

A question of confidence.
An appraisal of the operation of the *Gene Technology Act 2000*
by
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ABSTRACT

This article examines the *Gene Technology Act 2000* and its operation during its short existence. The Act is examined from the perspective that the regulatory regime in the controversial area of gene technology should engender the confidence of the public and industry if the innovative technology is to be accepted, especially in relation to food crops. The provisions of the Act are examined in comparison with *Environmental Protection and Biodiversity Conservation Act 1999*. The article also looks at the nature of some applications to the Regulator, the manner with which these have been dealt and some administrative issues which have arisen. Critical issues in relation to the operation of the Act are the absence of any economic or marketing considerations and the declaration or threatened declaration by some States of moratoriums on the commercial release of GMOs.

INTRODUCTION

Controversy continues to surround the use of genetic engineering, particularly in relation to food crops. On one hand there is enthusiasm to adopt the technology to take advantage of the opportunities presented by the biotechnology industry.¹ The promises for the rural sector include increased productivity and reduced use of chemicals.² On the other hand there are many concerns about the use of genetically modified organisms (GMOs), such as the potential health risks arising through allergies from the consumption of genetically modified food, unknown long term consequences and risks to the integrity of non-genetically modified crops through the spread of genetically modified crops.³

Internationally approaches to the use of genetic engineering vary widely. The European Union has been cautious about the new technology⁴ while North America has embraced it with large multinational corporations being its chief prophets in the food crop sphere.⁵

To take advantage of the benefits promised by the use of GMOs in the face of widespread scepticism, it is necessary that industry and the consuming public have confidence in the manner in which GMOs are assessed. This means that the regime established must have credibility.

The *Gene Technology Act 2000* (the Act) establishes Australia's primary approach to the assessment of gene technology.⁶ This Act replaced a voluntary scheme which oversaw the use of

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¹ Dr M Wooldridge, Minister for Health and Aged Care, *Hansard: House of Representatives* 22 June 2000 p18104; Commonwealth of Australia, *Australian Biotechnology: National Strategy* (Canberra: Commonwealth of Australia, 2000) p 9.

² Office of the Gene Technology Regulator, *General Information*, February 2002 at www.health.gov.au/ogtr/about/index.htm viewed 7 February 2003.

³ Office of the Gene Technology Regulator, n 2.

⁴ 19 GMO products (including 11 food crops) have been approved for commercial release in the EU up to 19 December 2002: European Commission Press Release, MEMO/02/160 15 October 2002 and MIDDAY EXTRACT 19/12/2002 at http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html viewed 25 February 2003.

⁵ There are currently 57 GMO crops approved for commercial release by the US Department of Agriculture: US Department of Agriculture Animal and Plant Health Inspection Service, *Current Status of Petitions* 25/02/2003 at <http://www.aphis.usda.gov/bbep/bp/petday.html> viewed 25 February 2003. 37 plants have been approved for unconfined release in Canada: Canadian Food Inspection Agency, *Status of Regulated Plants with Novel Traits in Canada* 19/12/2002 at <http://www.inspection.gc.ca/english/plaveg/pbo/pntvcne.shtml> viewed 25 February 2003.

⁶ The commercial availability of food, agricultural and veterinary chemicals and therapeutic goods in Australia requires final approval under additional regimes established for those specific purposes. Food: Food Standards Australia and New Zealand under the *Australia New Zealand Food Standards Act 1991*; therapeutic goods: Therapeutic Goods

biotechnology in Australia, with what is intended to be a nationally enforceable regime. The Act prohibits dealings with GMOs without a licence.⁷ To balance the pressures of the two divergent attitudes to the use of gene technology a position of Gene Technology Regulator (the Regulator) was created⁸ with the independence of the office enshrined in statute: “the Regulator is not subject to direction from anyone” in relation to his or her decisions on GMO licence applications.⁹ The object of the Act is:

to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.¹⁰

At the outset it should be noted that the Australian position as enunciated through the Act appears to be to facilitate the use of GMOs rather than taking a more even-handed approach to their use. This can be seen in the object where health and safety of people and the environment will be protected “by managing” any risks. The assumption is that any risks can be managed. The conclusion has rightly been drawn that Australia, through this legislation, has made a choice in favour of genetically modified (GM) foods.¹¹

