM and of those that do, not all will express the modification. In others, the harm could be considerable. For example, GMOs could

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[519] *Paris v Stepney Borough Council* [1951] AC 367.

contaminate a plaintiff's crop causing the loss of organic certification for that particular season's crop as well as for the years required to regain certification.[520] The GTR considers in this regard only whether the GMO under consideration may be toxic to other organisms, harmful to the environment or likely to transfer DNA to organisms other than its conventional counterpart. As noted before, possible economic harm to other farmers or to the agricultural industry generally is not considered by her. Economic harm would be considered by a court and would add to the gravity of the potential injury.

The balancing factor will therefore be whether the purposes of the defendant's activities are sufficiently socially desirable or necessary to justify a low, or even negligible as in the case of GM carnations, risk of harm which, if it eventuates, may cause harm ranging from minor to considerable.[521] Justifications for commercialisers releasing GMOs in field trials include testing a newly developed organism in its intended environment with the ultimate aim of raising and improving agricultural produce and expanding the choice of organisms available to farmers. Whilst these are desirable, they may not be of sufficient importance to justify the risks of release in every case. Essentially they are commercial benefits being sought by the commercialiser.[522]

In light of the above factors it is submitted that commercialisers will be required to take some steps to prevent harm. As to what those steps need be, this will of course depend upon on the particular facts. The potential for harm and appropriate measures to manage those risks differs substantially according to the organism and GM involved. GM pigs and carnations pose little risk to others; GM canola poses much greater risks.

It is submitted that in most cases, releasing GMOs in those States with moratorium legislation but which have not designated the entire jurisdiction to be 'GM-free', in accordance with that legislation and the GTR's conditions, should not be negligent. If this submission is not correct, the lawful use of this new technology will always be negligent because there will always be the potential to affect others. Some risk to others must be allowed without negligence arising for progress to occur.

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[520] Endres points out some commentators have claimed that the gravity of harm includes the loss of biodiversity and possible world food supply. AB 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 Los Angeles International & Comparative Law Review* 453, 486.
[521] *Watt v Hertfordshire CC* [1954] 1 WLR 835.
[522] Additional benefits to society can be claimed though. For eg, insect-resistant crops may mean less insecticide is used by farmers. Future developments, such as GM plants that produce rabies vaccines, may also lead to greater justification for risk.

In contrast, for GMO releases in or near areas designated GM-free, mere compliance with the GTR's requirements may be insufficient to avoid a finding of negligence.[523] In such cases, a court is likely to assess harm as being more likely to occur than the GTR will have concluded, the harm that occurs may be more serious than in areas that are not GM-free and the precaution of releasing in an area that is not in or near a GM-free area may be considered a reasonable one. Where such release occurs with an exemption/permit under State moratorium legislation though the court may be influenced by the fact that the State regulator has decided economic interference is acceptable. However, the lack of clarity of the relevant considerations in such legislation lessens the influence of such decisions.

The position of commercialisers releasing in States without moratorium legislation is uncertain. The GTR not being required to consider the same harms as the courts means compliance with the *GT Act* alone will be insufficient to establish reasonable behaviour. Without evidence of a determination by a State regulator that economic harm caused by GMO releases is acceptable, courts will be more likely to make their own assessment of reasonableness. This means it will be the courts rather than Parliament who will decide whether releases in those States are acceptable.

(b) Causation

Plaintiffs must establish that the commercialiser's breach of duty caused or materially contributed to their injury.[524] Negligence proceedings in respect of GMO releases do not raise unique legal questions with respect to this part of the tort. Success depends upon the application of well established principles to the particular facts of the case.[525] That the infliction of harm required that the plaintiff, for example, be an organic farmer, does not mean GM contamination is not also a cause of the harm.

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[523] See D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 156 who suggests a higher standard of care may be imposed where organic farms are at risk of contamination as opposed to non-organic farms.

[524] See *Civil Law (Wrongs) Act 2002* (ACT) s 46; *Civil Liability Act 2002* (NSW) s 5E; *Civil Liability Act 2003* (Qld) s 12; *Civil Liability Act 1936* (SA) s 35; *Civil Liability Act 2002* (Tas) s 14; *Wrongs Act 1958* (Vic) s 52; *Civil Liability Act 2002* (WA) s 5D.

[525] The court will begin by considering whether the plaintiff's harm would have occurred without the commercialiser's wrongful act or omission having first occurred (*Haber v Walker* [1963] VR 339). If the harm probably would have occurred anyway, the commercialiser's wrongful act or omission is unlikely to be the cause for legal purposes (*Chappel v Hart* (1998) 195 CLR 232 at 269 (Kirby J)). The court also applies commonsense (*Chappel v Hart* (1998) 195 CLR 232) and perhaps value judgments (*March v E & MH Stramare Pty Ltd* (1991) 171 CLR 506 at 515-6 (Mason CJ), 524 (Deane J) and 524 (Toohey J)), in determining whether the defendant's wrong is a cause of the plaintiff's harm.

In the practical matter of proof, contamination or the lack thereof may at first glance seem to be simpler to establish than in many other negligence cases.[526] There is likely to be a characteristic DNA sequence present in the commercialiser's organisms which should be present in the plaintiff's organisms if there has been contamination.[527] DNA detection methods are available to detect that novel DNA.[528] However, the key requirement for successful testing is prior knowledge of the precise DNA sequence of at least part of the modified gene. This may be a stumbling block as more gene constructs are used by commercialisers. Where isolated genes are patented, the complete DNA sequence is published and appropriate diagnostic tests can be devised. Further, if the GMO is legally sold as food in Australia, the full DNA sequence of the modification and adjoining plant or animal genome will have been provided to FSANZ as part of the safety assessment process.[529] However, reliable tests are not obvious where isolated genes are kept and deployed as trade secrets and the organism is not to be sold as food. Moreover, as more modified genes are incorporated into breeding programmes they are likely to accumulate in organisms. Further, the diversity of modified genes and promoters available is likely to make unequivocal testing for the presence of particular GMs impractical in the not too distant future. Additional problems arise if the combined effects of a number of GMOs caused the damage to the plaintiff over a period of time or where there are many GMO growers around the plaintiff.[530] In such cases it would be difficult or impossible to establish that any individual or group of GMOs caused the damage.[531]

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[526] For a description of testing methodologies see Australian Government Analytical Laboratories, *Review of Technologies for Detecting Genetically Modified Materials in Commodities and Food*, prepared for Dept of Agriculture, Fisheries and Forestry – Australia (undated, circa 2002).

[527] Much of the information in this paragraph is taken from UK, Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (Latimer Trend & Co, Plymouth, UK, 1999), [2.36]-[2.37].

[528] The most commonly used DNA detection method is the polymerase chain reaction (PCR). The test can be sensitive to a fraction of 1 percent.

[529] Australian Government Analytical Laboratories, *Review of Technologies for Detecting Genetically Modified Materials in Commodities and Food*, prepared for Dept of Agriculture, Fisheries and Forestry – Australia (undated, circa 2002), p 13.

[530] Where a plaintiff is claiming in respect of property damage or economic loss, proportionate liability has been introduced in seven Australian jurisdictions as part of tort law reform. See *Civil Law (Wrongs) Act 2002* (ACT) ss 19-22; *Civil Liability Act 2002* (NSW) ss 5D and 5E; *Civil Liability Act 2003* (Qld) ss 11 and 12; *Civil Liability Act 2002* (Tas) ss 13 and 14; *Civil Liability Act 1936* (SA) ss 34 and 35; *Wrongs Act 1958* (Vic) Part IVAA; *Civil Liability Act 2002* (WA) s 5C.

[531] New Zealand, Law Commission, *Liability for Loss Resulting From the Development, Supply, or Use of Genetically Modified Organisms* Study Paper 14 (Wellington, 2002) at [78]. See also D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 144. See also recent personal injury decisions indicating that contributing to the risk of harm can be sufficient for causation. *Chappel v Hart* (1998) 72 ALJR 1344 at 1367-8 (Kirby J); *Fairchild v Glenhaven Funeral Services Ltd* [2003] 1 AC 32. It is submitted that because the human interest concerns in such cases will not be present in claims with respect to pure economic loss that this developing principle will not be applied to assist plaintiffs in GMO release cases.

Contaminated organisms or material may also or alternatively contain novel proteins or possess novel traits encoded for by the modified DNA. The presence of such proteins or traits can also be tested for.[532] As with DNA detection tests, there are practical limits with the available tests that may cause difficulties with proof. However, difficulties of proof of this kind are not unique to biotechnology. In *Perre*, where the 'contaminating agent' was a bacterium there was a dispute as to the source of infection in the Sparnons' crops.[533] Further, the GTR now requires as a licence condition that the commercialiser provide a testing methodology that can reliably detect the presence of the GMO concerned and any transferred GM material.[534]

Dalton suggests that in GM contamination cases courts should have discretion to shift the onus of proof in causation where it is unreasonable to require the plaintiff to prove causation.[535] He further suggests such shift should occur where there is disparity of knowledge concerning testing for GMO presence and the likelihood and extent of spread.[536] It is submitted that the difficulties of proof here are not so different from those in other negligence cases as to justify such a change. Information on these matters provided to the GTR by the commercialiser is available to the public.[537] Similarly the results of the GTR's risk assessment on these issues is available. True, the GTR will not have assessed the risks to the economic interests of others but commercialisers will not necessarily have that information either. That harm to another's economic interests will be caused by a GMO and difficulties in assessing the likelihood of such harm does not seem of itself enough to justify changing the burden of proof in GMO cases. Further, that it may be expensive to prove causation is not unique to GMO contamination cases.

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[532] For description of methods see Australian Government Analytical Laboratories, *Review of Technologies for Detecting Genetically Modified Materials in Commodities and Food*, prepared for Dept of Agriculture, Fisheries and Forestry – Australia (undated, circa 2002).

[533] The Trial Judge found against the defendant on this and the finding was initially challenged on appeal. However, on hearing the appeal, it was no longer in issue. *Perre and Others v Apand Pty Ltd* (1997) 80 FCR 19 at 26.

[534] Aust, OGTR, *Commercial release of InVigor canola* (Brassica napus) *for use in the Australian cropping system DIR 021/2002 Bayer CropScience Pty Ltd. Licence conditions and reasons for the conditions* (undated) and Aust, OGTR, *Conditions of Licence – DIR 030/2002Florigene Ltd – Colour modified carnation* (undated, circa June 2003) (http://www.ogtr.gov.au/ir/dir030.htm) (copy on file with author).

[535] D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 172.

[536] D Dalton 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 172.

[537] Subject to any CCI declaration under the *GT Act*.

(c) Remoteness

Commercialisers are liable only for those consequences of their breach of duty which are not too remote. This requires that the damage suffered by the plaintiff be reasonably foreseeable as a consequence of the defendant's negligence by a reasonable person in the defendant's position.[538] If the defendant has knowledge relevant to the risks posed by the GMO, as some commercialisers may have, they cannot escape liability because others in the industry do not have that knowledge.[539] Furthermore, the extent of the damage suffered by the plaintiff does not have to be reasonably foreseeable.[540] The kind of damage must be. 'Kind' means the general class of damage[541] although class can be defined with varying degrees of specificity in different cases. In cases where the manner of occurrence is particularly unusual, kind can be defined quite narrowly.[542]

Commercialisers will therefore not be liable if they could not be aware of the consequences caused by the release because, for example, of limitations in current scientific knowledge or unusual natural conditions of which they could not be expected to be aware.[543] However, in respect of the consequences described in Chapter 1 damage is arguably not too remote. It is the very kind of damage foreseeable as a consequence of commercialisers' failure to take reasonable care when releasing GMOs. That the plaintiff was affected only because they had some particular characteristic, such as being an organic farmer, is unlikely to make the loss too remote. In cases of personal or psychological injury, the defendant must take their victim as they find them.[544] Such an approach should by analogy apply to characteristics such as organic certification which will determine the actual loss suffered by plaintiffs following GMO releases.[545]

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[538] *Overseas Tankship (UK) Ltd v Mort's Dock & Engineering Co Ltd (The Wagon Mound (No 1))* [1961] AC 388

[539] *Overseas Tankship (UK) Ltd v The Miller Steamship Co Pty Ltd (The Wagon Mound (No 2))* [1967] 1 AC 617.

[540] *Watts v Rake* (1960) 108 CLR 158.

[541] *Hughes v Lord Advocate* [1963] AC 837. See also *Mount Isa Mines Ltd v Pusey* (1970) 125 CLR 383.

[542] Eg, *Doughty v Turner Manufacturing Co Ltd* [1964] 1 QB 518; *Tremain v Pike* [1969] 3 All ER 1303.

[543] G Cross, 'Does Only the Careless Polluter Pay? A Fresh Examination of the Nature of Private Nuisance' (1995) 111 *Law Quarterly Review* 445, 474. Eg, *Roe v Minister of Health* [1954] 2 QB 66.

[544] *Smith Leech Brain & Co Ltd* [1962] 2 QB 405; *Stephenson v Waite Tileman Ltd* [1973] 1 NZLR 152.

[545] See *McColl v Dionisatos* (2002) Aust Torts Report 81-652 at [33]. See also R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), [9.12].

(d) Defences

Two common law defences are particularly relevant. They are *volenti non fit injuria*[546] and contributory negligence. Volenti, being a complete defence, is the better defence from the commercialiser's perspective. However, the defence of contributory negligence is more commonly allowed by the courts. As with nuisance, that the commercialiser is acting lawfully under the *GT Act* and State moratorium legislation is not a defence. Further, the statutory defence included in the South Australian *Genetically Modified Crops Management Act 2004* will not protect commercialisers.[547]

Contributory negligence

Pursuant to statute, the court is to apportion blame and reduce any damages payable by the defendant in proportion to the plaintiff's responsibility.[548] The defendant must show that the plaintiff failed to take such precautions as a reasonable person would have taken for their own protection in that situation and that that failure contributed to the injury. For example, if a non-GM farmer could have planted their crops elsewhere on their property on learning of the proposed GMO release with no great inconvenience to themself, then arguably the plaintiff will have been contributorily negligent if they do not do so.[549] In most cases though there will be little that the plaintiff could and should have done.

The courts are more lenient when judging plaintiffs' behaviour for the purposes of contributory negligence than when judging defendants' behaviour for the purposes of breach of duty. Therefore plaintiffs can be inadvertent or careless but still not be contributorily negligent.[550] For example, the courts take into account that the defendant's negligence has put the plaintiff in a situation of risk. Nevertheless, given that GMO releases are unlikely to occur unexpectedly, the commercialiser having been required by

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[546] 'To one who is willing, no legal wrong is done'.
[547] *Genetically Modified Crops Management Act 2004* (SA) s 27(2).
[548] *Law Reform (Miscellaneous Provisions) Act 1965* (NSW) s 9; *Law Reform (Miscellaneous Provisions) Act 1956* (NT) s 16; *Law Reform Act 1995* (Qld) s 10; *Law Reform (Contributory Negligence and Apportionment of Liability) Act 2001* (SA) s 7; *Wrongs Act 1954* (Tas) s 4; *Wrongs Act 1958* (Vic) s 26; *Law Reform (Contributory Negligence and Tortfeasors Contribution) Act 1947* (WA) s 4. See also *Civil Law (Wrongs) Act 2002* (ACT) s 47; *Civil Liability Act 2002* (NSW) ss 5R-5S; *Civil Liability Act 2003* (Qld) ss 23-24; *Civil Liability Act 1936* (SA) s 50; *Civil Liability Act 2002* (Tas) s 23; *Wrongs Act 1958* (Vic) ss 62-63; *Civil Liability Act 2002* (WA) s 5K.
[549] By analogy with comments re the obligations of pedestrians in motor accident cases. See, for eg, *Sibley v Kais* (1967) 118 CLR 424 at 427; *Purcell v Watson* (1979) 26 ALR 235 at 240.
[550] The plaintiff must behave as a person of ordinary prudence. R P Balkin and J L R Davis, *The Law of Torts* (3rd ed, LexisNexis Butterworths, Sydney, 2004), p 358.

However, commercialisers will know that harm can be caused to individuals even when a release is licenced and in compliance with State legislation. It is unnecessary that a GMO pose a material threat to agriculture for it to cause harm to an individual.[503] Nor is harm dependent on authorities reacting to such a threat. In *Dovuro* the High Court proceeded on the basis that there was only a risk of injury to farmers if the plants concerned were considered to pose a material threat to agriculture and therefore declared weeds. There is no discussion of the reasonable foreseeability of harm caused by unwanted contamination of a particular property as would be the case in GM contamination proceedings. Further, unlike seed merchants such as Dovuro whom Gummow J[504] thought would have less knowledge of the risks of every exotic weed than a regulatory authority, commercialisers will have knowledge of the threat to others posed by their organism and that knowledge may be greater than that possessed by the GTR or State authorities.

Calculus of negligence

The important and more difficult issue for commercialisers is whether releasing GMOs with GTR approval, in compliance with State legislation, is negligent; that is, something that a reasonable person in the commercialiser's position would not do. Commercialisers cannot rely on the fact that a government regulator, such as the GTR, has approved the organism's release to escape liability.[505] Nor can commercialisers be assured that they will not have breached the relevant standard of care because they have complied with all relevant regulatory standards.[506]

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[503] Although authorities' reactions may increase the harm suffered. For eg, if destruction of a crop is ordered or future use of land limited under State moratorium legislation.
[504] *Dovuro* (2003) 201 ALR 139 at [65].
[505] See, eg, *McMullin v ICI Australia Operations Pty Ltd* (1997) 72 FCR 1. The regulatory approval of a pesticide, 'Helix', with which the case was concerned did not absolve ICI of liability.
[506] See recent legislative changes with respect to standard of care: *Civil Law (Wrongs) Act 2002* (ACT) ss 42-43; *Civil Liability Act 2002* (NSW) s 5B(2); *Civil Liability Act 2003* (Qld) s 9; *Civil Liability Act 1936* (SA) s 32(2); *Civil Liability Act 2002* (Tas) s 11; *Wrongs Act 1958* (Vic) s 48; *Civil Liability Act 2002* (WA) s 5B. These changes are unlikely to change conclusions reached in this study.

the GTR to notify their neighbours of the forthcoming release, bizarre and badly thought through reactions of the plaintiff to releases are unlikely to be considered reasonable.

Volenti non fit injuria

Where commercialisers can prove that the plaintiff consented to the risk of harm from negligence on the part of the defendant they will escape liability.[551] So, for example, a commercialiser may point to the fact that a plaintiff moved to a State with moratorium legislation but which has not designated the jurisdiction generally GM-free. However, the defence requires that the plaintiff know[552] of the facts constituting the danger from which the risk arose *and* appreciated the risk in the factual situation *and* freely and willingly consented to that particular risk which caused the injury.