The other issue in relation to the scope of the Act is that it excludes from the assessment of GMOs any economic or financial impacts. One of the claims of the anti-GM lobby is that ultimately the promised financial gains of GM crops for farmers may not materialise. In addition, the segregation costs of GM and non-GM crops further reduces economic viability and is of concern to non-GMO farmers wishing to maintain their status.¹² In a post-Hilmer¹³ economic environment the Government response would be that economic viability of such crops is a matter for the market not government. However, it is this issue which has caused the potential breakdown of the national scheme with States imposing and threatening to impose moratoriums on that basis.¹⁴

The *Gene Technology Act* commenced on 21 June 2001. With the Act now in effect for almost two years it is an appropriate time to review the manner of its operation. This article examines the framework of the Act highlighting those provisions which have caused concern and in doing so compares the Act with the *Environmental Protection and Biodiversity Conservation Act 1999*. It also looks at the nature of some applications to the Regulator and the manner with which they have been dealt and some administrative issues which have arisen. A critical issue in relation to the assessment of such applications is the absence of any economic or marketing considerations from the assessment. A current issue examined is the declaration or threatened declaration by some States of moratoriums on the commercial release of GMOs within and outside the framework of the Act. All of these factors lead to the ultimate question regarding the effectiveness of this Act. Whether it establishes a credible framework engendering the confidence of Australian industry and the public to accept gene technology?

FRAMEWORK OF ACT

Object

Administration under the *Therapeutic Goods Act 1989* (inter alia); agricultural and veterinary chemicals: Australian Pesticides and Veterinary Medicines Authority under the *Agricultural and Veterinary Chemicals Code Act 1994* (inter alia).

⁷ *Gene Technology Act 2000*, s 32.

⁸ *Gene Technology Act 2000*, s 26.

⁹ *Gene Technology Act 2000*, s 30.

¹⁰ *Gene Technology Act 2000*, s 3.

¹¹ M Hain, C Cocklin & D Gibbs, “Regulating Biosciences: The Gene Technology Act 2000” (2002)19 EPLJ 179.

¹² Biological Farmers of Australia Co-op Ltd, *Genetic Engineering in Food and Agriculture*, (Toowoomba, 2002) p 3.

¹³ *National Competition Policy: Report by the Independent Committee of Inquiry*, (Australian Government Publishing Service, Canberra, 1993)

¹⁴ See below at STATE MORATORIUMS ON GM CROPS.

As stated previously the object of the Act favours the approval of the use of GMOs on the basis that risks can be managed. This is balanced by the inclusion of the precautionary principle as one of the methods by which the object should be achieved.¹⁵ The precautionary principle has been described as the “cautious approach”¹⁶ and has undergone several permutations since it was enunciated in the Rio Declaration in 1992:

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.¹⁷

This Act reproduces the wording of the Rio Declaration, above, faithfully but it is the use of the phrase “cost effective” which has drawn some comment.¹⁸ The principle has undergone some transformation in Australian environmental law from the Intergovernmental Agreement on the Environment¹⁹ which did not include “cost effective” but still had a similar implication being “wherever practical”, to its most recent Commonwealth enunciation in the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) which makes no mention of “cost effective measures”.²⁰ The inclusion of “cost effective” can diminish the application of the principle.

The comparison with the EPBC Act reveals a further divergence in the use of the precautionary principle. The importance of the principle in the EPBC Act is embedded by requiring the Minister to take account of the principle when making crucial decisions under that Act.²¹ There is no similar requirement under the *Gene Technology Act* which would require the principle to be foremost in the Regulator’s thinking when making a decision to grant a licence for a dealing with a GMO.

The second manner in which the Act achieves its objective is it:

provides an efficient and effective system for the application of gene technologies.²²

This indicates that it is to a large degree an enabling Act which simply provides the mechanism by which such technologies can be applied. A more even handed term such as “assessment” instead of “application” could have been used indicating that a decision on the technology is still to be made.

The Operation of the Act

As stated earlier, the Act prohibits dealings with GMOs unless they are somehow authorised under the Act. The authorisations available are:

- The dealing is included in the GMO Register;²³
- The dealing is an exempt dealing;²⁴
- The dealing is a notifiable low risk dealing;²⁵
- The dealing is licensed.²⁶

¹⁵ *Gene Technology Act 2000*, section 4(aa).