Even following the recent statutory changes to the defence, it will be extremely unlikely that a defendant could make out this defence in the scenarios described in Chapter 1 or the example given above.[553] The plaintiff coming or continuing to farm in a particular State would be insufficient. This is because the plaintiff could in most cases establish that they had no other real option. If they own the land, then financially they will need to farm it. If the plaintiff was looking for land to use, there may have been no other reasonable alternative. In such cases the plaintiff could show that they did not freely and willingly consent to the particular risk that caused their injury. This is also consistent with the court's attitude to the defence of 'coming to the nuisance' in nuisance cases.[554]

(e) Remedy

If a commercialiser is liable in negligence, the court may make an award of damages against them. Injunctions it seems are not available.[555] The amount of such damages is the sum necessary to put the plaintiff in the same position they would have been in had the

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[551] *Rootes v Shelton* (1967) 116 CLR 383.
[552] It is not enough that the plaintiff ought to have known of the risk. *Scanlon v American Cigarette Company Overseas Pty Ltd* [1986] VR 289.
[553] See *Civil Liability Act 2002* (NSW) ss 5F-5I; *Civil Liability Act 2003* (Qld) ss 13-16; *Civil Liability Act 1936* (SA) ss 36-39; *Civil Liability Act 2002* (Tas) ss 15-17; *Wrongs Act 1958* (Vic) ss 53-56; *Civil Liability Act 2002* (WA) ss 5F and 5N-5P.
[554] Discussed in section 5.2.5 above.
[555] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 653 n 186.

negligence not occurred.[556] This principle of law has been consistently referred to with approval and followed in Australia many times.[557]

5.3.6 *Conclusion with respect to Case Studies*

Predicting the outcome of negligence actions brought with respect to the consequences of GMO releases is difficult, particularly because of the importance of the facts of each case and because of the policy factors relevant in determining whether a duty of care is owed.[558] Different courts may reach different conclusions with respect to policy matters because of 'differences in social and economic conditions and in judicial assessments of community values and the proper role and scope of tort law'.[559] Nevertheless, the following conclusions are suggested.

Whether or not a defendant will be liable in negligence largely depends upon how the harm caused to the plaintiff is classified by the court. The type of harm largely determines whether the tort of negligence is relevant and the ease with which a duty of care will be established.

Claims arising because of social impacts will generally be in respect of harm not compensable in negligence. Negligence is available though where claims are made on the basis of economic impacts. If contamination of the plaintiff's property occurs causing a physical change to a more than trifling level and that change has an adverse effect on the property concerned, there will be property damage and consequential economic loss. Where the level of contamination is too low to be legally relevant or there has been only genetic contamination, it has been submitted there is no property damage. This is the case even if the plaintiff suffers some adverse consequence because of the contamination. This could occur, for example, where GMOs are released in a GM-free area causing other farmers in the area to lose some market advantage they previously held because of that designation even though the GMO has not spread to their land. There has been no physical change to the plaintiff's property for these purposes. Instead the plaintiff suffers pure economic loss.

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[556] *Livingstone v Rawyards Coal Co* (1880) 5 App Cas 25 at 39 (Lord Blackburn).
[557] Gillard J notes this in *Esso* [586]. For a recent discussion of the calculation of loss of profits and other loss caused by harm to a product's marketability see *Dowdell v Knispel Fruit Juices Pty Ltd* [2003] FCA 851. (The successful action was actually breach of contract rather than negligence but Selway J noted that on the facts of the case there was no difference between the torts measure of damages and those in contract.)
[558] See *Woolcock Street Investments Pty Ltd v CDG Pty Ltd* [2004] HCA 16 at 46 [123] (Kirby J).
[559] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999) p 352.

The classification of the other harms resulting from contamination or threatened contamination largely depends upon whether or not the contamination/threatened contamination caused property damage to the plaintiff. If there has been contamination causing property damage, other harms following that contamination would largely be consequential economic loss. For example, costs arising because of the need to pay patent licence fees or to comply with the *GT Act* or other regulatory regime that the plaintiff previously did not have to comply with and the costs of cleaning up after an invasion would all be classified as consequential economic loss. If there was no property damage, such costs would be pure economic loss.

There are two exceptions to this. The cost of precautions taken to avoid contamination will always be pure economic loss. Claims for lost profits while the plaintiff's land is being remediated would also always be pure economic loss regardless of whether property damage led to the need for such remediation.

To recover in respect of damage that is compensable by the law of negligence, the plaintiff must then make out all of the elements of the tort. Regardless of the type of damage suffered by the plaintiff, compliance with the *GT Act* and State moratorium legislation will not automatically relieve the commercialiser of liability in negligence. It will, however, be relevant in the assessment of whether there is a duty of care and whether there has been a breach of that duty.

It has been submitted that a duty will be owed with respect to both property damage and pure economic loss. This does not mean that commercialisers will be liable in negligence, only that the first of the elements of the tort has been established. Liability will then be determined by the court more closely considering the commercialiser's behaviour in deciding whether there has been a breach of duty. This arguably provides the court with more flexibility to respond to individual cases than an approach that results in no duty arising.

Steps taken by commercialisers to minimise harm to others will therefore be crucial. Compliance with any conditions imposed by the GTR will be essential but not necessarily sufficient. It has been submitted that:

- In areas not in or near GM-free areas in States with moratorium legislation, release in compliance with the *GT Act* and State legislation should not be a breach of duty.

- In areas in, or near, GM-free areas harm is more likely to occur and such harm may be serious. Accordingly even releases authorised under the *GT Act* and State moratorium legislation are likely to be a breach of duty. Commercialisers could be negligent in such cases by failing to take the relatively 'simple' precaution of releasing the GMO elsewhere.

- In States without moratorium legislation, commercialisers' liability is less certain. The lack of such legislation weakens their position and may mean courts are more willing to find negligence than in those States where there is such legislation.

In SA, WA and Tasmania, the entire jurisdiction has been designated a 'GM-free area'. This removes the possibility of the first scenario above arising. In the ACT, NSW and Victoria, the State is designated as one where the cultivation of certain GMOs is prohibited rather than being generally 'GM-free'. It is arguable that in these latter States the first alternative above is applicable for commercialisers of GMOs other than specifically prohibited GMO(s) and release may occur without negligence.

Causation and remoteness are unlikely to raise significant unique legal questions with respect to GMOs, although evidentiary difficulties may arise with respect to causation. These difficulties though are not unique to harm caused by GMOs. Further, licence conditions now being imposed by the GTR may help to overcome some of these problems. With respect to remoteness, it is expected that in most cases plaintiffs will be able to establish that the kind of harm they have suffered because of the GMO release was not too remote.

The tort of negligence may therefore be made out in many cases of GMO release even when the release is in accordance with the *GT Act*. Although defences are theoretically available they are unlikely to be of assistance in most cases. In those cases where the tort is made out, commercialisers will be liable in damages.

5.4 CONCLUSION

Two causes of action have been examined in this Chapter – private nuisance and negligence. It has been submitted that some such actions may succeed against commercialisers despite the relevant GMO release having been authorised under the *GT Act* and complying with State moratorium legislation. It is submitted that in light of that risk, there is in some cases no real freedom to release GMOs even if all relevant legislative

requirements are met. The real risk of liability in tort must be considered when deciding what GMO (and where) to commercialise. It may mean that the commercialisation of GMOs is no longer a viable possibility in many cases. In the case of nuisance proceedings, liability can arise without the court even considering the value of GMOs to the community.

Private nuisance rather than negligence is relevant where the plaintiff claims only interference with their use or enjoyment of land rather than material damage to property or chattels. Further, if the plaintiff's concerns are about the future activities of the commercialiser and an injunction is sought, the claim must be brought in nuisance. Where the plaintiff claims compensation in respect of property damage though, the two torts may be identical at least with respect to liability for the infliction of the damage.[560] However, where private nuisance is established, damages in respect of pure economic loss can be recovered without satisfying the stringent conditions for such recovery in negligence actions.[561] In respect of actions in both torts it is important to note that, as discussed in Chapter 3, the ability of GMOs to move and reproduce without human intervention has led to a new statutory defence to tort proceedings in SA. That defence is not available to commercialisers.

The first of the two groups of possible harm examined was claims in respect of social impacts. Such 'harm' is generally not compensable in negligence. Nor is it likely to be an interference with an interest in property for the purposes of nuisance although fear of harm to person or property may be an exception to this. In respect of the latter, liability will instead depend upon whether the fear is reasonable. It has been submitted that it is not reasonable given the GTR approval. Nevertheless, in both negligence and nuisance, if the torts can be made out on other grounds additional damages in respect of distress may be given.

With respect to the second group of possible harm, those arising with respect to economic impacts, an analysis of negligence law shows that liability largely depends upon how that impact is classified by the court: as property damage or pure economic loss. A judgment on the type of interference involved is also crucial in nuisance proceedings. Determining acceptable thresholds for consequences caused by GM contamination creates important uncertainty here. In some cases there will clearly be property damage (in negligence) or

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[560] C D Baker et al, *Torts Law in Principle* (Revised 3rd ed, LawBook Co, Sydney, 2002), p 16-12.
[561] F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, Oxford University Press, Melbourne, 1999), p 650.

material damage (in nuisance) to the plaintiff. In other cases, how different a contaminated organism is from a non-contaminated organism will have to be assessed by the court. The court must decide whether there has been an adverse consequence for the purposes of negligence and more than trifling damage for the purposes of nuisance. It has been submitted that this should be decided by reference to the legislative and regulatory requirements in respect of the characteristic claimed to be adversely affected by the invasion. Where there is no such requirement, for example, with respect to organic certification, it has been submitted that the court should find that there has been no property damage (in negligence) or material damage (in nuisance). Rather the damage should be treated as pure economic harm in negligence and an interference with the use or enjoyment of land in nuisance.

In both cases such an approach gives the courts a better opportunity to balance the interests of both parties when judging liability. In negligence, that balancing primarily occurs in determining whether there is a duty of care. In nuisance, the balancing takes place in determining whether the interference was substantial and unreasonable. Some socio-economic considerations are relevant in both torts. In negligence, relevant considerations include the social and economic utility of *the GMO*. That factor is largely irrelevant in nuisance proceedings given that public interest in the defendant's activity is generally not taken into account in the assessment of reasonableness. However, in both negligence and nuisance proceedings the social and economic utility of the *plaintiff's* crops and form of agriculture is relevant.

In negligence actions, the socio-economic consequences of GMO releases, the interests of both parties and of the community in GMO releases are relevant in determining whether a duty of care is owed. Similarly, the effect of a finding of negligence on the GT regulatory scheme and State moratorium legislation will be taken into account. It has been submitted that on the basis of recent High Court decisions a duty of care is likely to be owed by commercialisers to third parties even where only pure economic loss is suffered. Where property damage has been caused, there will almost certainly be a duty of care.

The value of the parties' activities is also relevant to whether there has been a breach of duty in negligence. The value of the plaintiff's interests is reflected in the assessment of the gravity of harm caused to them. The value of the commercialiser's activities is also weighed up in determining the standard of care in the circumstances. It has been submitted that a court should usually find no breach of duty by releases not in or near GM-free areas

in States with moratorium legislation and that comply with the *GT Act* and State moratorium legislation. In States without moratorium legislation or in areas in or near GM-free areas in States with such legislation, a finding of breach is more likely. However, it has been suggested that the decision of the State regulator to issue an exemption/permit or the State Parliament not to regulate particular GMOs, may make the court reluctant to find a breach of duty.

As noted above, in nuisance actions where there is no material damage any action will be on the basis of a substantial and unreasonable interference with the plaintiff's use or enjoyment of land. In determining that, the court balances the interests of both parties. General public or community concerns are of only limited relevance. The introduction of the *GT Act* is of limited assistance to commercialisers in so far as providing protection from nuisance proceedings. The State moratorium legislation though is very significant. It has been submitted that in most cases interferences caused by GM contamination or threatened contamination outside a designated GM-free area should not be considered unreasonable if the release complies with the GTR's conditions. However, as with negligence proceedings releases in or near GM-free areas would be a nuisance. Where such releases occur pursuant to an exemption/permit though, it has been submitted there should be no nuisance. Finally, as with negligence, in those States without moratorium legislation commercialisers' liability is uncertain. It has been submitted there should be no nuisance in such cases.

Although all farmers can be liable in nuisance or negligence, on the basis of the above conclusions GMO commercialisers face an increased risk of liability. It is submitted that it is fair and just that commercialisers, like other farmers, be liable for property or material damage their GMO releases cause to others. However, the possible expansion of property or material damage to include effects classified as harm under voluntary standards created by plaintiffs puts commercialisers at greater than usual risk of liability. Commercialisers may then be liable only because some groups have for their own reasons adopted particular thresholds.

It is therefore suggested that in those States without moratorium legislation, commercialisers lobby for such legislation to be introduced with the relevant Minister then announcing that no GM-free areas will be declared and no GMO releases prohibited. In those States with such legislation, commercialisers should seek to have the legislation amended to clearly provide for thresholds for 'GM' that can be used in both proceedings

under the legislation and tort proceedings. This will address the significant problems arising where harm is alleged following the contravention of some self-imposed definition of 'GM', such as the standards regarding organic certification.

It is also submitted that the approach of SA, WA and Tasmania in declaring their entire jurisdictions GM-free significantly increases the risk of GMO commercialisers' liability in tort even where GMO releases lawfully occur. If some moratorium is considered necessary, it is in the commercialisers' interests to have all States adopt the approach of ACT, NSW and Victoria. Such an approach allows other factors to be relevant in the balancing of parties' common law rights rather than having the matter heavily weighted in favour of GM opponents.

CHAPTER 6

STATUTORY LIABILITY FOR GMO RELEASES

6.1 INTRODUCTION

The Commonwealth and State Governments intended that the GT scheme discussed in Chapter 2 will avoid negative impacts by GMOs on the environment. This is evidenced by the fact that licences to release GMOs must not be granted unless the GTR is satisfied that any risks posed by it can be managed in a way that protects the environment.[1] However, a licence under the *GT Act* does not exempt commercialisers from the obligation to comply with environmental legislation. Similarly, the State moratorium legislation does not purport to affect the operation of environmental legislation. Accordingly, potential liability under environmental legislation following GMO releases causing the socio-economic impacts for third parties described in Chapter 1 is a relevant concern for GMO commercialisers in Australia.[2]

Part 6.2 of this Chapter describes the background to the environmental regulation of GMOs. There are hundreds of Australian Acts, at the Commonwealth and State level, with environmental ramifications.[3] Accordingly, this study considers the topic selectively – only selected examples of legislation most likely to be of concern are considered. Such legislation can be divided into two groups: environmental protection legislation and legislation prohibiting pollution. Part 6.3 of this Chapter concerns the first and Part 6.4 the latter.

Environmental protection legislation aims to protect the environment from harm brought about by human activities.[4] Generally, activities that may significantly affect the environment must be approved by relevant government regulators. Legislation requiring such approval exists at both the Commonwealth and State levels.[5] Such legislation differs

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[1] *GT Act* s 56.
[2] Dalton submits that one of the primary reasons no specific remedies are included in the *GT Act* was the perceived protection offered by environmental legislation. D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 161.
[3] Environmental law is mainly to be found in legislation. G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), p 7.
[4] D E Fisher, *Australian Environmental Law* (Lawbook Co, Sydney, 2003), p 233.
[5] The following may be of particular relevance to GMO commercialisers: *Land (Planning and Environment) Act 1991* (ACT); *Environmental Planning and Assessment Act 1979* (NSW); *Environmental Assessment Act*

markedly from jurisdiction to jurisdiction. The Commonwealth Act, the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) ('*EPBC Act*'), is used as the example of environmental protection legislation because it is the Australian Government's principal environmental legislation.

Environmental harm through the discharge of pollution is generally prohibited throughout Australia. There is no significant Commonwealth legislation in this area. Each State has its own legislation concerning environmental harm and pollution.[6] In light of word limitations, only the most significant agrarian pollution control provisions in Victoria are examined.[7]

Conclusions from all Parts of the Chapter are brought together in Part 6.5.

6.2 GMOS AND ENVIRONMENTAL REGULATION

Australia is not a signatory to any international convention directly regulating GMOs. It is a signatory to the Convention on Biological Diversity.[8] That Convention aims, inter alia, to conserve and encourage the sustainable use of biological diversity.[9] The *EPBC Act* adopts the Convention's provisions into Australian law.[10] 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 on Biological Diversity was finalised in Cartagena, Columbia.[11] The Protocol is known as the Cartagena

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1982 (NT); *Environmental Assessment Administrative Procedures 1984* (NT) in force pursuant to *Environmental Assessment Act 1982* (NT); *Integrated Planning Act 1997* (Qld); *State Development and Public Works Organisation Act 1971* (Qld); *Environmental Protection Act 1994* (Qld); *Development Act 1993* (SA); *Environmental Management and Pollution Control Act 1994* (Tas); *Environmental Effects Act 1978* (Vic); *Environmental Protection Act 1986* (WA).

[6] See, for eg, *Environment Protection Act 1997* (ACT); *Protection of the Environment Operations Act 1997* (NSW); *Waste Management and Pollution Control Act 1998* (NT); *Environmental Protection Act 1994* (Qld); *Environment Protection Act 1993* (SA); *Environmental Management and Pollution Control Act 1994* (Tas); *Environment Protection Act 1970* (Vic); *Environmental Protection Act 1986* (WA) and *Environmental Protection Act Amendment Act 2002* (WA) (to be proclaimed).

[7] With respect to NSW legislation and GM contamination, see D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 161-4.

[8] Convention on Biological Diversity ATS 1993 No 32. Signed for Aust 5 June 1992. Instrument of ratification deposited for Aust on 18 June 1993.

[9] Branson J has said that biodiversity (or biological diversity) as used in the *EPBC Act* means 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 at 43.

[10] *EPBC Act* Chap 5 provides for Australia's obligations with respect to protecting Australia's biodiversity.

[11] With respect to the Protocol generally see P Sands, *Principles of International Environmental Law* (2nd ed, Cambridge University Press, Cambridge, 2003), pp 652-8.

Protocol on Biosafety.[12] 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[13] ('LMOs').[14] 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.[15] Parties are free to take action that is more protective of biological diversity but such action must still be consistent with the objective and provisions of the Protocol and in accordance with other international law obligations.[16]

Australia, although a signatory to the Convention, has not signed the Protocol. Nevertheless the Protocol affects those Australians exporting LMOs to countries party to the Protocol.[17] However, the Protocol does not affect domestic regulation of GMOs. Further, the Protocol does not affect Australian importers of LMOs because existing domestic regulation rather than the Protocol would apply.[18] This study is concerned only with regulation of GMOs in Australia.

The Commonwealth and States have concurrent legislative power to deal with environmental issues in Australia.[19] To better protect the environment and give greater certainty to government and business decision-making, a special Premiers' Conference in

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[12] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (http://www.biodiv.org/biosafety/protocol.asp) (copy on file with author), opened for signature 29 January 2000. This is the first public international law to regulate GT. There were earlier international legal acts regulating biotechnology in the EC. See Council Directive 90/219/EEC of 23 April 1990, OJ L117, 8 May 1990 (re contained use) and Council Directive 2001/18/EC, OJ L106, 17 April 2001, replacing Directive 90/220/EEC of 23 April 1990, OJ L117, 8 May 1990 (re deliberate release into the environment).

[13] See Cartagena Protocol on Biodiversity to the Convention on Biological Diversity Article 3(g) 'Living modified organism' and 3(i) 'Modern biotechnology'. A GMO for these purposes is essentially an organism possessing a novel combination of genetic material obtained through the application of in vitro nucleic acid techniques or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and are not techniques used in traditional breeding and selection.

[14] Cartagena Protocol on Biodiversity to the Convention on Biological Diversity Article 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 (2/3) *BINAS News* (http://binas.unido.org/...show.php3??id=10&type=html&table=book_sources&dir=binasnew accessed 23/06/00).