¹⁶ *Leatch v National Parks and Wildlife Services and Shoalhaven City Council* (1993) 81 LGERA 270 at 282 and 283.

¹⁷ Rio Declaration, Principle 15.

¹⁸ 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 EPLJ 209.

¹⁹ Clause 3.5.1

²⁰ *Environmental Protection and Biodiversity Conservation Act 1999*, sections 391(2) & 3A(b).

²¹ *Environmental Protection and Biodiversity Conservation Act 1999*, section 391.

²² *Gene Technology Act 2000*, s 4(a).

²³ *Gene Technology Act 2000*, s 76 and following.

²⁴ *Gene Technology Act 2000*, s 32(3).

²⁵ *Gene Technology Act 2000*, s 74.

²⁶ *Gene Technology Act 2000*, s Part 5.

The GMO Register

A listing in the GMO Register is a determination made by the Regulator that she²⁷ is satisfied the risks posed by the GMO are minimal such that it is not necessary for persons dealing with the GMO to hold a licence.²⁸ In effect a listing in the Register allows the GMO to be dealt with in the same manner as a non-genetically modified organism. This is an example of a decision by the Regulator which could have been specifically made subject to the precautionary principle.

There are no listings at the time of writing in the GMO Register. This does not mean that there are no GMOs available on a commercial basis in Australia. Bt cotton, a GMO containing a soil bacteria which resists caterpillar pests, and Roundup Ready Cotton, which is herbicide resistant, were first commercially released in Australia in 1996 and 2000 respectively. There are also two strains of GM carnations able to be commercially grown. These GMOs have deemed licences under the transitional provisions²⁹ since their release predated the commencement of the *Gene Technology Act*. These dealings are subject to licence applications or licences granted under the new Act. It would be expected that these GMOs would be early entries in the Register.

Exempt Dealings

Exempt dealings are those which are specified in the *Gene Technology Regulations 2001* to be exempt.³⁰ The Regulations provide a detailed list of the requirements, such as not involving any intentional release and are of a type of dealing which is conducted in contained laboratory facilities.³¹ These are not the type of dealings which raise general concern amongst those opposed to GM foods and crops. If the dealing falls within the regulatory guidelines, then it may be conducted without any other notification or application.

Notifiable Low Risk Dealings

Notifiable low risk dealings are of a similar nature to exempt dealings, also involving no intentional release and are conducted in contained facilities.³² The regulations again outline the requirements of these dealings.³³ There are currently 1221 notifiable low risk dealings on the GM Record. These are notified by a variety of organisations but the majority being those involved in medical research. The other interesting feature of these dealings is that they all relate to dealings which were sanctioned under the previous regime and have the benefit of the transitional provisions³⁴ until 20 June 2003 when they will be required to be notified again under the new Act if it is intended to continue with them.

Dealings Not Involving Intentional Release

Dealings not involving intentional release (DNIR) of GMOs and those involving intentional release both require specific consideration by the Regulator and the issue of a licence with appropriate conditions. A DNIR requires an application by the proponent, thereafter a risk assessment and a risk management plan must be prepared by the Regulator which must protect the health and safety of people and the environment.³⁵ The regulator may, but under the Act is not required, to consult with various persons such as the States, the Gene Technology Advisory Committee set up under the Act,

²⁷ The position of Regulator is currently held by Dr Sue Meeks.

²⁸ *Gene Technology Act 2000* s 78 & 79.

²⁹ *Gene Technology Act 2000*, s 190.

³⁰ *Gene Technology Act 2000*, s 32(3) & (4)

³¹ *Gene Technology Regulations 2001*, s 6 and schedule 2 Parts 1 & 2.

³² *Gene Technology Act 2000*, s 74.

³³ *Gene Technology Regulations 2001*, s 12, 13 and Schedule 3.

³⁴ *Gene Technology Act 2000*, s 190.

³⁵ *Gene Technology Act 2000*, s 46 & 47.

other Commonwealth agencies, local councils and other persons whom the regulator considers appropriate.³⁶ These licences give no opportunity for public input generally and leave it entirely to the discretion of the Regulator whether there is any input from other persons whatsoever.