[15] Cartagena Protocol on Biodiversity to the Convention on Biological Diversity Article 2(1) and (2).

[16] P Sands, *Principles of International Environmental Law* (2nd ed, Cambridge University Press, Cambridge, 2003), p 653. See also Cartagena Protocol on Biodiversity to the Convention on Biological Diversity Article 2(4).

[17] Aust, Productivity Commission, *Productivity Commission Submission to the Department of Foreign Affairs and Trade on the Cartagena Protocol on Biosafety* (November 2000), p 9.

[18] Aust, Productivity Commission, *Productivity Commission Submission to the Department of Foreign Affairs and Trade on the Cartagena Protocol on Biosafety* (November 2000), p 9. 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.

[19] G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), p 49.

October 1990 endorsed a cooperative approach between the Commonwealth and the States to environmental issues. An issued statement identified a national approach to, amongst other things, environmental impact assessment ('EIA')[20] and control of GMOs. The *Inter-Governmental Agreement on the Environment* was signed in 1992.[21] In that Agreement, the Commonwealth, States and local government agreed to integrate environmental considerations into government decision-making at all levels[22] and pursue the principles of ecologically sustainable development.[23] One of the principles set out as informing policy making is that of intergenerational equity. This principle provides that:

> The present generation should ensure that the health, diversity and productivity of the environment is maintained or enhanced for the benefit of future generations.[24]

The Agreement also provides that the adoption of sound environmental practices 'requires the effective integration of economic and environmental considerations in decision-making processes'.[25] The Agreement therefore reflects a policy to which all Australian Governments have agreed of integrating environmental considerations with economic and social considerations.[26] However, the Agreement does not have any direct legal effect.[27]

During 1996 and 1997 the Council of Australian Governments reviewed the Commonwealth role in environmental law. This resulted in the *Agreement on Commonwealth-State Roles and Responsibilities for the Environment*. Of particular relevance here is that it was agreed that inter-governmental relations on the environment are to be based on the principles of co-operation, effectiveness, efficiency, simplicity, transparency and seamlessness.[28] Further, project approval was to be 'streamlined' to rely on accredited State processes.[29]

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[20] See section 6.3.4 below.
[21] The Agreement is set out in the Sch to the *National Environment Protection Council Act 1994* (Cth). Information regarding the history of the Agreement is from G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), pp 76-7.
[22] *Inter-Governmental Agreement on the Environment*, 1992 [3.1].
[23] *Inter-Governmental Agreement on the Environment*, 1992 [3.2].
[24] *Inter-Governmental Agreement on the Environment*, 1992 [3.5.2].
[25] *Inter-Governmental Agreement on the Environment*, 1992 [3.2].
[26] D E Fisher, *Australian Environmental Law* (Lawbook Co, Sydney, 2003), p 111.
[27] D E Fisher, *Australian Environmental Law* (Lawbook Co, Sydney, 2003), p 111.
[28] *Agreement on Commonwealth-State Roles and Responsibilities for the Environment*, 1997, cl 2.
[29] Aust, Law and Bills Digest Group, *Shades of Green? Proposals to change Commonwealth Environmental Laws* Research Paper 16 1997-98 by J Prest and S Downing, Canberra, p 5.

6.3 ENVIRONMENTAL PROTECTION

6.3.1 *Environment Protection and Biodiversity Conservation Act 1999* (Cth)

It is an offence under the *EPBC Act* to undertake certain actions, called 'controlled actions' which are described in section 6.3.4 below, unless that action has been approved by the Commonwealth Environment Minister.[30] It will be demonstrated in this Part that the *EPBC Act* applies to commercialisers releasing GMOs. The legal challenges for commercialisers arising from the Act's application are then explored.

Previously proposed amendments to the *EPBC Act* are described in the next section, 6.3.2. The current interaction between the *GT Act* and Commonwealth Environment Minister is summarised in section 6.3.3. Section 6.3.4 describes, by reference to the relevant terms used in the legislation, why GMO releases will attract the operation of the Act. The general process followed under the *EPBC Act* is then outlined in sections 6.3.5 and 6.3.6. The review provisions of the Act are outlined in section 6.3.7. The final section, 6.3.8, discusses the implications of the application of the *EPBC Act* for commercialisers.

6.3.2 *Proposed Amendments*

The *EPBC Act* came into operation on 16 July 2000. It was a major change to Commonwealth environmental law. However, it applies in only relatively limited circumstances.[31] GMOs are not expressly mentioned in the 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 GTR, certain proposed GMO dealings were to undergo the assessment, but not the approval, process in the *EPBC Act*.[32]

Following the release of the GT Bill 2000 (Cth) for public comment, the proposed amendments to the *EPBC Act* were also released. The public was assured that the

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[30] *EPBC Act* Part 3.
[31] See section 6.3.5 below.
[32] Aust, Dept of Environment and Heritage, Explanatory material 'Environmental Assessment of Genetically Modified Organisms. Draft amendments to the *Environment Protection and Biodiversity Conservation Act 1999*' (2000) (http://www.environment.gov.au/epbc/gmos/gmoexp.html) (copy on file with author) released with Aust, Senator Robert Hill, Media Release, *Environmental Assessment of Genetically Modified Organisms* (21 January 2000) (http://www.environment.gov.au/minister/environment/2000/mr21jan00.html) (copy on file with author) ('Explanatory material re *EPBC Act* amendments').

proposed amendments would 'not establish a dual approval regime, but will establish a transparent mechanism for ensuring the [GTR] is properly advised on any environmental risks'.[33]

Specifically, it was proposed that whenever the GTR 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.[34] The Minister would then determine whether the risk assessment process carried out by the GTR was adequate to ensure a full assessment of environmental risks and, if not, what further environmental assessment under the *EPBC Act* was necessary.[35] It was envisaged that the Minister could accredit the GTR's risk assessment process in relation to a particular process or direct some other assessment be done.[36] Any advice of the Minister, following an environmental assessment, was then to be taken into account by the GTR when making the licensing decision.[37]

6.3.3 *Current Interaction between GTR and Commonwealth Environment Minister*

Although the *GT Act* was enacted, the *EPBC Act* was not amended as 'promised'. Instead the *GT Act* requires the Commonwealth Environment Minister, amongst others, be consulted during the DIR licensing process. As discussed in Chapter 2, consultation with the Commonwealth Environment Minister must occur both when RA&RMPs are being prepared and after the draft RA&RMPs have been completed.[38] The State Ministers with responsibility for the environment must also be consulted at these stages.[39] 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

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[33] Explanatory material re *EPBC Act* amendments.
[34] Explanatory material re *EPBC Act* amendments, cl 43B.
[35] Explanatory material re *EPBC Act* amendments, cls 43D and 43E.
[36] For criticisms of the proposed arrangement see Australian Biotechnology Association Submission on Draft EPBC Act Amendments (12 March 2000) (http://www.aba.asn.au/pages/epbc_act.html accessed 27/8/01).
[37] Explanatory material re *EPBC Act* amendments, cl 43F(5). The GTR was then to report to the Minister on how the environmental advice had been dealt with. Explanatory material re *EPBC Act* amendments, cl 43G.
[38] *GT Act* ss 50(3)(d) and 52(3)(d). That advice must then be taken into account. Sections 51(1)(f), (2)(f) and 56(2)(c).
[39] *GT Act* ss 50(3)(a) and 52(3)(a). Local councils that the GTR considers appropriate must also be consulted. Sections 50(3)(e) and 52(3)(e).

dealings not involving intentional release into the environment, whether or not they pose significant risk to the environment.[40]

Conversely, there is no provision in the *EPBC Act* exempting those with DIR licences 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, the requirements of any other Commonwealth law.[41] The Commonwealth *EPBC Act* has no provision dealing with its relationship to other Commonwealth Acts generally.[42] Therefore if a GMO release is an offence under the *EPBC Act*, that release remains an offence even if licensed under the *GT Act* and in compliance with the State moratorium legislation. The *EPBC Act* does provide that actions can be exempted by the Minister where the action has been approved by a Commonwealth or a Commonwealth agency.[43] However, no such declaration has been made with respect to GTR decisions.[44] Further, although assessment processes under Commonwealth or State law can be accredited on a case-by-case basis,[45] assessment under the *GT Act* has not been accredited.[46]

Contravention of the Act can result in criminal, civil and administrative penalties.[47] For example, undertaking an action to which the legislation applies without approval may incur a penalty of up to $5.5 million[48] or imprisonment for up to seven years.[49] Further, commercialisers' GMOs can be removed if the Minister suspects there has been a contravention of the Act, whether or not an offence has been committed.[50] This includes the destruction of organisms inadvertently contaminated by a GMO if GMO releases are controlled actions. Contraveners of the 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

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[40] The GTR has discretion to consult in such cases. *GT Act* s 47(4).
[41] As to the possibility of a constitutional challenge to the *GT Act* see N 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.
[42] *EPBC Act* s 9 deals with the Act's relationship with certain expressly described Acts which do not include the *GT Act*.
[43] See *EPBC Act* Pt 4, Div 2, sub-div A-D.
[44] Personal communication with Judy Johnson, Director, Biotechnology Section, Aust, Dept of the Environment and Heritage (Canberra, 5 February 2004).
[45] *EPBC Act* s 87(4).
[46] Personal communication with Judy Johnson, Director, Biotechnology Section, Aust, Dept of the Environment and Heritage (Canberra, 5 February 2004).
[47] See Aust, The Auditor-General, *Referrals, Assessments and Approvals under the Environment Protection and Biodiversity Conservation Act 1999*, Audit Report No 38 Performance Audit (2002-2003) Tabled 10 April 2003, [40].
[48] Eg, *EPBC Act* s 12(1).
[49] Eg, *EPBC Act* s 15A.
[50] *EPBC Act* s 499.

action.[51] The compensatory provisions of the Act are not limited to property damage. They include expenses reasonably incurred in repairing or removing conditions arising from the contravention that relate to the environment.[52] Given the definition of environment in the legislation, which is discussed below,[53] this would include, for example, the costs of recertification of an organic farm. Contraventions of the Act may also be publicised by the Minister in anyway that the Minister thinks appropriate.[54]

Injunctions to restrain field trials which contravene the legislation can also be obtained by any 'interested party'.[55] Non-GM 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 commercialiser's conduct.[56] Similarly, GM opponents 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 commercialiser's conduct.[57] 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.[58]

Amongst the monitoring powers under the Act,[59] authorised officers may enter and search premises with the owner's consent.[60] Search warrants can also be obtained.[61] Commercialisers should keep this in mind when considering adopting CI as the form of IP protection for their GMOs.

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[51] *EPBC Act* s 500(1).
[52] *EPBC Act* s 500(2)(a).
[53] See section 6.3.4(c).
[54] *EPBC Act* s 498(1).
[55] *EPBC Act* s 475(1). 'Interested party' is defined in ss 475(6) and (7) and 528. Injunctions can also be sought by the Minister or a person acting on behalf of an unincorporated organisation that is an interested person.
[56] *EPBC Act* s 475(6). In the case of organisations, the organisation must be Australian. *EPBC Act* 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. *EPBC Act* s 475(7). The environmental activities need not have been in Australia.
[57] *EPBC Act* s 475(6).
[58] *EPBC Act* s 478.
[59] See *EPBC Act* Part 17. It has been claimed though that the *EPBC Act* does not provide for proper monitoring and review of developments once the EIA has been completed. L Hughes, 'Environmental Impact Assessment in the Environment Protection and Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 441, 459.
[60] *EPBC Act* s 405(1).
[61] *EPBC Act* Part 17, Div 4.

6.3.4 *Application of Act to GMOs*

An 'action' includes a project, a development, an undertaking, and an activity or series of activities.[62] Seeking and granting a DIR licence under the *GT Act* are not actions for these purposes.[63] The actual releasing of the GMO or raising of a GMO would, however, be an action. However, the Act applies only to 'controlled actions'.

'Controlled actions' are:[64]

> 1. Actions that have, or are likely to have a significant impact on a matter of national environmental significance (MNES) and do not fall within an exception provided in the Act.
>
> 2. Actions that will have or are likely to have a significant impact on the environment associated with a Commonwealth area,[65] 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 agency[66]).[67]

Whether a GMO release could be a controlled action is now considered.

(a) Matters of National Environmental Significance

The *EPBC Act* applies if the commercialiser's action of field trialling a GMO has, will have or is likely to have a significant impact on a MNES and is not subject to one of the exceptions provided for in the Act.[68] The Act lists six MNES. These are: World Heritage

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[62] *EPBC Act* ss 528 (definition of 'action') and 523-524.
[63] *EPBC Act* ss 524-524A. See I Thomas, *Environmental Impact Assessment in Australia. Theory and Practice* (3rd ed, The Federation Press, Sydney, 2001), p 126 with respect to governmental authorisations generally.
[64] I Thomas, *Environmental Impact Assessment in Australia. Theory and Practice* (3rd ed, The Federation Press, Sydney, 2001), p 126.
[65] See *EPBC Act* s 525 with respect to a 'Commonwealth area'.
[66] See *EPBC Act* s 528 (definition of 'Commonwealth agency').
[67] *EPBC Act* Division 2 Part 3.
[68] I Thomas, *Environmental Impact Assessment in Australia. Theory and Practice* (3rd ed, The Federation Press, Sydney, 2001), p 126.

properties;[69] Ramsar wetlands of international importance;[70] listed threatened species and ecological communities;[71] listed migratory species;[72] nuclear activities[73] and Commonwealth marine areas.[74] 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.[75] They could also now be prescribed as an additional matter of national environmental significance.[76] However, this has not occurred.

Although commercialisers 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* can be triggered if a GMO release is likely to have a significant impact on a MNES although the action itself is not within the area.[77] Field trialling a GMO may therefore be considered to have a significant impact on a nearby MNES. For example, the escape of a GMO into the MNES may trigger the Act. Similarly, although commercialisers 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 habitat of a particular species may cause such a trigger.[78]

(b) 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 commercialiser 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.

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[69] *EPBC Act* s 12.
[70] *EPBC Act* s 16.
[71] *EPBC Act* s 18
[72] *EPBC Act* s 20
[73] *EPBC Act* s 22.
[74] *EPBC Act* s 23.
[75] Environment Defender's Office, *Submission on the Consultation Paper* (Sydney, March 1998), p 4 (not seen) 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.
[76] *EPBC Act* s 25.
[77] *EPBC Act* ss 12(1), 16(1) and 23(2). See also *Booth v Bosworth* (2001) 114 FCR 39.
[78] However, in all of these cases the Minister is permitted only to assess those parts of the project which specifically affect the MNES. The remainder of the proposal must be assessed by the States. L Hughes, 'Environmental Impact Assessment in the Environment Protection and Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 441, 452. See *EPBC Act* s 133.

(c) Environment

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).[79]

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).[80] 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 GTR's current approach, will not be under the *GT Act*.[81] 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 research in this country, would not, however, fall within the *EPBC 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.[82]

(d) Assessment of Significant Impact

Neither the *EPBC Act* nor the Regulations deal with when actions have a significant impact.[83] There are, however, Administrative Guidelines issued by the Department of the

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[79] *EPBC Act* s 528.
[80] *GT Act* s 10.
[81] See discussion in section 2.8.5.
[82] See, for eg, *Coastal Waters Alliance of Western Australia v EPA* (1996) 90 LGERA 136 (FC) which discusses such requirements with respect to WA legislation.
[83] The *EPBC Act* 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. *EPBC Act* s 520.

Environment and Heritage.[84] 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.[85] 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.[86]

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'.[87] Her Honour also indicated, without deciding, that she thought that to be 'likely' in the context of 'likely to have a significant impact' meant an impact was prone or liable rather than more likely than not.[88]

The onus on proponents to decide whether an action will have a significant impact has been described by one commentator as onerous.[89] 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 commercialisers will be required to look for impacts beyond the immediate vicinity of the project area.[90] In the Administrative Guidelines though, in respect of most MNES[91] it is noted that an action has a significant impact if it results in an invasive species becoming established in the MNES 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 *EPBC Act* to include a definition of invasive species.[92] That definition expressly includes GMOs.[93]

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[84] Aust, Dept of the Environment and Heritage, *EPBC Administrative Guidelines on Significance* (July 2000) (http://www.environment.gov.au/epbc/proponents/significance_guidelines/significance_guidelines.html) (copy on file with author).
[85] I Thomas, *Environmental Impact Assessment in Australia. Theory and Practice* (3rd ed, The Federation Press, Sydney, 2001), p 127.
[86] I Thomas, *Environmental Impact Assessment in Australia. Theory and Practice* (3rd ed, The Federation Press, Sydney, 2001), p 127.
[87] (2001) 114 FCR 39 at 65.
[88] (2001) 114 FCR 39 at 64.
[89] B Kennedy, 'The operation of the new *EPBC Act*' (2000) 74 *Law Institute Journal* 61, 63.
[90] B Kennedy, 'The operation of the new *EPBC Act*' (2000) 74 *Law Institute Journal* 61, 63.
[91] The exceptions are World Heritage properties, nuclear actions and marine environments.
[92] Environment Protection and Biodiversity Conservation Amendment (Invasive Species) Bill 2002 (Cth) introduced into the Senate on 19 November 2002 by Senator Bartlett. See also Cth, *Parliamentary Debates*, Senate 19 November 2002, 6738-43 (Bartlett, Qld-Leader of the Australian Democrats). The Bill has been referred to the Senate Environment, Communications, Information Technology and the Arts References Committee (on 26 June 2003) which is due to report on 25 November 2004.

6.3.5 *Referrals and Environmental Assessment*

If a commercialiser believes that their proposed field trial is an action to which the *EPBC Act* applies 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.[94] It is not an offence to fail to refer, but commencing the action without a referral can lead to the penalties described above. Commonwealth agencies such as the GTR may also refer proposals to the Minister for determination.[95] However, given that the obligation is imposed on the proponent to have approval, commercialisers should not rely on referral by the GTR. Of interest for commercialisers 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 Internet[96] and the Minister is required to consider public comments on them.[97] Further, reports by the public to the Department of the Environment and Heritage of activities potentially in breach of the Act are investigated.[98]

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.[99] Unfortunately for commercialisers, the Minister must not consider any beneficial impacts.[100] Adverse impacts include all likely impacts including those caused by third parties in response to the commercialiser's action.[101] For example, that the introduction of 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.

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[93] Environment Protection and Biodiversity Conservation Amendment (Invasive Species) Bill 2002 (Cth) (as read for the first time) Sch 1, proposed s 266AB(1).
[94] *EPBC Act* s 68. The Regulations prescribe the form and content of the referral. *EPBC Act* s 72 and Environment Protection and Biodiversity Conservation Regulations 2000 (Cth) Part 4 and Sch 2.
[95] *EPBC Act* s 71. The Environment Minister may also trigger the Act in the absence of a referral. *EPBC Act* s 70. See also s 69 regarding State agencies.
[96] *EPBC Act* s 74(3).
[97] *EPBC Act* s 75(1A).
[98] Aust, Environment Australia, *Environment Australia Annual Report 2001-02* (2002). Indeed, the Dept relies heavily on third parties to identify non-compliance with the Act. Aust, The Auditor-General, *Referrals, Assessments and Approvals under the Environment Protection and Biodiversity Conservation Act 1999*, Audit Report No 38 Performance Audit (2002-2003) Tabled 10 April 2003, [6.11].
[99] *EPBC Act* s 75(2)(a).
[100] *EPBC Act* s 75(2)(b).
[101] *Queensland Conservation Council Inc v Minister for the Environment and Heritage (Nathan Dam Case)* [2003] FCA 1463 (19 December 2003). 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.

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. The Minister decides, subject to certain prerequisites and standards being met, which of the assessment approaches in the *EPBC Act* should be used.[102] 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 commercialisers 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 Commonwealth Minister at its conclusion.[103]

One method of assessment is by State assessment.[104] State EIA[105] processes may be accredited under the Act by bilateral agreement.[106] 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'.[107] The *EPBC Act* provides for a minimum standard before a State EIA process can be accredited.[108] It does not, though, prohibit more stringent EIA requirements.[109] Nor can the Commonwealth force States to seek accreditation. Commercialisers will therefore need

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[102] *EPBC Act* s 87(1). See I Thomas, *Environmental Impact Assessment in Australia. Theory and Practice* (3rd ed, The Federation Press, Sydney, 2001), pp 131-6 with respect to the assessment process.
[103] *EPBC Act* s 130(1)(a).
[104] Alternatively assessment may be done on preliminary documentation, Public Environment Report (PER), Environmental Impact Statement (EIS) or assessment by Public Enquiry. *EPBC Act* s 87(1). For a description of such processes see G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), pp 289-90.
[105] See generally I Thomas, *Environmental Impact Assessment in Australia. Theory and Practice* (3rd ed, The Federation Press, Sydney, 2001). See also Cth Dept of the Environment and Heritage website http://www.environment.gov.au/epg/eia.html which provides information on Cth procedures and links to State activities.
[106] Standards for drawing up bilateral agreements are set out in the Environment Protection and Biodiversity Conservation Regulations 2000 (Cth) Part 3. There are bilateral agreements in place with NT, Tasmania and WA. Aust, Dept of the Environment and Heritage, *Department of the Environment and Heritage Annual Report 2002 – 2003* (2003). State approval processes can also be accredited.
[107] L Hughes, 'Environmental Impact Assessment in the Environment Protection and Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 441, 447.
[108] See *EPBC Act* ss 29 and 45-65A re national benchmarks for State legislation to meet to receive accreditation. Essentially, management plans can only be accredited if the plan and relevant State or Cth law meet criteria specified in the Regulations, have been tabled in both Houses of Parliament and not been disallowed.
[109] L Hughes, 'Environmental Impact Assessment in the Environment Protection and Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 441, 448.

to consider whether any particular State is a better jurisdiction, in terms of its EIA, in which to release GMOs.

6.3.6 *Approval*

Two types of matters are described as mandatory considerations in the Minister's decisions regarding approval of controlled actions.[110] The first are essentially environmental and ecological matters.[111] In complete contrast to the *GT Act*, 'economic and social matters' are the second type of mandatory considerations.[112] 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.[113] In considering those matters, the Minister is required to take into account the principles of ecologically sustainable development[114] and any assessment report.[115] Relevant principles of ecologically sustainable development include long and short-term economic, environmental, social and equitable considerations.[116] As in the *GT Act* the precautionary principle must also be taken into account.[117] However, unlike the *GT Act*[118] there is no mention of cost-effective measures. Arguably the principle therefore has wider application in the *EPBC Act* than the *GT Act*.[119] A further principle relevant to this study which is also to be taken into account is that of inter-generational equity described in the 1992 Inter-Governmental Agreement on the Environment.[120]

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[110] *EPBC Act* s 136(1). See *EPBC Act* ss 136-140A with respect to other relevant matters. See also S Campbell, 'Governance, Responsibility and the Market: Neo-liberalism and Aspects of the Environment Protection And Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 290, 299.
[111] *EPBC Act* s 136(1)(a).
[112] *EPBC Act* s 136(1)(b).
[113] D E Fisher, *Australian Environmental Law* (Lawbook Co, Sydney, 2003), p 120.
[114] *EPBC Act* s 136(2)(a).
[115] *EPBC Act* s 136(2)(b)–(e).
[116] *EPBC Act* s 3A(a).
[117] *EPBC Act* 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 J Frangos, 'Environmental Science and the Law' (1999) 16 *Environmental and Planning Law Journal* 175. See generally A Deville and R Harding (eds), *Applying the Precautionary Principle* (Federation Press, NSW, 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; G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), pp 129-35.
[118] *GT Act* s 4(aa).
[119] M Tranter, 'A question of confidence: an appraisal of the operation of the Gene Technology Act 2000' (2003) 20 *Environmental and Planning Law Journal* 245, 247.
[120] *EPBC Act* s 3A(c).

Also of relevance here, other Commonwealth Ministers[121] 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.[122]

The Environment Minister may also take into account whether the commercialiser is a suitable person to be granted approval in light of their environmental record[123] but cannot take into account any other matters.[124] There is no explanation of 'environmental record'. However, given the broader understanding of 'environment' in the *EPBC Act*[125] 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 community[126] and the views of those communities about the action.[127]

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.[128] This will be of advantage in respect of many GMOs where, for example, there are economic benefits to adopting GM technology. However, the Minster may also take into account negative effects of a GMO release. GM opponents could, for example, point to potential effects on non-GM agriculture to put pressure on the Minister to refuse to grant approval to a GMO commercialiser.

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[121] If that Minister has administrative responsibilities relating to the proposed action. *EPBC Act* s 131(1)(a).
[122] *EPBC Act* s 136(2)(f).
[123] *EPBC Act* s 136(4).
[124] *EPBC Act* s 136(5).
[125] See subsection 6.3.4(c).
[126] See Aust, Dept of the Environment and Heritage, *Preliminary Information Form*, Part 9.
[127] Aust, Dept of the Environment and Heritage, *Preliminary Information Guide*, Part 1(9).
[128] S Campbell, 'Governance, Responsibility and the Market: Neo-liberalism and Aspects of the Environment Protection And Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 290, 299.

6.3.7 *Rights of Review*

Of further concern to commercialisers is that, unlike the *GT Act*, the *EPBC Act* expressly extends the meaning of a 'person aggrieved' in the *Administrative Decisions (Judicial Review) Act 1977* (Cth).[129] 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 individuals[130] who have engaged in environmental protection, conservation or research in Australia in the two years preceding the decision they wish to challenge.[131] Many GM opponents may have standing for these purposes. They therefore, together with landowners and residents adjoining the commercialiser's land as in the case of the *GT Act*,[132] clearly have standing to challenge the Minister's decision that a particular GMO release is not a controlled action or to approve an action.[133] However, no merits review of a Ministerial decision on approval of an action is possible.

Commercialisers are also entitled to challenge the Minister's decisions regarding whether a field trial 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.[134] Such reasons can make challenging a decision simpler because they should include all matters, relevant and irrelevant, considered by the Minister. This means that decisions made very early in the process by commercialisers may have significant repercussions on their rights to obtain reasons.[135] Reasons for approval or otherwise are not available.

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[129] *EPBC Act* s 487.
[130] Including organisations.
[131] *EPBC Act* s 487(1) and (2). In the case of organisations, the organisation's objects or purposes must also include environmental protection, conservation or research. *EPBC Act* s 487(3). See also *Booth v Bosworth* (2001) 114 FCR 39; *Schneiders v State of Queensland* [2001] FCA 553; *Queensland Conservation Council Inc v Minister for the Environment and Heritage (Nathan Dam Case)* [2003] FCA 1463 (19 December 2003).
[132] See subsection 2.9.5(b) above.
[133] *EPBC Act* ss 487 and 488. Although see *Tasmanian Conservation Trust Inc v Minister for Resources (Gunns [No 2])* (1996) 90 LGERA 106 (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.
[134] *EPBC Act* s 77(5).
[135] L Hughes, 'Environmental Impact Assessment in the Environment Protection and Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 441, 456.

6.3.8 *Consequences for Commercialisers*

Field trialling GMOs may in some cases be considered to have or be likely to have a significant impact on a MNES 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 trialling. If the *EPBC Act* is amended as discussed in subsection 6.3.4(d) 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 commercialiser's perspective, the possible application of the *EPBC Act* is of concern for a number of reasons. These are discussed below. Possible solutions are suggested in Part 6.5.

First, and most obviously, the application of the *EPBC Act* to GMO releases means commercialisers, like other proponents under the Act, have the problem of predicting what environmental assessment process will be used by the Minister. This makes it difficult to accurately predict what the approval process will cost or what data is required.[136] Such uncertainty has been noted by the peak body representing the biotechnology industry in Australia as a deterrent to GMO commercialisation.[137]

Secondly and more importantly, the overlap between the *GT Act* and the *EPBC Act* means some commercialisers will need to comply with more than one regulatory system whose objects are both to protect the environment.[138] Many activities require licences 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,[139] complexity and possible inconsistency between regulations. Further, given that the Minister will be engaged in a weighing up of the socio-economic impacts of a GMO

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[136] See Australian Biotechnology Association Submission on Draft EPBC Act Amendments (12 March 2000) (http://www.aba.asn.au/pages/epbc_act.html accessed 27/8/01), Point 4.

[137] See Australian Biotechnology Association Submission on Draft EPBC Act Amendments (12 March 2000) (http://www.aba.asn.au/pages/epbc_act.html accessed 27/8/01), Point 4. Hughes has also noted that if a commercialiser 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.' L Hughes, 'Environmental Impact Assessment in the Environment Protection and Biodiversity Conservation Act 1999 (Cth)' (1999) 16 *Environmental and Planning Law Journal* 441, 452.

[138] *EPBC Act* s 3(1)(a); *GT Act* s 3.

[139] 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. Aust, Bureau of Industry Economics, *Environmental Assessment – Impact on Major Projects*, Research Report (AGPS, Canberra, 1992).

release, many of the same considerations relevant under the State moratorium legislation will be relevant here. Exactly what the overlap will be though is unclear because of the lack of detail in the State legislation. Nevertheless it gives rise to the possibility that a State Minister[140] may determine that a GMO release may proceed but the Commonwealth Environment Minister may refuse approval. This can be explained on the basis that the Commonwealth Minister is acting in the interests of the environment. However, if a DIR licence has been granted the GTR will have already assessed environmental risks as manageable taking into account the Commonwealth Environment Minister's comments.

If the Commonwealth Minister is unlikely to refuse approval in such cases because of the GTR's assessment process and the Environment Minister's involvement in it, then the power to do so should be removed to provide legal certainty to commercialisers. If the Minister continues to have the power to refuse approval in such circumstances that creates additional problems for commercialisers. First, third parties may seek to take advantage of this overlap to in effect nullify the State or GTR decision as the case may be. Third parties may seek an injunction pursuant to the *EPBC Act*, taking advantage of the increased standing provisions in that Act. The State moratorium legislation, except for the NSW Act, does not provide for the issuing of injunctions even where the legislation has been contravened. The NSW Act limits the availability of injunctions to the Minister.[141] Injunctions may be sought by third parties under the *GT Act* but, as discussed in Chapter 2, socio-economic impacts are not so clearly relevant there. For an injunction under the *EPBC Act*, the third party must satisfy certain conditions, including showing that the commercialiser has or will contravene the *EPBC Act*.[142] A court in deciding this will consider the socio-economic impacts of the release. However, how the discretion will be used is difficult to predict creating uncertainty for commercialisers. 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,

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[140] Secretary of the Department for Primary Industries and Water in Tasmania. See Chapter 3.
[141] *Gene Technology (GM Crop Moratorium) Act 2003* (NSW) s 32(1).
[142] *EPBC Act* s 475(2).

> should prevail over interests recognised by the international community and the Parliament of Australia as being of international importance.[143]

This comment could be expected to also apply matters involving threats to other MNES under the Act. Therefore it seems the court will prefer environmental matters to economic ones when making such decisions.

Secondly, that the Environment Minister can render worthless DIR licences under the *GT Act* by refusing to approve a controlled action proposed by a commercialiser opens the decision-making process on GMO releases to political influence and encourages political conflicts, something which the creation of the GT regulatory scheme was supposed to avoid.[144]

6.4 POLLUTION OFFENCES

6.4.1 *Introduction*

In Victoria, responsibility for controlling environmental harm rests mainly with a central environmental protection authority, the Environment Protection Authority ('EPA'), under the *Environment Protection Act 1970* (Vic) ('*EP Act*').[145] The Victorian Department of Primary Industries ('DPI'), in administering the *Agricultural and Veterinary Chemicals (Control of Use) Act 1992* (Vic) ('*AVCC Act*'), can also prosecute those who cause harm whilst pursuing agricultural pursuits. Other authorities have control over processes that may lead to environmental harm as well. For example, local authorities have responsibility for the control of noise, water, air and visual pollution.[146] Whilst GMO releases could cause pollution in many forms, such as air pollution if GM pollen enters the air or water pollution if GMOs or parts of them enter the waterways, the most common complaint could be expected to be pollution of land. Accordingly that is the type of harm that is the subject of this examination.

The DPI considers that it would be difficult to prove an offence under the *AVCC Act* when the GTR, in consultation with the Commonwealth Department of the Environment and Heritage has already assessed the GMO as posing no undue risk to the environment or

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[143] (2001) 114 FCR 39 at 68.
[144] *GT Act* s 30. See Australian Biotechnology Association Submission on Draft EPBC Act Amendments (12 March 2000) (http://www.aba.asn.au/pages/epbc_act.html accessed 27/8/01), Point 3 making these points with respect to proposed amendments to *EPBC Act*.
[145] *EP Act* s 13(1)(b). The Authority is established pursuant to the *EP Act*.
[146] Pursuant to the *Local Government Act 1989* (Vic) and *Health Act 1958* (Vic).

human health.[147] It is submitted that this is not correct and that an offence may be made out even if the releaser concerned holds a licence under the *GT Act*.

The EPA's approach to GMO releases is that although the Victorian legislation allows for investigation in the circumstances of GMO releases causing harm to the environment, the EPA has never undertaken such an investigation and is unlikely to do so.[148] The *GT Act* is considered by the EPA to be the primary legislation with respect to harm caused by GMO releases.[149] Complaints of that nature received by the EPA would be referred on to the GTR.[150] Although the EPA may not intend to pursue commercialisers in such cases, the concern for commercialisers is that the EPA or the relevant Minister may be put under pressure to do so. Further, changes in public opinion may cause the EPA to change its practice.[151]

Section 6.4.2 discusses the effect of any inconsistency between the relevant legislation. The relevance of the *AVCC Act* and *EP Act* to GMO releases is then discussed in sections 6.4.3 and 6.4.4 respectively.

6.4.2 *Inconsistency between Legislative Provisions*

(a) *GT Act* and State legislation

Generally Commonwealth law prevails over State law if such laws are inconsistent.[152] Therefore if the State environmental law under which proceedings are threatened is inconsistent with the Commonwealth *GT Act*, the relevant State environmental law will be invalid.[153] A State law can be inconsistent with a Commonwealth law for several reasons, including if a Commonwealth law confers immunity from liability under State law[154] or if

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[147] Personal communication with Chris May, Senior Project Officer Legislation, Victorian Department of Primary Industries, Chemical Standards Branch (Melbourne, 23 October 2003).
[148] Personal communication with Michael Hodder, EPA Victoria, Manager Prosecutions Unit (Melbourne, 6 November 2003).
[149] Personal communication with Cecelia Davis, EPA Victoria, Policy Officer, Strategic Coordination Unit (Melbourne, 6 November 2003).
[150] Personal communication with Cecelia Davis, EPA Victoria, Policy Officer, Strategic Coordination Unit (Melbourne, 6 November 2003).
[151] The ALRC 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 65 (April 2003), [5.5].
[152] *Commonwealth Constitution* s 109.
[153] L McIntosh, 'Liability for loss of Biodiversity caused by the release of Genetically Modified Organisms' (2002) 4 *National Environmental Law Review* 40, 43.
[154] *Council of the Municipality of Botany v Federal Airports Corporation* (1992) 175 CLR 453 at 464.

the Commonwealth intends to exclusively govern the particular matter to which its attention is directed.[155]

The *GT Act* does not clearly state whether it is intended to confer immunity from prosecution under State environmental legislation or exclusively govern a particular aspect of the licensing of GMO releases.[156] Section 16 provides that it is not intended to exclude the operation of any State laws provided that the State law is capable of operating concurrently with the Commonwealth Act. No guidance is given as to which State laws can do that. However, if Parliament wanted to exempt commercialisers from the need to comply with other legislation it could more clearly have said so.[157]

Subsection 16(1) provides that a State law can be prescribed by the regulations as one that *cannot* operate concurrently with the *GT Act*. No State law has been so prescribed and this may only be done, inter alia, if there is no corresponding law[158] in the State concerned.[159] The *Gene Technology Act 2001* (Vic) ('*Vic GT Act*') and accompanying regulations have been declared corresponding State law.[160] Therefore Victoria's laws cannot be prescribed. However, not all States have corresponding State law for these purposes. The possibility of future prescription therefore exists in those jurisdictions.

It is clear that the Commonwealth *GT Act* does not govern the field. The making by the GTMC of the Designated Areas Policy Principle and the subsequent State moratorium legislation are evidence of that. Even before those steps, it is submitted it did not cover the field. The *GT Act* makes no provision with respect to liability for harm caused by GMO releases. Nor does it provide for compensation to those affected by releases. In those

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[155] *Ex parte McLean* (1930) 43 CLR 472 at 483 (Dixon J).

[156] L McIntosh, 'Liability for loss of Biodiversity caused by the release of Genetically Modified Organisms' (2002) 4 *National Environmental Law Review* 40, 43. The Explanatory Memorandum to the Cth Act stated that:

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

Cth House of Representatives, Gene Technology Bill 2000 Explanatory Memorandum (2000) Notes re Clause 16.

[157] See, for eg, *Corkill v Forestry Commission of NSW [No 2]* (1991) 73 LGRA 126 and *Forestry Commission of NSW v Corkill* (1991) 73 LGRA 247 where the prevailing licensing Act expressly provided that it prevailed over other legislation.

[158] As to meaning of this phrase see *GT Act* s 12.

[159] *GT Act* s 16(2).

[160] 'Declaration That State Laws are Corresponding State Law' 16 May 2001, *Cth of Aust Gazette*, No GN 21 (29 May 2002), p 1517. The laws of SA and Qld have also been declared corresponding State laws. See ibid regarding SA and 'Declaration That State Laws are Corresponding State Law' 20 November 2002, *Cth of Aust Gazette*, No GN 50 (18 December 2002), p 3793 regarding Qld.

circumstances a court is unlikely to find that the Commonwealth Government intended to remove all responsibilities of commercialisers other than compliance with the *GT Act* and all rights of third parties affected by a release. Finally, it is likely that a court would find that an Act which creates a pollution offence, such as the *EP Act*, is concerned with a different field to that of a licensing Act such as the *GT Act*. Although the purposes of both Acts include environmental protection,[161] the general object of the Acts is different, the *GT Act* being the only one aimed at regulating GT.[162] Commercialisers will therefore need to comply with obligations under State environmental legislation in addition to obligations under the *GT Act* if the State legislation is applicable.