The decision whether or not the Regulator will issue a licence to conduct the dealing is made under s55 of the Act, the same section under which the decisions are made with respect to dealings involving intentional release (DIR). The Regulator before issuing a licence must be satisfied that risks to the health and safety of people and the environment can be managed as well as being satisfied that the applicant is a suitable person.³⁷ There are a range of matters in making these decisions to which the Regulator must have regard but there is no specific reference to the precautionary principle as being one of those matters.³⁸ It is stated that in making the decision on a DIR, the regulator must have regard to the risk assessment and risk management plan prepared under the relevant section for DIR applications, whereas for these DNIR applications the Act does not refer back to the risk assessment and risk management plans prepared for those applications.³⁹ This would appear an omission.

There have been 170 of these DNIR applications under the Act. 99 of these have been approved and 17 withdrawn. 11 of these withdrawals took place because the dealings could be classified as notifiable low risk dealings and therefore the applications were not required. The rest remain under consideration.

Importation of Grain – An Unusual Dealing Not Involving Intentional Release

When the DNIR applications are examined the vast majority relate to human, animal or plant research. However, two applications are of a totally different nature. They were made by Hunter Grain Pty Ltd and related to the importation of corn and soybeans from the United States of America intended to be used as animal feed to supplement depleted local grain supplies as a result of drought. Importation is specifically defined as a dealing under the Act.⁴⁰ The probability was that because of their source, the United States, the imports were likely to contain GMO grain and so applications were made as dealings not involving intentional release.⁴¹ Licences were issued on 3 January 2003 and the bulk carrier *Ocean Emperor*, carrying 49,750 tonnes of corn, docked at its first port of call, Brisbane, on 9 January 2003.⁴² It then went on to discharge the rest of its cargo in Newcastle and Melbourne.

These applications reveal a number of deficiencies in the regulatory and administrative regime. Firstly, the category of dealings not involving intentional release is mainly directed towards those dealings in which the GMO would be contained in a facility. The Regulations require details of the certification of the facility in which the GMO will be contained⁴³ and the only example given in the Explanatory Memorandum, which accompanied the original bill, of the application of this division is where the GMO is dealt with within a contained facility.⁴⁴ While neither of these references exclude the possibility of treating the importation of 49,750 tonnes of GM corn into the country as an application for a dealing not involving intentional release, an examination of the Regulations and the explanatory memorandum, as well as the nature of the other DNIR applications, leads to the strong implication that this is not the expected nature of a DNIR application. This is reinforced

³⁶ *Gene Technology Act 2000*, s 47(4).

³⁷ *Gene Technology Act 2000*, s 56 & 57.

³⁸ *Gene Technology Act 2000* s 56 & 58.

³⁹ *Gene Technology Act 2000*, s 56.

⁴⁰ *Gene Technology Act 2000*, s 10 definition of “deal with” (g).

⁴¹ Office of the Gene Technology Regulator, *Applications to the Register for licences to conduct dealings not involving intentional release of the GMO into the environment (DNIR)* DNIR 168 & 169/2002 at <http://www.ogtr.gov.au/rtf/gmorec/dnir3101.rtf> viewed as at 5 March 2003.

⁴² *The Courier Mail*, 10 January 2003 p 4.

⁴³ *Gene Technology Regulations 2001*, Schedule 4 at 1.1.4.

⁴⁴ Explanatory Memorandum to the Gene Technology Bill 2000, p 61.

when the magnitude of the task of containing such an amount of grain by the use of bulk handling facilities is compared with the containment of a GMO within a certified laboratory facility.

The agency charged with ensuring the grain was adequately handled and the primary source of the conditions imposed on its importation was the Australian Quarantine and Inspection Service (AQIS). This was to be done in cooperation with the Regulator. The conditions of licences issued under section 55 are to be contained in the Record of GMO and GM Product Dealings.⁴⁵ This Record is to be available for inspection by any person.⁴⁶ The Regulator has utilised its website as a place where the Record can be accessed.⁴⁷ However, the licence conditions of this particular dealing are not available on the website nor the specific licence conditions of any other DNIR. These licence conditions have not been made available despite the statutory requirement that they be available for inspection by any person. There is a provision of the Act which says the Regulator should ensure the Record is maintained “as soon as reasonably practical”⁴⁸ but the passage of several months since the issue of the licence would seem to be testing the limits of “as soon as reasonably practical”.