(b) Inconsistency between Victorian legislation

The *Vic GT Act* provides that its provisions are additional to and not in substitution for any other Victorian laws.[163] The Victorian *EP Act* on the other hand provides that its provisions take precedence over inconsistent provisions in any other State legislation.[164] There is no equivalent provision in the *AVCC Act* or *Control of Genetically Modified Crops Act 2004* (Vic) ('*Vic GM Act*'). Accordingly if there is an inconsistency between the State Acts, the *EP Act* takes priority. Commercialisers with a licence under the *Vic GT Act* or an exemption under the *Vic GM Act* could therefore still be prosecuted under the *EP Act* and/or *AVCC Act*.[165]

6.4.3 *Agricultural and Veterinary Chemicals (Control of Use) Act 1992* (Vic)

(a) Legislative provisions

The 'overwhelming purpose' of the *AVCC Act* is 'to protect human health and the environment'.[166] Application of the relevant part of the *AVCC Act* is limited to harm caused by agricultural chemical products. Some GMOs will be agricultural chemical

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[161] *GT Act* s 3; *EP Act* s 1A(1).
[162] For eg, in *Associated Minerals Consolidated Ltd v Wyong Shire Council* [1975] AC 538 at 554 the Privy Council held, by considering the purpose of the two Acts before it, that the purposes were quite different 'each of which is capable of being fulfilled'. The two duties not to do particular things were separate and independent and the obligation to comply with both was not removed by a licence to do one.
[163] *Gene Technology Act 2001* (Vic) s 15.
[164] *EP Act* s 3(2).
[165] See, for the same conclusion with respect to WA legislation, L McIntosh, 'Liability for loss of Biodiversity caused by the release of Genetically Modified Organisms' (2002) 4 *National Environmental Law Review* 40, 42.
[166] *Wilson v Gahan* [1999] VSC 72 (Unreported, Warren J, 18 March 1999). See also *AVCC Act* s 1; Vic, *Parliamentary Debates*, Legislative Assembly, Second Reading Speech, 9 May 1991, 2039-40 (Baker, Minister for Agriculture).

products for the purposes of the legislation.[167] The definition of agricultural chemical product refers to *substances* having certain effects on plants or animals. 'Substance' is defined as including 'an organism or part of an organism, including a genetically manipulated organism or part of a genetically manipulated organism'.[168] There is no definition of genetically manipulated organism but its natural meaning could be presumed to include organisms regulated by the GT regulatory scheme.

Pursuant to s 40 *AVCC Act* it is an offence to spray, spread or disperse agricultural chemical products[169] which injuriously affects -

(a) any plants or stock outside the target area; or

(b) any land outside the target area so that growing plants or keeping stock on that land can be reasonably expected to result in the contamination of the stock or of agricultural produce derived from the plants or stock.

Section 41 makes it an offence to spray, spread or disperse agricultural chemical products[170] -

(a) which contaminates any stock outside the target area; or

(b) which is likely to contaminate any agricultural produce derived from plants or stock outside the target area.

The penalty in the first case is a $40,000 fine if the defendant is a corporation and $20,000 in other cases[171] and in the second case, $20,000 in the case of corporations and $10,000 in other cases.[172] The offences are ones of absolute liability[173] and there are no defences other than as provided in the legislation.[174] Offenders can be ordered to compensate persons suffering loss or destruction of or damage to property as a result of an offence under the Act.[175]

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[167] *AVCC Act* s 4(1) (definition of 'agricultural chemical product') which in effect adopts the definition of the same term in s 4 Agricultural and Veterinary Chemicals Code, Sch to *Agricultural and Veterinary Chemicals Code Act 1994* (Cth). See also *Agricultural and Veterinary Chemicals (Victoria) Act 1994* (Vic) s 5.
[168] Agricultural and Veterinary Chemicals Code, Sch to *Agricultural and Veterinary Chemicals Code Act 1994* (Cth), s 3 (definition of 'substance' para (b)).
[169] See *AVCC Act* s 4(1) (definition of 'agricultural spraying').
[170] See *AVCC Act* s 4(1) (definition of 'agricultural spraying').
[171] *AVCC Act* s 40(1).
[172] *AVCC Act* s 41(1).
[173] *Wilson v Gahan* [1999] VSC 72 (Unreported, Warren J, 18 March 1999) with respect to s 40(1).
[174] See *AVCC Act* ss 40(2) and 41(2).
[175] *Sentencing Act 1991* (Vic) s 86.

'Plant' is defined broadly.[176] 'Stock' is limited to animals which are used as or produce products used as food for humans.[177] Any adverse effect on an animal kept or raised for non-food purposes, such as horses or dogs, would therefore not be sufficient.

With respect to a s 40 offence there is no explanation of when something has been 'injuriously affected' although s 40(2) provides that it is a defence that the plants or stock affected have no economic value. Presumably affecting the economic value of the plants or stock even though there is no physical harm is sufficient.[178] However, harm to the environment generally such as reduction in biodiversity where there is no 'economic value' involved, would not be.

'Contamination' as used in ss 40(1)(b) and 41 is defined as meaning in relation to an animal or agricultural produce that the contaminant is present 'at such a level that the produce does not, or that food produced from the animal or produce is not likely to, comply with the **Food Act 1984**;'.[179] 'Contaminant' is defined broadly.[180] 'Agricultural produce' means plants or parts thereof whether harvested or not or any carcass or commodity from a plant or animal which is used as food for humans or animals.[181]

(b) Application to GMOs

If a GMO release results in the GMO, its parts or progeny spreading to another's plants or stock to such a level that Standard 1.5.2 of the Australia New Zealand Food Standards Code, adopted into law under the Victorian *Food Act*, applies there may be contamination for the purposes of the *AVCC Act*.[182] For example, if the contamination is by a GMO not approved for sale under the Standard, then the contaminated produce would not be permitted to be sold as food under Victorian law. As discussed in Chapter 2, the labelling provisions of the Standard have a minimum threshold of one percent where the presence of GM product is unintended.[183] However, this threshold does not apply to the approval

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[176] *AVCC Act* s 4(1) (definition of 'plant').
[177] *AVCC Act* s 4(1) (definition of 'stock'). See also definition of 'animal' in s 4(1).
[178] See Vic, *Parliamentary Debates*, Legislative Assembly, 23 August 2001, 231-3 (Hamilton, Minister for Agriculture).
[179] *AVCC Act* s 4 (definition of 'contaminated'). Alternatively it means the animal or produce has a contaminant present in excess of the maximum residue limit.
[180] *AVCC Act* s 4 (definition of 'contaminant'). The definition simply provides that the term includes radioactive substances.
[181] See *AVCC Act* s 4 (definition of 'agricultural produce').
[182] With respect to the Standard see Part 2.10 above.
[183] Australia New Zealand Food Standards Code Standard 1.5.2 cl 4(1)(f).

provisions.[184] Approval is necessary even in the case of very low levels of contamination by a GMO not approved for sale as food. Invasion of a non-GM crop by a GMO therefore could mean the crop no longer complies with the *Food Act* and is therefore 'contaminated' for the purposes of the *AVCC Act*.

However, stock on another's property eating grass or other feed to which a GMO, its parts or progeny have spread, would not be contaminated for these purposes. An editorial note in Standard 1.5.2 expressly provides that the Standard does not apply to food derived from organisms that have been fed food produced using GT unless the organisms were created using GT. Further, contamination by a GMO that has been approved under the Standard would not render the food not in compliance with the *Food Act*. The produce may require labelling under the Standard but it is submitted that this should not be sufficient to be contamination for these purposes. Produce should not be treated as 'not likely' to comply with the *Food Act* when a label is all that is required to satisfy the law.

In the cases described above, the contaminated plant or stock may be physically unhurt. Nevertheless, its economic value may be reduced. That could be sufficient. First, as noted above economic harm alone may be sufficient to found an offence under s 40. Secondly, the purposes of the Act expressly include the protection of domestic and export trade in agricultural produce and livestock.[185] This would, it could be argued, include protecting trade from harm due to GM contamination.

Because the GTR does not consider the economic impacts of GMOs when making licensing decisions, a DIR licence is not evidence that there are no such implications in allowing a release. Therefore the appropriateness of the DPI's deferral to GTR decisions is questionable. The enactment of the *Vic GM Act*, though, strengthens the DPI's position. It is now arguable that the same considerations relevant under the *AVCC Act* have been assessed by either the GTR or State Minister. However, as discussed in Chapter 3 the *Vic GM Act* does not apply to all GMOs. Furthermore, because it is not clear from the *Vic GM Act* what considerations are relevant to decisions made under it, it is difficult to judge whether the same considerations as relevant under the *AVCC Act* will actually have been assessed. For example, the *Vic GM Act* is intended, in part, to preserve the identity of GM and non-GM crops for marketing purposes.[186] Marketing is not defined and it is unclear

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[184] Unless it is a food additive or food processing aid.
[185] *AVCC Act* s 1(a)(iv).
[186] *Vic GM Act* s 1(a)(i).

whether it includes the same trade issues falling within the scope of the *AVCC Act*. If it does not, then the fact that a particular GMO is not prohibited under the *Vic GM Act* or is exempted from any prohibition is not evidence that there has been an assessment by the State Minister that there will be no harm to relevant interests by the GMO release for the purposes of the *AVCC Act*. A final reason why compliance with the *Vic GM Act* should not be taken as evidence that there has been no breach of the *AVCC Act* relates to the issue of thresholds. The *Vic GM Act* provides that the Minister can determine the threshold amounts for the presence of a GMO in crops.[187] If the amount of GMO present in a crop does not exceed that amount, its presence can be disregarded.[188] Difficulties for commercialisers will arise if such thresholds are different to thresholds in, for example, the *Food Act*. If the threshold is lower than that in the *Food Act*, contamination caused by commercialisers may be irrelevant for the purposes of the *Vic GM Act* but still be sufficient for the purposes of the *AVCC Act*. If the *Vic GM Act* threshold is higher than that in the *Food Act*, the situation will be the reverse.

6.4.4 *Environment Protection Act 1970* (Vic)

The *EP Act* creates a legislative framework for the protection of the Victorian environment.[189] Amongst other things, it creates offences relating to pollution. The EPA[190] and commentators[191] agree that GMO releases into the environment could be offences pursuant to the *EP Act*. The most relevant for the purposes of this study are the prohibition of pollution of land and aggravated pollution. These are considered in subsections (a) and (b) respectively. Monitoring and enforcement issues are then considered in subsection (c).

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[187] *Vic GM Act* s 7(1).
[188] *Vic GM Act* s 7(3).
[189] *EP Act* s 1A(1).
[190] Personal communication with Michael Hodder, Manager Prosecutions Unit, EPA Victoria (Melbourne, 6 November 2003).
[191] See, eg, D E Fisher, 'The Use of DNA and the Law in Australia' (1982) 56 *Australian Law Journal* 6, 15; L Skene, 'The release of genetically manipulated organisms into the environment' (1988) 62 *Law Institute Journal* 278, 281; K Andrews, 'Australian Controls on the Environmental Application of Biotechnology' (1988) 5 *Environmental and Planning Law Journal* 194, 202. Although these comments were regarding the previous form of the *EP Act* the differences are not such that it is likely the opinions of the commentators would be different under the amended legislation.

(a) Pollution of land

Legal requirements

Pollution of land is prohibited under s 45.[192] Contravention of the prohibition is an indictable offence punishable by fine of up to $240,000.[193] The offence is one of absolute liability.[194] There is no defence, even of honest and reasonable mistake of fact or due diligence.[195]

Section 45(1) provides that a person shall not pollute land so that the condition of the land is so changed as to make or be reasonably expected to make the land or the produce of the land:

(a) noxious or poisonous;

(b) harmful or potentially harmful to the health or welfare of human beings;

(c) poisonous, harmful or potentially harmful to animals, birds or wildlife;

(d) poisonous, harmful or potentially harmful to plants or vegetation;

(e) obnoxious or unduly offensive to the senses of human beings; or

(f) detrimental to any beneficial use made of the land.[196]

'Pollute' is defined as including causing or permitting pollution[197] and 'pollution' as being the condition of the environment described and referred to in, inter alia, s 45(1).[198] 'Land'

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[192] *EP Act* s 45.

[193] Or where the offence continues after conviction or service by the EPA of a notice of contravention, to a daily penalty of up to $120,000 for each day the offence continues. *EP Act* s 45(3). Pursuant to s 67AA where the offence was committed intentionally the penalties may be increased to a maximum of $500,000 and in the case of a continuing offence to $250,000 for each day the offence continues after conviction. Executive officers including partners in a partnership and managers of unincorporated associations can also be criminally liable. See *EP Act* s 66B. There are defences available to officers. See *EP Act* s 66B(1A) and (4B).

[194] See *Allen v United Carpet Mills Pty Ltd* [1989] VR 323 at 330 re s 39(1) of the same Act.

[195] *Allen v United Carpet Mills Pty Ltd* [1989] VR 323 at 330. But see *EP Act* ss 30A and 30B re offences occurring as a result of an emergency.

[196] *EP Act* s 45(1) and s 4(1) (definitions of 'pollute' and 'polluted'). See also s 45(2).

[197] *EP Act* s 4(1) (definition of 'pollute').

[198] *EP Act* s 4(1) (definition of 'pollution'). The term 'pollution' has been interpreted narrowly by the courts. See *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184. See also *Palos Verdes Estates Pty Ltd v Carbon* (1991) 6 WAR 223 at 236-8 (FC) (Malcolm CJ).

is not defined. It therefore has its ordinary meaning. 'Beneficial use', a term used in s 45(1), means:[199]

> a use of the environment or any element or segment of the environment which –
>
> > (a) is conducive to public benefit, welfare, safety, health or aesthetic enjoyment and which requires protection from the effects of waste discharges, emissions or deposits or of the emission of noise; or
> >
> > (b) is declared in State environment protection policy to be a beneficial use.

'Environment' means 'the physical factors of the surroundings of human beings including the land, waters, atmosphere, climate, sound, odours, tastes, the biological factors of animals and plants and the social factor of aesthetics'.[200] Detriment is not defined. Case law in relation to similar legislation, establishes that 'the ordinary meaning of "detriment" is loss or damage done to or sustained by any person or thing; that which causes a loss'.[201]

There are two strands to an analysis of commercialisers' position under s 45(1). The first is what is included within the individual paragraphs of the section. The second is what considerations are relevant in deciding whether there has been pollution by virtue of a change to land or its produce in a way described in such paragraphs. These are considered separately below.

Paragraphs (a) – (d)

GM opponents may argue that GMO releases are or lead to pollution pursuant to all or some of paragraphs (a) to (d). It may be asserted that the presence of GM material changes the condition of land so as to make it or its' produce noxious or poisonous for the purposes of paragraph (a), harmful or potentially harmful to the health or welfare of human beings for the purposes of paragraph (b) or poisonous, harmful or potentially harmful to animals, birds or wildlife, plants or vegetation pursuant to paragraphs (c) and (d). For example, it could be claimed that genetic contamination of a plant is 'harmful' to the contaminated organism.

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[199] *EP Act* s 4(1).
[200] *EP Act* s 4(1).
[201] *Palos Verdes Estates Pty Ltd v Carbon* (1991) 6 WAR 223 at 236 (FC).

It is submitted that the 'harm' referred to in paragraphs (b) to (d) is physical harm such as where an organism is killed or sickened by its contamination rather than economic harm, such as where a plant is of less value because it has been contaminated but is otherwise unaffected by the contamination. This is because 'harm' with respect to human beings is linked to humans' health and welfare. In the case of other living things the word 'harmful' is preceded by 'poisonous', indicating that it is physical rather than economic or aesthetic effects that are of concern.

When an offence is based on a claim that the GMO release is 'potentially harmful' pursuant to paragraph (b) to (d) it is submitted that it would be difficult for a court to find the offence made out. To be licensed the GTR must have concluded that any risks posed by the GMO can be managed in a way that protects public health and safety and the environment.[202] The GTR in reaching that conclusion would have considered, amongst other things, whether the GMO may be toxic to other organisms, whether it might be harmful to the environment because of inherent weediness or increased potential for weediness and whether the new genes might transfer to related or other organisms. The information available to the GTR would come from much wider sources, including the Commonwealth Environment Minister and the States, than a court would have access to. In light of this it is difficult to imagine a court reaching a different conclusion to the GTR on this aspect of risk assessment.

With respect to paragraph (a), 'noxious' is not defined in the Act. Given that it appears in the description of an offence of absolute liability, it should be construed restrictively. The common meaning of the word is 'injurious, hurtful, harmful; unwholesome'.[203] It is submitted that being offensive to those who oppose GM or its consequences should not be sufficient for these purposes given that the purpose of the legislation is to protect the environment rather than ethical views or other preferences of particular sectors of the community. Contamination of non-GM canola by GM canola, for example, is analogous to contamination of canola seed with prohibited weed seeds in *Dovuro*.[204] Three members of the High Court agreed in that case that the weeds, although commercially undesirable, were not 'dangerous' for the purposes of a negligence action.[205] Similarly, 'welfare' in

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[202] See Chapter 2.
[203] *The Oxford English Dictionary* (2nd ed, Clarendon Press, Oxford, 1989).
[204] See subsection 5.3.2(d) above.
[205] (2003) 201 ALR 139 at [174]. Cf Kirby J who said the weed seeds were noxious (at [110]).

paragraph (b) should not include economic or social welfare, particularly in light of paragraph (f) in the section.

In light of the above, it is submitted that a court would not usually find that there has been pollution by a GMO release pursuant to the provisions of any of paragraphs (a) to (d). The exception would be where the contamination has caused the organism concerned to sicken or die. Contamination causing only the loss of organic certification or some other market advantage should not, it is submitted, be sufficient.

Paragraph (e)

With respect to an argument that there has been pollution by virtue of land or its produce being made obnoxious or unduly offensive to the senses of human beings under paragraph (e), it is submitted that there should also be no finding of pollution.

Stephen J[206] in *Phosphate Co-operative Co of Australia Ltd v EPA* ('*Phosphate*') said in relation to the then definition of pollution in the *EP Act* that it was concerned 'exclusively with the effect of the discharge of wastes upon the environment and not at all with the nature of the activities productive of those wastes'.[207] The comment is equally applicable to the current definition of pollution. It is important to note that many organisms or agricultural practices may be considered obnoxious or unduly offensive to the senses of human beings by some members of the public. Yet the consequences caused by such organisms or practices are rarely described as pollution.[208] Commentators have observed that 'technically many everyday activities may be categorised as pollution' but that 'both the regulatory authorities and the courts will take a commonsense approach in directing resources at important rather than trivial sources of such harm'.[209] Further, as noted by Malcolm CJ with respect to the definition of 'pollution' in similar legislation,[210] if the definition of pollution is read too widely, many activities undertaken in daily life will be pollution.[211] Similarly, in *Electricity Commission of NSW v EPA*[212] the Court stressed that the broad definition of pollution before it had to be applied in a commonsense fashion. Finally, Aickin J in *Phosphate* noted that many everyday domestic activities fell within the

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[206] With whom Mason J agreed.
[207] *Phosphate Co-operative Co of Australia Ltd v EPA* (1977) 138 CLR 134 at 139.
[208] This does not mean though that a court would not find pollution in such cases.
[209] Z Lipman and G Bates, *Pollution Law in Australia* (LexisNexis Butterworths, Aust, 2002), p 10.
[210] *Environmental Protection Act 1986* (WA).
[211] *Palos Verdes Estates Pty Ltd v Carbon* (1991) 6 WAR 223 at 237-8. See also Rowland J at 251.
[212] (1992) 28 NSWLR 494 at 498. The Court also referred (at 499) to the *de minimis* rule as having a role to play.

definition of pollution and that this should be kept in mind when construing the powers given under the legislation.[213] Accordingly not all things that render land or its produce obnoxious or unduly offensive are or can be pollution for the purposes of the legislation.

Knowledge of and objection to the presence of GMOs should not of itself be sufficient. The Tasmanian Resources Management and Planning Appeal Tribunal ('TRMPAT') has observed in relation to a claim that distress would be caused to certain people by the knowledge that chemicals had contaminated their land,[214] that it did not consider:

> [a]n objection in principle to the presence of any chemicals means that the presence of those chemicals constitutes an unreasonable interference with a person's enjoyment of the environment, if that chemical is not in quantities likely to cause any harm.[215]

Given 'in principle' objections to particular types of waste are insufficient in themselves, the GM quality of the invading pollen, seed or progeny should not of itself justify that pollen, seed or GM agriculture being treated differently to any other pollen, seed or agricultural practice. Only if the consequences of the contamination are harm should there be pollution. This could occur in some circumstances, for example, if the offspring of a non-GM pig inseminated by a GM pig were modified so that they were seriously and obviously disfigured, such as by having only three legs. But it is submitted that objection based only on the way an organism was created rather than its appearance or welfare should not be sufficient for the purposes of this paragraph.

Paragraph (f)

GMO releases may be pollution pursuant to paragraph 45(1)(f). It is submitted that it could be successfully asserted that GMOs pollute land by changing the condition of the land as to make it or its produce 'detrimental to any beneficial use made of the land'.

As noted in the description of the legal requirements of the offence above, beneficial use means a use of the environment or any element or segment of it which, amongst other things, 'is conducive to public benefit, welfare, ... or aesthetic enjoyment'.[216] The

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[213] *Phosphate Co-operative Co of Australia Ltd v EPA* (1977) 138 CLR 134 at 147 (Aickin J, in dissent).
[214] In a case concerning whether there was pollution under the *Environmental Management and Pollution Control Act 1994* (Tas).
[215] *F Giles and J Weston v Break O'Day Council* [2001] TASRMPAT 115 (Unreported, 23 July 2001) at [65].
[216] *EP Act* s 4(1) (definition of 'beneficial use').

definition of 'environment', a term used in the definition of beneficial use, expressly includes 'the social factor of aesthetics'.[217] Stephen J in *Phosphate* said that the inclusion of the term 'beneficial use' was 'greatly to complicate and obscure the meaning of pollution'.[218] He nevertheless went on to say that to be pollution there must be 'an alteration of the environment by discharge of wastes which adversely affects a use of the environment wh[illegible]s in itself conducive to (inter alia) public benefit and welfare'.[219]

In *Tarrant v S[illegible]ectricity Commission of Victoria*[220] ('*Tarrant*') it was proposed that a power station would be built at the mouth of a major river and cooling water drawn from the river and later discharged to another part of the waterway. The beneficial uses to be protected in the immediate surrounding area were described as:

1. Support of fish and other aquatic life…
2. Navigation and shipping.
3. Industrial water supply.[221]

A degree of pollution was acceptable provided it did not interfere with these uses.[222] There is no reference to any hardship suffered by any particular individual(s).

The Victorian Environmental Protection Appeal Board in *Tarrant* also said that beneficial uses included the right to 'conserve in unaltered state, the natural habitat of other creatures'.[223] Although opponents may seek to rely on this, agriculture whether GM or not can hardly be said to be an 'unaltered state'. In a case with respect to the bulldozing of a path on a foreshore reserve, it was noted that the area had been disturbed prior to the bulldozing in finding that there was no pollution.[224] Further, the Board in *Tarrant* also referred to the right to destroy and to modify the natural habitat of other creatures as beneficial uses and these had no less priority than the right to conserve such habitats.[225]

Importantly for commercialisers the Board observed that the *EP Act* 'envisages that the environment shall be used and enjoyed and *adapted to modern life* as well as being preserved for the use, enjoyment and adaptation of future generations. It is not necessary

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[217] *EP Act* s 4(1) (definition of 'environment').
[218] *Phosphate Co-operative Co of Australia Ltd v EPA* (1977) 138 CLR 134 at 142.
[219] *Phosphate Co-operative Co of Australia Ltd v EPA* (1977) 138 CLR 134 at 143.
[220] [1974] VPA 184.
[221] *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184 at 196.
[222] *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184 at 200.
[223] *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184 at 199.
[224] *Palos Verdes Estates Pty Ltd v Carbon* (1991) 6 WAR 223 at 243.
[225] *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184 at 199.

that all sections of the environment require protection from the effect of waste discharges but only such segments of the environment that are conducive to public benefit, welfare, safety, or health, and which for such purposes require protection.'[226] Commercialisers could assert that changes to the way agriculture is engaged in and to the level of interference to other forms of agriculture are adaptations to modern life and not something that protection under the *EP Act* is required from.

GM opponents could, however, respond that non-GM agriculture is a beneficial use of the environment, in particular of land and the biological factors of plants and animals, because it gives the public the benefit of a choice of products to buy and the opportunity to avoid GM produce. Such claims could be framed as matters 'conducive to public benefit' rather than a particular opponent's interests. Such assertions are much stronger than claims based on some individual(s) losing income because of GMO releases, such as where organic certification of a crop has been lost. It is submitted that in the later case, it would be more difficult to convince a court that the 'public's benefit' has been affected but even then it may not be impossible. For example, TRMPAT have noted interference with a farmer's right to conduct an accredited organic farm on their property as significant. However, there was no evidence of a sufficient risk of contamination in that case for the Tribunal to consider the matter further. [227]

Finally, in addition to an argument based on public benefit, GM opponents may assert that GMO releases are pollution because they are detrimental to beneficial use of land by detracting from the 'aesthetic enjoyment' of the land. Such an assertion, it is submitted, is unlikely to be successful. The Board in *Tarrant*, in relation to aesthetic objections to the proposed power station, observed that it would not find there was pollution on that basis. It said '[n]oxious trades and other industries are essential and it is for those responsible for town planning to say where they are to go. It is not for this Board to determine that they cannot be located where the responsible authority has prescribed zones for the appropriate land use.'[228] Subject to any legislatively created GM-free areas, a licensed GMO release would also be in accordance with relevant legislation with respect to permitted land use and would have been authorised under the *GT Act* and the *Vic GM Act*.

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[226] *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184 at 199 (emphasis added).
[227] *F Giles and J Weston v Break O'Day Council* [2001] TASRMPAT 115 (23 July 2001) at [65].
[228] *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184 at 233.

Relevant considerations

If there has been a change to land or its produce in a way described in s 45(1), it must then be determined whether that change is pollution. The High Court has said that the Victorian EPA is to be concerned with 'regulation and control of the extent to which wastes are discharged which may adversely affect the environment and not with the economic consequences of preventing or restricting their discharge'.[229] It also said that the *EP Act* and the EPA 'are intended to be single-minded in approach being concerned, regardless of consequences, with the protection of the environment'.[230] That a finding of pollution means commercialisers will suffer financial hardship and may not be able to exercise their rights under DIR licences granted under the *GT Act,* effectively preventing commercialisation of GMOs, will therefore not be taken into account by the EPA or the court.[231]

However, as noted by one prominent commentator, statutory interpretation today may be expected to be influenced by the trend in modern legislation to encourage economic responses to pollution problems.[232] Further, the *EP Act* now provides for 11 principles of environment protection[233] that must be considered when administering the Act.[234] Four of these principles in particular will be relevant to whether GMO releases are pollution pursuant to s 45(1). It is submitted that none of these will advance the position of commercialisers.

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[229] *Phosphate Co-operative Co of Australia Ltd v EPA* (1977) 138 CLR 134 at 137 (Stephen and Mason JJ agreeing). Cf Aickin J, in dissent, who held that the EPA was required to take into account economic consequences. (1977) 138 CLR 134 at 148 and 151. The decision was in respect of licensing decisions under Victorian environment protection legislation. The Act has been amended since this decision. Nevertheless Fisher suggests that the analysis is still valid. D E Fisher, *Australian Environmental Law* (Lawbook Co, Sydney, 2003), p 235.

[230] *Phosphate Co-operative Co of Australia Ltd v EPA* (1977) 138 CLR 134 at 141. The approach in *Phosphate* was applied by the Environment Protection Appeal Board in *International Harvester Australia Ltd v Dandenong Valley Authority* (1978) 13 VPAD 164 where the Board held that the fact it would cost the appellant money to comply with the Board's requirements was not something it could take into acount. Compare the decision in *Wilke & Co Ltd v Environment Protection Authority* (1983) 8 APAD 38 at 47 where the Victorian Planning Appeals Board held that the risk of the potential loss of business to overseas was a legitimate consideration to whether a licence should be issued and subject to what conditions. See also *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184 at 197 where Environment Protection Appeal Board held that if a beneficial use to be protected is likely to be adversely affected by an action, a licence should be refused no matter what may be involved by way of economic loss to the applicant or public.

[231] *Tarrant v State Electricity Commission of Victoria* [1974] VPA 184 at 199.

[232] G Bates, *Environmental Law in Australia* (5th ed, Butterworths, Aust, 2002), p 444.

[233] *EP Act* ss 1B-1L. This includes the precautionary principle as in the case of the *EPBC Act*. *EP Act* s 1C.

[234] *EP Act* s 1A(3).

The first of these is the principle of integration of economic, social and environmental considerations.[235] This is said to require the effective integration of economic, social and environmental considerations in decision making processes with the need to improve community well-being and the benefit of future generations.[236] It could be asserted that this means that the fact GMO releases may interfere with other types of agriculture or be contrary to the views of certain parts of the community must be taken into account. Alternatively though it could be asserted that it means the fact prosecution will in some cases render ineffectual a national regulatory scheme specifically established to govern GMOs and that the public may be denied all or some of the advantages of GM should be taken into account. In either case, the principle is limited by the requirement that any measures adopted must be cost-effective and in proportion to the significance of the *environmental problems* being addressed. Commercialisers could assert that if the risks of a release have already been assessed by the GTR and are not prohibited under State legislation, it is arguably out of proportion to the environmental problems raised by a GMO release to prosecute commercialisers for polluting.

However, 'environment' for the purposes of the *EP Act* includes 'the social factor of aesthetics'. That factor is not taken into account by the GTR. Nor, it seems, is it relevant under the *Vic GM Act*. Further, 'environment' is not interpreted by the GTR as including other agriculture. Therefore a licence under the *GT Act* and compliance with the *Vic GM Act* may be insufficient to render prosecution under s 45(1) not cost-effective or out of proportion where pollution is alleged on the basis of aesthetics or interference with agriculture.

The principle of intergenerational equity originally set out in the 1992 *Inter-Governmental Agreement on the Environment* must also be considered.[237] It may be argued that GMO releases negatively affect the diversity or productivity of agricultural land and that such effects will be long term contrary to that principle. Thirdly, the conservation of biological diversity and ecological integrity which GMO releases may affect is also a fundamental consideration.[238] Finally, enforcement of environmental requirements is to be undertaken for the purpose of –

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[235] *EP Act* s 1B. The Act says that sound environmental practices and procedures are to be adopted as a basis for ecologically sustainable development for the benefit of all human beings and the environment. *EP Act* s 1B(1).
[236] *EP Act* s 1B(2).
[237] *EP Act* s 1D.
[238] *EP Act* s 1E.

(a) better protecting the environment and its economic and social uses;

(b) ensuring that no commercial advantage is obtained by any person who fails to comply with environmental requirements;

(c) influencing the attitude and behaviour of persons whose actions may have adverse environmental impacts or who develop, invest in, purchase or use goods and services which may have adverse environmental impacts.[239]

Opponents could argue that prosecuting commercialisers for polluting where they release GMOs is better protecting the *economic and social uses of the environment.* Further, it could be asserted that not prosecuting commercialisers is giving them a commercial advantage by allowing them to fail to comply with environmental requirements. Similarly it could be argued that such enforcement influences the attitude and behaviour of other commercialisers considering GMO releases in Victoria.

Conclusions with respect to GMOs

GMO releases can be or can lead to one of the conditions or changes described in paragraphs 45(1)(a) to (d). It has been submitted that this should require physical change and adverse physiological consequences. What level of change and consequences are required though is unclear. Economic harm alone should not be sufficient. It has also been submitted that there should be no finding of pollution pursuant to paragraph (e) except where the GMO or the contaminated organisms have been seriously and obviously disfigured. Paragraph (f) is likely to be applicable in some cases given that public benefit is relevant.

In all of the above cases, the EPA and court must still determine whether the consequences described above as being within a paragraph of s 45(1) are pollution. It is submitted that the EPA and the courts, being able to take into account factors other than purely scientific ones regarding physical or actual harm to the environment or organisms that live in it in deciding whether there has been pollution may reach a different conclusion to the GTR regarding the appropriateness of GMO releases. Differences in the definition of environment and the inclusion of principles of environmental protection in the *EP Act* also increase the likelihood of GTR licensed GMO releases being considered pollution.

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[239] *EP Act* s 1K.

(b) Aggravated pollution

The offence of aggravated pollution provided for in s 59E is an indictable offence for which a fine of $250,000 or seven years imprisonment or both may be imposed.[240] In respect of a corporation the maximum fine is $1 million.[241] Section 59E provides that:

> A person who intentionally, recklessly or negligently pollutes the environment or intentionally, recklessly or negligently causes or permits an environmental hazard which results in-
>
> (a) serious damage to the environment; or
>
> (b) a serious threat to public health; or
>
> (c) a substantial risk of serious damage to the environment; or
>
> (d) a substantial risk of a serious threat to public health –
>
> is guilty of an indictable offence.

'Environmental hazard' means 'a state of danger to human beings or the environment whether imminent or otherwise resulting from the location, storage or handling of any substance having toxic, corrosive, flammable, explosive, infectious or otherwise dangerous characteristics'.[242]

Whether a GMO release is pollution of the environment has been discussed in relation to s 45(1). Section 59E though also makes it an offence to cause or permit certain environmental hazards. Opponents may argue that GMOs are environmental hazards because they have a toxic, infectious or otherwise dangerous characteristic given that their modification may be passed on to any offspring and may also be spread to other organisms. If that is correct, they could then claim that the release of an organism with that characteristic in particular locations gives rise to a state of danger to humans or the environment. However, given that conditions caused by genetic defects, such as diabetes, are not referred to as toxic, infectious or otherwise dangerous to others in human or veterinary medicine, it is unlikely that a court would accept this description of GMOs.

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[240] *EP Act* s 59E. The minimum fine is $1000. *EP Act* s 67AB.
[241] *EP Act* s 59E. The minimum fine is $5000. *EP Act* s 67AB.
[242] *EP Act* s 4(1) (definition of 'environmental hazard').

Even if GMOs are pollution or environmental hazards, it also needs to be shown that their release results in one of the consequences described in s 59E. There is no definition of 'damage', 'serious damage' or 'serious threat' in the legislation. In regard to whether there has been damage to the environment, it is likely that the amount required to remedy the loss or damage will be relevant.[243] It is possible that one of the consequences described in paragraphs (a) to (d) of s 59E could occur even where the release has been licensed by the GTR. As with respect to s 45 offences, however, it is submitted that the 'damage' must be physical rather than economic.

A section 59E offence also requires mens rea. It is uncertain whether the mens rea requirements of intention, recklessness or negligence in s 59E apply only to the polluting or creation of an environmental hazard or also to the consequences of the pollution or hazard.[244] It seems that it applies only to the first part of the offence, that is the pollution or hazard.[245] Although the matters considered under the *Vic GM Act* and *GT Act* may be different to those relevant to whether there has been an offence under the *EP Act*, it is likely to be difficult for the EPA to prove relevant intent beyond reasonable doubt with respect to an offence under s 59E where the commercialiser complies with the *Vic GM Act* and has sought and obtained a licence from the GTR.[246] However, the inclusion of negligence in the description of the required mens rea means that commercialisers could guilty of this offence in similar circumstances to where common law negligence applies. Given the standard of negligence required for the offence is likely to be the lower criminal standard rather than the higher standard required in civil actions,[247] they may even be guilty where they would not be liable in common law.

(c) Monitoring and enforcement

The Act gives broad powers to 'authorized officers'[248] to investigate complaints made to the EPA by third parties about possible offences under the Act. These include entering upon land,[249] taking samples, taking photos and films, making video and other recordings,

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[243] Z Lipman and G Bates, *Pollution Law in Australia* (LexisNexis Butterworths, Aust, 2002), p 137.
[244] Z Lipman and G Bates, *Pollution Law in Australia* (LexisNexis Butterworths, Aust, 2002), p 137.
[245] Z Lipman and G Bates, *Pollution Law in Australia* (LexisNexis Butterworths, Aust, 2002), pp 137-8.
[246] See *EP Act* ss 57A, 59A and 59AB which relax some rules of evidence to assist prosecution.
[247] Z Lipman and G Bates, *Pollution Law in Australia* (LexisNexis Butterworths, Aust, 2002), p 138.
[248] See *EP Act* s 4(1) (definition of 'authorized officer').
[249] Usually private homes cannot be entered. *EP Act* 62(5).

examining and copying documents and inspecting equipment with or without the permission of the occupier.[250]

Of relevance here, amongst the various offences created to facilitate investigations and enforcement, it is an offence to refuse or fail to give information regarding an industrial or trade process being carried on when requested to by an authorised officer.[251] Accordingly, commercialisers may be asked to reveal confidential information ('CI'). That information may then be used in any proceedings against the commercialiser unless the commercialiser at the time of giving the information claimed that the information may incriminate them.[252] This may harm the value of such information and again limits the usefulness of this form of IP protection.

In addition to the criminal remedies referred to in subsections (a) and (b) above, the court has considerable discretion to impose alternative sentences either in addition to or in place of any other penalty the court may impose.[253] This includes publicity through, for example, notices in newspapers, annual reports or on the commercialiser's website.[254] Civil remedies are also available [255] Importantly, if GMOs are pollutants,[256] the EPA may remove or destroy organisms, whether they are the commercialiser's or the contaminated organisms of a third person[257] and recover its expenses from the occupier or person responsible for the pollution.[258] Alternatively it may direct the occupier of premises or the person who caused the pollution to clean it up.[259] The EPA may also serve abatement notices on occupiers of premises at which, inter alia, they are satisfied a process or activity being carried or proposed to be carried on will cause or is likely to cause pollution.[260]

The court may also order a person found guilty under the Act to compensate persons suffering loss or destruction of or damage to *property* as a result of the offence.[261] Non-

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[250] *EP Act* s 55.
[251] *EP Act* s 54(2).
[252] *EP Act* s 54(3).
[253] *EP Act* s 67AC.
[254] R Martin, 'Alternative sentencing in environment protection: Making the punishment fit the crime' (2003) 77 *Law Institute Journal* 33, 34-5. See *EP Act* s 67AC(2)(a).
[255] These would be in addition to any common law remedies available against the commercialiser. *EP Act* s 65(1).
[256] Pollutant is not defined in the Act but see subsection 6.4.4(a) with respect to meaning of 'pollution'.
[257] *EP Act* s 62.
[258] *EP Act* s 62(2).
[259] *EP Act* s 62A.
[260] *EP Act* s 31A.
[261] *Sentencing Act 1991* (Vic) s 86 and *EP Act* s 65A (emphasis added). Proceedings are currently underway in Canada, brought by organic farmers against agbiotech companies. One claim seeks compensation under similar legislation to the *EP Act*. See *Hoffman v Monsanto Canada Inc* 2003 SKQB 174.

GM farmers suffering property damage from pollution by GM pollen, can therefore seek compensation under the Act. However, as Dalton suggests, such compensation is likely to be limited to physical damage rather than pure economic loss.[262] Finally, the EPA may seek an injunction from the Supreme Court to restrain a breach or threatened breach of the Act.[263]

6.5 CONCLUSION

Commercialisers must be aware of obligations imposed on them under environmental legislation. As with tort liability, authorisation under the *GT Act* and compliance with State moratorium legislation is no defence to proceedings under Commonwealth or State environmental legislation.

Two examples from the most significant types of environmental legislation have been considered. These are the *EPBC Act* and the *EP Act*. The closely related Act, the *AVCC Act*, is also considered with the *EP Act*. GMO releases will in appropriate circumstances require approval under the *EPBC Act* whether or not licensed under the *GT Act* and in compliance with the State moratorium legislation. Releases can also be an offence under ss 40 and 41 of the *AVCC Act* despite being licensed under the *GT Act* and approved under the *EPBC Act*. Although the DPI considers it unlikely that prosecution under the *AVCC Act* would be successful where the commercialiser is licensed under the *GT Act*, it has been submitted that the different considerations to which the court may have regard in such prosecutions compared with those considered by the GTR means that an offence can be made out in some cases. It has been submitted that there may be an offence even where there is no physical harm to the contaminated organisms. However, releases causing only social objections will not be an offence under the *AVCC Act*.

The offence of pollution of land under the *EP Act* will also be established in some cases where there has been contamination.[264] However, it has been submitted that in this case physical harm is required. Purely economic consequences, such as loss of organic certification, should not be sufficient. It is also possible that the offence may occur where

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[262] D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 162.

[263] *EP Act* 64A.

[264] Cf Dalton who considers 'it is unlikely that environmental protection legislation will provide any remedy for victims of contamination'. D Dalton, 'Transgenic Crops and Genetic Contamination: Assessing the Need for a Regulatory Response to Protect Organic Farmers' (2003) 8 *The Australasian Journal of Natural Resources Law and Policy* 129, 164.

there is only social objection to the release. However, it has been submitted that objections on such grounds should not be sufficient for a change to land or produce for the purposes of s 45(1). It is unlikely that the offence of aggravated pollution on the basis of intention or recklessness could be made out. Such an offence could, however, be established on the basis of pollution rather than environmental hazard where the facts would also constitute negligence for the purposes of the common law and perhaps even where common law negligence cannot be proven.

Such conclusions are consistent with the broader perspective that can be taken by the Commonwealth Environment Minister, EPA and DPI in administering the environmental legislation than is possible under the GTR's current approach under the *GT Act*. That perspective is possible because of the three significant differences in the legislation and its operation described below. Even when the same considerations are seemingly relevant under the GMO regulatory legislation and the environmental legislation, the scope of the overlap is unclear. For example, economic implications of GMO releases are relevant under both the *Vic GM Act* and *AVCC Act*. The extent to which they are the same though is unclear. Similarly, environmental risks are relevant under both the *GT Act* and *EPBC Act*. Once again the differences, if any, in assessment of those risks under the two Acts is unclear.

The first significant difference in the legislation is in the considerations relevant under the legislation. The relevant Acts all include the protection of the environment in their objects or purposes.[265] They all also define 'environment'.[266] However, the definition differs. For example, 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 means matters such as the effect on trade and agricultural implications of GMO releases and social objections to the technology or its products are relevant. The Victorian *EP Act* on the other hand defines environment to mean physical surroundings including the 'biological factors of animals and plants and the social factor of aesthetics'. The *GT Act* definition makes no reference to social, economic and cultural aspects or living things or social factors.

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[265] *GT Act* s 3; *EPBC Act* s 3(1)(a); *AVCC Act* s 1(a)(ii); *EP Act* s 1A(1).
[266] Except the *AVCC Act*. See *GT Act* s 10(1); *EPBC Act* s 528; *EP Act* s 4(1).

Secondly, by virtue of the description of the consequences that constitute the offence in s 45(1) of the *EP Act* and the environment protection principles that must now be considered in administering the Act it has been submitted that the Victorian EPA can take into account implications for agriculture and consumers following the introduction of GMOs into an area. Aesthetic objections also seem relevant to whether the offence is made out. Under the *AVCC Act*, economic harm is relevant to whether there has been an offence. Social objections may also be relevant depending upon how broadly the term 'trade' is interpreted. For example, consumer objections to GMOs may be said to be relevant to trade. With respect to the *EPBC 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. All such considerations are irrelevant under the *GT Act*. Such considerations are also broader than those relevant to a torts action in that the social factor of aesthetics and distress reflecting social disapproval are sufficient for certain purposes of the environmental legislation but rarely sufficient under the common law.[267]

A third significant difference is that the *EPBC Act* and *EP Act* both require principles of ecologically sustainable development[268] or environmental protection[269] respectively, be taken into consideration. This reflects the policy set down in the 1992 *Inter-Governmental Agreement on the Environment*.[270] These principles are irrelevant under the *GT Act* and *Vic GM Act*. Further, the precautionary principle in neither the *EPBC Act*[271] nor the *EP Act*[272] is limited by reference to cost-effective measures as is the case in the *GT Act*. There is no reference to the precautionary principle in the *Vic GM Act*.

The application of environmental legislation is of concern for commercialisers for many reasons. In particular, doubts as to whether it applies and will be enforced adds to the uncertainty regarding their legal position. Such uncertainty and the possibility of multiple approvals and licences being required is not in the spirit of the 1997 *Agreement on Commonwealth-State Roles and Responsibilities for the Environment* which provided that inter-governmental relations on the environment were to be based on the principles of,

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[267] This may reflect a trend in environmental legislation. Sands has concluded that '[w]ithin the past five years, there has been increasing recognition of a place for social and other values as legitimate factors influencing environmental decision-making'. P Sands, *Principles of International Environmental Law* (2nd ed, Cambridge University Press, Cambridge, 2003), p 9.
[268] *EPBC Act* ss 136(2)(a) and 3A (with respect to decisions as to approval of actions).
[269] *EP Act* s 1A and ss 1B–1L.
[270] See Part 6.2.
[271] *EPBC Act* s 3A(b). See also s 391(2).
[272] *EP Act* s 1C.

inter alia, co-operation, efficiency and seamlessness. Whilst the practices of the Victorian DPI and EPA and the fact that there seem to have been no referrals as controlled actions to the Commonwealth Environment Minster under the *EPBC Act* with respect to GMOs may reflect that agreement, it is arguable that the legislation does not. Further, it creates a piecemeal approach to the regulation of GMOs rather than the national approach to GMO control touted in the 1990 Premiers' Conference statement.[273]

Secondly, if the legislation applies, there will be another layer of regulation to comply with adding to the expense and difficulty of GMO commercialisation. The penalties if there is a breach of the legislation are serious often involving substantial fines and jail terms. Adverse publicity may also result, which may be of significance given the importance of consumer acceptance to successful commercialisation of GMOs.

Thirdly, both the *GT Act*[274] and *EPBC Act*[275] require licence holders/proponents to be a 'suitable person'. An offence under these Acts or other environmental legislation could mean that they are not such persons and therefore affect commercialisers' ability to secure licences needed for future commercialisation.

A further concern arises with respect to commercialisers' CI. Under the *EP Act* commercialisers can be required to disclose CI which can then be used in court, perhaps destroying its value. Under all of the *AVCC Act*, *EPBC Act* and *EP Act* authorised officers may enter commercialisers' premises and undertake a wide range of activities and in doing so see confidential material, again affecting its value as a means of IP protection.[276]

Fifthly, application of the *EPBC Act* means that decisions by the Commonwealth Environment Minister can effectively nullify the usefulness of a DIR licence. Whilst this may be appropriate because the Minister is an elected representative and the GTR is not, it may also open the GT regulatory scheme to political influence. Those opposed to GMO releases on the basis of economic or social considerations could seek to circumvent the operation of the *GT Act* and decisions by State Governments with respect to moratorium legislation using the *EPBC Act*. They could do this by seeking to influence the Commonwealth Environment Minister or, where there has been a contravention of the legislation, seeking an injunction. Whilst injunctions are also available under the *GT Act*,

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[273] See Part 6.2.
[274] *GT Act* s 58.
[275] *EPBC Act* s 136(4).
[276] See *AVCC Act* s 63.

they may be available to a wider class of people under the *EPBC Act* and socio-economic implications which are irrelevant under the *GT Act* will be relevant.

Finally and perhaps most importantly, all of the *EPBC Act*, the *AVCC Act* and the *EP Act* allow any third person who suffers loss or damage because of a contravention of the legislation to obtain compensation from the commercialiser, something the *GT Act* does not provide for.

Although only Victorian legislation concerning environmental harm has been considered, it could be expected that similar challenges will arise under the legislation of other States. The central issue is therefore whether it is appropriate that GMO commercialisers be subject to such challenges and the consequences arising because of the application of the environmental legislation when their behaviour is already regulated under specific GT legislation at both the Commonwealth and State levels. Advocates for the current arrangements could assert that GMO commercialisation should be treated no differently to other industries and compliance with environmental legislation should be required even if other legislative requirements must also be satisfied. It is submitted that it is inappropriate that environmental legislation apply to GMO commercialisers given that all relevant considerations will now be assessed by an independent expert regulator or a State Minister through the operation of the *GT Act* and the State moratorium legislation respectively. The continuation of present arrangements only imposes additional 'red-tape' for commercialisers with no significant environmental advantage.

The *EPBC Act*, *EP Act* and *AVCC Act* should be amended to exclude those actions licensed under the *GT Act* and in compliance with State moratorium legislation if any from their operation. This will mean that decisions as to the acceptability of particular socio-economic consequences of GMO releases will be made by the relevant State Minister when making decisions under the moratorium legislation rather than a government department such as the EPA or DPI and will provide GMO commercialisers with greater certainty with respect to their legal position than is presently the case.

The analysis in this Chapter also again demonstrates the need for State moratorium legislation to be improved by clarification of the issues relevant to decisions under the legislation and how those issues are to be assessed. However, for the unnecessary legal challenges to commercialisation created by the current legislation to be properly addressed, nationally consistent legislation in all States will be critical. The penalties available under

the State moratorium legislation should also be reviewed to determine whether they should be expanded to be the same as those available under the environmental legislation. The issue of the availability of compensation to individuals harmed by GMO releases, also provided for in the environmental legislation but not included in the *GT Act* or all of the State moratorium legislation, is taken up in the next, and final, Chapter.

CHAPTER 7

CONCLUSION

The first Part of this Chapter summarises the conclusions reached in each of the substantive Chapters. Part 7.2 summarises the effect of those conclusions with respect to the case studies. Part 7.3 comments on those conclusions and, in Part 7.4, possible reforms are discussed. The thesis concludes with Part 7.5.

7.1 GENERAL CONCLUSIONS

It was suggested in Chapter 2 that the introduction of the GT regulatory scheme generally is an improvement for commercialisers. However, the GTR's approach of excluding socio-economic impacts of GMO releases from consideration in licensing decisions under the *GT Act* is disadvantageous. In particular, it causes uncertainty regarding whether that approach is correct. The GTR's approach is also significant because of its implications for what can lawfully be required of commercialisers by the GTR under the *GT Act*. For example, it has been submitted that if the GTR's approach of excluding socio-economic impacts is correct, then commercialisers cannot lawfully be required by the GTR to act to prevent GM contamination if the only harm threatened is to another's method of agriculture. It also has implications for the type of insurance that can be required as a licence condition. Most significantly though, exclusion of socio-economic impacts from consideration by the GTR has been important in the States' decision to introduce their own legislation dealing with such consequences.

The State moratorium legislation was reviewed in Chapter 3. Pursuant to that legislation certain field trials will be prohibited. Further, the legislation creates additional offences and also obligations to compensate third parties which commercialisers must be aware of. The legislation also creates additional 'harm' for parties inadvertently contaminated by GMOs, such as the destruction of crops or limitations on future use of land, for which such parties may seek recompense from commercialisers. Interestingly here, it is the States that have declared their entire jurisdiction GM-free, namely SA, WA and Tasmania, and where therefore there is the greatest likelihood of compensation being available in tort, that have created a statutory obligation by commercialisers to compensate those inadvertently contaminated by GMO releases. It was submitted that in addition to these intended obstacles to commercialisation, the legislation creates further unnecessary legal obstacles

for commercialisers. First, the legislation is not uniform throughout Australia. This creates jurisdictional differences leading to the need to 'forum-shop' by commercialisers. The greatest challenge though is the lack of detail in the legislation regarding what socio-economic impacts of GMOs are relevant and how they are to be measured and their acceptability judged.

Chapter 4 examined the legal challenges to commercialisers regarding the availability and scope of IP protection for GMOs and their products. It was not intended that IP laws be affected by the *GT Act*. The State moratorium legislation also has very limited relevance to IP protection. Only in SA is there an attempt to impose additional liabilities specifically on those with a proprietary interest in GMOs. It was suggested in Chapter 4 that the unique traits of GMOs and their products do not, of themselves, limit the availability of IP protection. The possible socio-economic impacts of GMO releases should also not cause protection to be denied. Nevertheless, there is the possibility that patent protection could be denied because of such traits and/or because of the socio-economic impacts of GMO releases. Further, the patent law requirement of inventiveness can be expected to cause difficulties for future commercialisers. The ability to self-reproduce also presents legal challenges for IP protection under all regimes. PBR protection will be considerably limited if the exemption allowing farmers to use seed saved from legitimately obtained propagating material includes seed from GM contaminated plants. Similarly, the scope of protection given by patent law is both limited and uncertain because of GMOs' ability to self-reproduce. At the very least, that ability to spread and reproduce without human intervention can be expected to affect the remedies a court will be willing to award to commercialisers if their patent is infringed. Protection as confidential information ('CI') will quickly become unavailable as a form of protection once the GMO is released. Also of relevance here, as discussed in Chapter 2, there is some uncertainty regarding when CI will be protected under the *GT Act*. That uncertainty is relevant when predicting the value of CI as the form of IP protection for GMOs or their products. Similarly, uncertainty as to the application of the environmental legislation discussed in Chapter 6 and therefore whether CI would have to be divulged to authorities under that legislation, adds to the difficulty of making that prediction.

Commercialisers' liability in tort for harm arising from agricultural GMO releases into the environment is analysed in Chapter 5. Once again the unique traits and socio-economic impacts of GMOs create uncertainty for commercialisers in predicting the likely outcome

of proceedings against them. Contrary to Rogers assertion that 'the [*GT Act*] provides a legitimating mechanism for rampant genetic pollution'[1] it was submitted that the GTR's failure to consider socio-economic concerns whether legally correct or not makes it less likely that a court will accept a DIR licence under the *GT Act* as a 'legitimating authority' in legal proceedings. The GTR's findings do not, of course, bind a court but they are relevant. Nevertheless, despite Lawson's argument that the GTR's 'decision to release GMOs into the environment is an assessment that any damage suffered by others as a result of an adverse event is objectively acceptable',[2] it was submitted that a court faced with that very issue may disagree after reviewing different factors to those considered by the GTR.

It has been concluded in Chapter 5 that, as would be expected, commercialisers can be liable in private nuisance and negligence following GMO releases which have been licensed under the *GT Act* and permitted under State moratorium legislation. It has been suggested though that there should be no liability only on the basis of social impacts of GMO releases. Accordingly, distress caused by GMO releases should not be compensable under either of the torts considered. Uncertainty as to tort liability exists though with respect to economic impacts. Of particular importance here is the courts' determination of whether third parties who have been contaminated or threatened with contamination have suffered material damage (in nuisance) or property damage (in negligence). In cases where there is no obvious adverse physical effect this requires the court, inter alia, to determine a threshold for GM contamination. It has been submitted that this should be decided only by reference to legislative and regulatory requirements regarding the characteristic claimed to have been adversely affected by the contamination. In this regard most States have lost an obvious opportunity to provide some certainty to commercialisers by failing to provide for thresholds of 'GM' following contamination. In those States that have provided for such thresholds to be set, there is uncertainty because the thresholds have not yet been set and it is not clear how they will be determined. It is hoped the thresholds are set quickly and at a reasonable level. The legislation should also be amended to provide that the thresholds are relevant for all proceedings with respect to inadvertent contamination, whether pursuant to common law or statute.

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[1] N 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, 10.

[2] C 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, 197.

Further uncertainty arises where the court must go on to decide liability where there has been no material damage or property damage. In both private nuisance and negligence, the courts must balance the interests of both parties. Socio-economic factors will be relevant in both cases although in nuisance, the social and economic utility of the particular GMO or GMOs generally is largely irrelevant. This is unfortunate for commercialisers given that some GMOs can be expected to provide benefits to society. The *GT Act* and State legislation will have important implications for that balancing process despite the legislation not expressly addressing commercialisers' liability. In particular, it has been submitted that whether the GMO is released in a State with moratorium legislation and whether the release is in or out of a GM-free area will be of utmost importance. It has been submitted that for those States with moratorium legislation pursuant to which only certain GMO releases are prohibited, releases complying with the legislation will usually not be negligent or a private nuisance if no material or property damage has been caused. However, the position of commercialisers releasing under an exemption/permit in those States which have designated themselves as GM-free areas or releasing in States without moratorium legislation is less certain. It has been suggested that there should be no liability in such cases, assuming compliance with the *GT Act* and State legislation if applicable. The introduction of moratorium legislation was a response to the possible economic impacts of GMO releases for the State and individual farmers. Similarly, decisions to issue exemptions/permits will presumably be made after assessment of the economic impacts of a release. Given that the economic impacts of GMOs will have been addressed by the State Governments, Ministers or, in Tasmania, the Department Secretary as the case may be, and health, safety and environmental issues will have been assessed by the GTR, it has been submitted that courts should be reluctant to find such releases are wrongful.

Nevertheless, as noted above the court will be balancing individuals' rights rather than the socio-economic interests of the community. Further, there is lack of clarity in the State legislation regarding what matters are relevant and how they are to be balanced when deciding whether to designate areas GM-free, prohibit certain GMOs or making exemption/permit decisions. Finally, it is not certain that those States that do not have moratorium legislation intended that the courts deal with socio-economic impacts rather than deciding that protection from socio-economic impacts was not warranted. These facts mean that a court may still decide that it can legitimately find commercialisers liable although a release is otherwise lawful.

In Chapter 6 the relevance of environmental legislation to selection of GMOs for commercialisation was considered. It was demonstrated that the *EPBC Act* applies to GMO releases. Amongst other things, this means some commercialisers will need approval under that Act before releasing their GMOs. In deciding whether to grant that approval, the Commonwealth Environment Minister can take into account some socio-economic issues. How wide these issues are and what use will be made of them by the Minister in the context of GMO releases is difficult to predict adding to the uncertainty facing commercialisers. However, it is a concern that the application of the legislation means that third parties may seek to use it to in effect nullify decisions to allow releases by the GTR and/or State Government under regulations introduced specifically to regulate GMOs. Further, where State assessment processes will be used under the *EPBC Act*, the need to consider in which State to release the GMO arises again.

The analysis in Chapter 6 also demonstrated that GMO releases could be offences under Victorian pollution legislation, namely the *AVCC Act* and *EP Act*. It has been concluded that deference by the Victorian EPA and DPI to GTR decisions is incorrect. In particular, the GTR's failure to consider socio-economic impacts means relevant considerations in the two cases are different. The enactment of the *Vic GM ACT*, however, may strengthen the EPA and DPI's position. They can now point to the fact that the Victorian State Government must have engaged in some weighing-up process in deciding to introduce the legislation and the relevant Minister must also have engaged in an assessment process in deciding whether to designate the State GM-free, prohibit particular GMO releases and/or issue exemptions/permits as the case may be. The influence of such decisions on the court should be greater than in the tort scenario because the rights of two individuals are not being balanced as in torts litigation. Instead the rights of the commercialiser and the community are to be balanced. This is closer to the balancing undertaken by the Government or Minister, as the case may be, in respect of decisions under the State moratorium legislation.

Finally, it was submitted in Chapter 6 that, amongst other things, the environmental legislation should be amended to clearly exclude its application to GMO releases in compliance with the *GT Act* and State moratorium legislation. Further, the findings in Chapter 6 support the submission made in Chapter 3 that the State moratorium legislation should be amended to clarify what socio-economic concerns are relevant under the

legislation, how they will be assessed and decisions made and that the State legislation should be nationally consistent.

7.2 CASE STUDIES

There is no significant difference in the treatment of the case studies under the *GT Act* although each GMO will be subject to its own risk assessment. GM canola and carnations have both been licensed for commercial release under the *GT Act*. GM carnations though, do not require any end product regulatory approval unlike the pig and canola. With respect to the State legislation the GM pig fares the best given that field trials of it will be regulated only under Tasmanian legislation assuming that the Tasmanian GM Bill is enacted. Field trials of GM carnations are or will be regulated in WA and Tasmania. However, GTR licensed field trials of the carnation are allowed in WA. Field trials of GM canola are regulated in all States with moratorium legislation.

With respect to IP protection, both GM carnations and canola can be protected under all three IP regimes considered here, whilst PBR protection is unavailable to GM pigs. GM carnations and pigs avoid many of the identified problems with respect to enforcement of IP rights following inadvertent contamination because it is unlikely that they will contaminate others' property or organisms. In contrast, issues regarding enforcement of IP rights following inadvertent contamination of another can be expected to be a significant problem for commercialisers of GM canola.

GM canola, being the organism most likely to contaminate other properties, is also the most likely to attract tort liability and to be an offence under environmental legislation. In summary therefore it is unsurprising given its greater tendency to spread and affect others, that GM canola faces the most legal obstacles to commercialisation. GM carnations fare the best of the case studies given the availability of an additional IP protection regime to its' commercialisers compared to GM pigs.

7.3 COMMENT

It seems inconsistent that GMO releases can be legal in one context but illegal in another – for example, a release may have been approved by the GTR and comply with State moratorium legislation but can still be the subject of a successful action in tort. That inconsistency can be explained on the basis that Parliament never intended the *GT Act* and State moratorium legislation to deal with such rights. The courts instead were intended to,

and will, be the forum in which a balance will be struck between the need and/or desire that Australia develop and use GMOs and the socio-economic impacts arising from GMO releases.

Leaving the matter to the courts may be thought to be an appropriate solution to the problem. It allows the circumstances of each individual case to be weighed. It also allows information relevant to the particular locality concerned to be considered by the court. However, in the case of the socio-economic impacts of authorised GMO releases if the courts find that there has been an offence under environmental legislation or that commercialisers are liable in tort, then the courts 'in essence allocate planting rights between neighbours and within society'.[3] As Hamilton concludes:

> the law will not just influence the adoption of some forms of biotechnology but it may alter traditional notions that landowners can plant whatever crops they desire. In so doing, the law will help shape the very face of agriculture by determining which crops dominate the landscape and by controlling the ability of individual landowners to use their property as they want.[4]

The difficulties associated with assessing whether there will be an offence under environmental legislation, assessing reasonableness in private nuisance and, in negligence, assessing whether there is a duty of care and has been a breach of that duty exemplify one of the central problems in reaching a fair solution to the issue of GMO commercialisation. Many of the concerns raised with respect to IP protection, such as the scope of protection, also reflect that problem. That is, there seems to be no reasonable compromise to be found between the contrasting interests of GM and non-GM farmers.

It is submitted that it is not in commercialisers' or Australia's best interests that the courts determine the type of agriculture that Australian farmers can pursue. First, as shown in this study, leaving the issue to the courts creates considerable uncertainty for commercialisers. Such uncertainty is undesirable if GMO commercialisation is to be encouraged. Legislation on the other hand means regulation and relevant considerations can be explicit and direct.[5] Secondly, private actions between two parties are not the

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[3] N D Hamilton, 'Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms' (2001) 6 *Drake Journal of Agricultural Law* 81, 109.
[4] N D Hamilton, 'Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms' (2001) 6 *Drake Journal of Agricultural Law* 81, 109.
[5] C H Schroeder, 'Lost in the Translation: What Environmental Regulation Does that Tort Cannot Duplicate' (2002) 41 *Washburn Law Journal* 583, 598.

appropriate forum in which to determine whether the social and economic impacts of GMO releases are such that GMO commercialisation should or should not proceed. The economic interests of the community must be adequately weighed in any balancing process. As suggested by Ogus and Richardson in relation to other matters, courts are likely to find that 'the principle of justice which postulates that existing property rights must be protected even where the result will impose greater costs on society at large' requires decisions in favour of farmers pursuing non-GM agriculture.[6] This is particularly likely in nuisance proceedings where the social and economic utility of the GMO is not a relevant consideration whilst the utility of the plaintiff's form of agriculture is. Further, in many cases the courts will be able to consider the matter only after harm of some sort has occurred. Thirdly, such matters are complex in terms of the policy decisions that must be made.[7] Policy on the matter should be determined by the legislature in light of society's best interests, not those of the parties before a court.

Amending the *GT Act* to provide that commercialisers are liable for all harm caused by them would, it is submitted, be an unsuitable solution to the problem of GM contamination. It is inflexible and does not allow the individual circumstances of each case to be taken into account. Further, it is submitted that although GMOs and the way they cause harm may be unique, there is nothing unique about the types of harm they cause. Contamination by non-GMOs may cause similar harms to GM contamination. Whilst non-GM contamination may not cause ongoing repercussions such as, for example, GM contamination has for organic farmers, that there are ongoing repercussions for organic farmers is because of the adoption of standards chosen by such farmers.

It must be asked whether it is appropriate that commercialisers acting in compliance with the *GT Act* and State moratorium legislation be liable wherever non-GM farmers suffer harm because of self-imposed standards. Two justifications could be suggested – because the 'polluter should pay' and because commercialisers are releasing GMOs for financial profit.[8] The first justification 'rests on the idea that those who cause harm to others ought

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[6] A I Ogus and G M Richardson, 'Economics and the Environment: A Study of Private Nuisance' (1977) 36 *Cambridge Law Journal* 284, 324. It is submitted that such costs include prevention of the introduction of GM technology.

[7] For a discussion of whether the courts or government are better suited to making such decisions see D Campbell, 'Of Coase and Corn: A (Sort of) Defence of Private Nuisance' (2000) 63 *Modern Law Review* 197.

[8] Cane suggests these with respect to environmental harms generally. P Cane, 'Are Environmental Harms Special?' (2001) 13 *Journal of Environmental Law* 3, 12-13.

to bear responsibility for it'.[9] However, as Cane has suggested, why should that be where the 'polluter' could not have done anything different except perhaps not pursue GM agriculture at all?[10] It is submitted that commercialisers who comply with the law but nevertheless cause harm to another only because of some standard set by the plaintiff should not be liable unless they are in some other way 'at fault'. There is no justification for non-GM farmers being liable for contamination of another's crop only if they are 'at fault' whilst commercialisers are, in effect, strictly liable. With respect to the second justification, other farmers are also seeking a financial profit and that ambition will often be the motive for their adopting self-imposed limitations such as organic agriculture. A decision to impose strict liability only on commercialisers would be a political decision to prefer one group to another.

Similarly, it is submitted that amending the *GT Act* to require the GTR to reject applications where there are non-GM farmers within a particular distance from the suggested release point of the GMO is not a fair solution.[11] Whilst it is acknowledged that the rights of all farmers should be respected, such a provision would mean that the rights of non-GM farmers to choose which type of agriculture to pursue would always dominate those of GM farmers.

McGrath has suggested that the GTR's risk assessment should be changed so as to be 'based on accepted minimum levels of contamination to [non-GM and organic] crops' determined on the basis of industry accepted standards.[12] It is submitted that such a solution is also going too far. As discussed in Chapter 5, it is inappropriate that standards other than legislative and regulatory requirements be used as the standard for damage in these circumstances. In particular using voluntary standards gives competing industries, such as the organic industry, the power to prevent GMO commercialisation. Tolerances set by particular industries are arbitrary and although they may be determined by what is in that industry's best interests, they are not necessarily in society's best interests or a fair basis on which to judge the behaviour of others. For example, some of those involved in

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[9] P Cane, 'Are Environmental Harms Special?' (2001) 13 *Journal of Environmental Law* 3, 12.
[10] P Cane, 'Are Environmental Harms Special?' (2001) 13 *Journal of Environmental Law* 3, 12.
[11] This suggestion has been made by the Organic Federation of Australia. Tas, Parliamentary Joint Select Committee, *Report on Gene Technology* (2001), p 87.
[12] C McGrath, 'A system under strain: The Regulation of Gene Technology' (2003) 2 *National Environmental Law Review* 32, 35. See also M Tranter, 'A question of confidence: an appraisal of the operation of the Gene Technology Act 2000' (2003) 20 *Environmental and Planning Law Journal* 245, 254 who suggests that the risk of contamination of non-GM crops 'should be assessed against *acceptable* industry standards for certification of such crops' (emphasis added). There is no explanation of what acceptable means in this context.

the organic industry are opposed to other types of agriculture or the practices involved in that agriculture because of concern about their social impact. Parliament has decided that community and ethical objections to GMOs are to be addressed and dealt with by the advisory committees and the Ministerial Council under the *GT Act*. Having as the relevant standard in a GTR risk assessment a standard set by a group which is perhaps acting on its own social and ethical agenda gives such groups the ability to override those advisory committees and the GTMC. This is inappropriate. In other cases economic concerns arising from trade and marketing issues may be the reason for an industry standard. Standards set by industry groups in such cases may be unrealistic.[13] Once again it is submitted that they are not necessarily a suitable standard.

The *GT Act* goes part way to creating an appropriate legislative solution. However, as discussed in Chapter 2, the GTR does not, or at least does not consider that she does, have the power to take into account socio-economic impacts of GMO releases. Many States have recently legislated regarding the rights of farmers to pursue different forms of agriculture. The GTR must now take into account designations under that legislation when making licensing decisions. However, not all States have adopted such legislation and uncertainty continues even in those States that have. More importantly, the *GT Act* does not provide for the liability or immunity of commercialisers acting in compliance with it. Accordingly further reform is required.

7.4 SUGGESTED REFORM

It is suggested that there be four reforms made to address the problems demonstrated by this study. Given that it seems likely that there will be adequate IP protection for GMOs and their products no reform is suggested in regard to that aspect of GMO commercialisation.

First, the *GT Act* should be amended to clarify whether or not socio-economic effects must be considered by the GTR when making licensing decisions. Regardless of whether they are included or not, such amendment will provide some protection for her decisions from

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[13] For eg, there have been international statements that the organic industry standards are not achievable. See Statement by EU Agriculture Commissioner Franz Fischler, 'GM free food is a Garden of Eden fantasy, says Fischler' (23/1/04), *Cordis News* (<wysiwyg://120/http://dbs.cordis.lu/cgi-...S&ACTION=D7SESSION=7RCN=EN_RCN_ID:21489> accessed 12/2/04). See also M Partridge and D J Murphy, 'Detection of genetically modified soya in a range of organic and health food products: Implications for the accurate labelling of foodstuffs derived from potential GM crops' (2004) 106 *British Food Journal* 166.

challenges under the *ADJR Act*. It will also clarify for commercialisers the cases in which remediation and clean-up operations can be undertaken by the GTR or imposed as licence conditions. Finally, it would clarify when insurance can be required by the GTR as a licence condition. It is submitted that it is preferable that the GTR consider socio-economic impacts of GMO releases during the risk assessment process when making licensing decisions rather than leaving the matter to the States. Leaving such assessment to the States opens the scheme to jurisdictional differences. Those differences allow for forum shopping by commercialisers and GM opponents. More importantly they make the legal position of commercialisers less certain because in many cases GMOs will not respect State or other human-made boundaries.

If socio-economic issues are to be considered by the GTR, the GTR could be required to prepare environmental impact statements or assessments as required under environmental legislation.[14] Alternatively reference to socio-economic impacts could be included in the GTR's Risk Assessment Framework. The equivalent New Zealand document, the Methodology Order, requires the regulator there, in assessing risk, to recognise and provide for the principle of maintenance and enhancement of the capacity of people and communities to provide for their own economic and social well-being.[15] The economic and related benefits of the use of the GMO are also taken into account.

Secondly, legislation should provide that only legislative and regulatory standards or standards set by government bodies such as the GTMC should be used as the standard for 'damage' in proceedings by third parties against commercialisers. The SA or Victorian moratorium legislation could be used as a model in regard to threshold setting. Interested groups can then lobby the relevant body with respect to the appropriate standard. This gives such groups the opportunity to address such concerns. It also provides commercialisers with certainty once the threshold is set. Use of predetermined measures of damage means, from a commercialiser's perspective, that they are not vulnerable to unrealistic or uncompromising standards set by particular interest groups. More

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[14] Such an approach was recommended in 1989 before the creation of the GTR. See Law Reform Commission of Vic, *Genetic Manipulation* Report No 26 (Melbourne, June 1989), Recommendation 13. The Commission also noted that the Victorian Ministry for Planning and Environment believed that any new Act to control GMO releases should include a definition of environment broad enough to include social and economic environments. Law Reform Commission of Vic, *Genetic Manipulation* Report No 26 (Melbourne, June 1989), p 36 fn 19.

[15] New Zealand, Environmental Risk Management Authority, *Annotated Methodology for the Consideration of Applications for Hazardous Substances and New Organisms under the HSNO Act 1996* (New Zealand, 1998) s 10(a)-(g).

importantly, it gives the community as a whole the chance to participate, at least through their elected representatives, in deciding the standard adopted.

Thirdly, the maze of State moratorium legislation should be addressed. Ideally for commercialisers such legislation should be repealed. However, if that is not to be done States should at least adopt a nationally consistent approach to such legislation to remove problems of forum shopping. From a commercialiser's perspective, legislation providing for the prohibition of certain releases rather than designating the entire State GM-free is preferable. Further, it should be made clear what considerations are relevant under the legislation and how such matters are to be weighed.

Finally, and most controversially, it is submitted that some legislative protection from liability at common law and pursuant to environmental legislation should be provided to commercialisers. If, after reviewing all available material, it is found that all or certain GMO releases, at least in some areas, are not in a community's best interests the State legislatures (or GTR as the case may be) should declare the relevant areas to be designated GM-free areas or prohibit those particular releases. However, if it is decided that it is in the community's interests for GMOs to be commercialised, those who comply with all of the conditions considered appropriate by the legislature and regulators should be reasonably protected. Commercialisers releasing GMOs in areas not designated GM-free or pursuant to an exemption/permit should be liable under common law or environmental legislation only where the *GT Act* or State moratorium legislation has not been complied with or where there has been property damage (in negligence) or material damage (in nuisance). Continued responsibility for property or material damage is fair, provided the thresholds for such damage are independently established as recommended in the second suggested reform above. Commercialisers then have a clear understanding of what damage is prohibited. If the total removal of common law rights in cases not involving property or material damage is considered to be going too far, a ceiling on possible liability could be imposed.

Such an approach means that policy decisions based on economic and social implications of GMO releases are properly considered and dealt with as necessary by the legislature. It also gives commercialisers extra incentive to comply with the *GT Act* and State

legislation.[16] Torts and environmental legislation then complement the regulatory scheme by providing additional deterrence and damage mitigation incentives where the regulatory regimes have not been complied with.[17] It has the further advantage of providing all parties with greater certainty as to what they must protect themselves from or, if they choose not to, what loss they may bear. Uncertainty as to when commercialisers will be liable or their IP rights enforceable means that third parties may choose not to protect themselves on the assumption that the common law or environmental legislation will compensate or protect them.[18] That assumption may prove incorrect. It should also discourage litigation undertaken in the hope that the proceedings come before a sympathetic court.[19] It also means that commercialisers will be better able to predict their liability and the value of their IP assets in advance.[20] In Australia, where courts are flexible in their approach particularly in cases of pure economic loss in negligence cases, there is arguably all the more need for statute to provide certainty. This in turn should encourage further use of the technology. It does require, however, the taking away of a right to compensation from those who may otherwise succeed at common law or under environmental legislation. It also requires reliance on the legislature's ability to determine what is in the country's best interests. By removing common law rights and providing protection from environmental offences, there will be no stop-gap where harm has not been prevented by the regulatory scheme. However, for commercialisation of GMOs to be attractive, it is submitted that 'harm' must be reasonably limited for these purposes.

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[16] P Cane, 'Using Tort Law to Enforce Environmental Regulations?' (2002) 41 *Washburn Law Journal* 427, 461.
[17] W Allen, 'The Current Federal Regulatory Framework For Release of Genetically Altered Organisms Into The Environment' (1990) 42 *Florida Law Review* 531, 554.
[18] B Feldthusen, *Economic Negligence. The Recovery of Pure Economic Loss* (3rd ed, Carswell Thomson Professional Publishing, Ontario, Canada, 1994), p 225.
[19] B Feldthusen, *Economic Negligence. The Recovery of Pure Economic Loss* (3rd ed, Carswell Thomson Professional Publishing, Ontario, Canada, 1994), p 225.
[20] B Feldthusen, *Economic Negligence. The Recovery of Pure Economic Loss* (3rd ed, Carswell Thomson Professional Publishing, Ontario, Canada, 1994), p 225.

7.5 CONCLUSION

A political decision to allow GMO commercialisation to proceed has been made.[21] Now a political decision must be made regarding how to respond to the legal challenges facing those wanting to commercialise GMOs.

It is difficult to predict the social and economic impacts of GMO releases. Those difficulties are compounded when they are balanced against the consequences of not allowing GM agriculture to proceed. There is doubt whether GMO and non-GM agriculture can co-exist. If they cannot, the question then is whether the benefits of GMOs outweigh the rights of those wanting to engage in non-GM agriculture. It is submitted that that is a question for Parliament rather than the courts. Further, the matter should be dealt with now. Society may decide that the commercialisation of GMOs is more, or less, important to it than the rights of those affected by their release. But it would be far better for commercialisers if that was made clear when they were selecting which piggy to send to market rather than after the market, and court, was reached.

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[21] Although not all States have enacted complementary legislation, the Commonwealth and all States participated in the creation of the GT regulatory scheme.

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