A further issue arose in connection with the handling of this GM grain. AQIS has admitted that a spillage of this grain occurred at the terminal in Melbourne.⁴⁹ The spillage contaminated a shipment of export wheat. This highlights further the absence of availability of the public scrutiny of the licence conditions which would include the use of handling equipment and ensuring that contamination of other grains does not occur. This is of great importance to Australia’s grain export industry which is able to market such produce as wheat as GM free at the present time.

Lack of Administrative Coordination

Further concern arises in relation to the coordination of Commonwealth agencies directly involved with the importation of potential GMOs. AQIS is responsible for ensuring that imports into Australia do not pose a threat to local industry. It is responsible for ensuring such imports comply with Australian law. As such it is the primary agency which will oversee the importation of GMOs into the country. It appears, however, that the special requirement for dealing with GMOs under the legislation administered by AQIS⁵⁰ and the *Gene Technology Act* is a matter that is left to importers to draw to the attention of AQIS. AQIS issued a Public Quarantine Alert PQA0251 on 24 January 2003 which stated:

Several consignments of genetically modified seed have recently been imported into Australia without an import permit.⁵¹

The Office of the Gene Technology Regulator was unaware of these consignments and the existence of the Public Quarantine Alert. At the time of writing the Regulator was engaged in investigating the incidents after the event.⁵² This highlights a breach of Australia’s policing of GMO imports as well as a lack of co-ordination between the relevant government agencies.

It is a disappointing feature of the Act and its administration that the importation of GM grain into the country does not allow a greater opportunity for public debate given the risks involved in the

⁴⁵ *Gene Technology Act 2000*, s138.

⁴⁶ *Gene Technology Act 2000*, s139.

⁴⁷ Office of The Gene Technology Regulator, GMO Record at <http://www.ogtr.gov.au/gmorec/recordinfo.htm#whatinfoecord> viewed 10 March 2003.

⁴⁸ *Gene Technology Act 2000*, s138(8).

⁴⁹ Personal communication AQIS to the writer, 24 March 2003.

⁵⁰ *Quarantine Act 1908* and *Quarantine Proclamation 1998*, s63.

⁵¹ Public Quarantine Alert PAQ0251, 24 January 2003, at http://www.aqis.gov.au/icon32/asp/ex_topiccontent.asp?TopicType=Quarantine+Alert&TopicID=7516 viewed 17 February 2003.

⁵² Personal communication from the Office of the Gene Technology Regulator to the writer, 17 February 2003.

handling of thousands of tonnes of grain. The DNIR category is not suitable for this type of dealing.

Dealings Involving Intentional Release

These are the GMO dealings which attract most attention because it is at the level of release into the environment that the issues in relation to contamination and loss of biodiversity arise. It is this licence which allows the commercial release of GM crops and it is also applications under this category which allow the opportunity for public submissions. If the Regulator is satisfied that a proposed dealing poses a significant risk to the health and safety of people or to the environment then an initial public notification of the application calling for submissions is required.⁵³ The purpose of submissions is to offer suggestions on the risk assessment and the risk management plan which the Regulator is required to prepare in connection with the dealing. In making a decision about the significance of the risk posed by the GMO the Regulator is to have regard to such matters as the potential spread or persistence of the GMO, the scale of the proposed dealing and impacts on the health and safety of people.⁵⁴ If the Regulator is satisfied that the proposed dealing does not pose a significant risk to health and safety of people or the environment, then this first round of public notification is not required.

Following the making of public submissions, if required, and a mandatory requirement to consult with the States, the Gene Technology Technical Advisory Committee, other Commonwealth agencies, the Environment Minister and local councils, the Regulator is to prepare the risk assessment and risk management plan.⁵⁵ In preparing the risk assessment and risk management plan the regulator is required to take into account various matters including public submissions and advice received from the other parties.⁵⁶ The Act does not specifically mention the precautionary principle, however, the risk analysis framework for licence applications does mention the precautionary principle as one of the parameters.⁵⁷ Another matter which fails to be part of the considerations are any economic or financial issues associated with the introduction of GM crops. This aspect will be discussed further in the following section relating to the GM Canola Applications

The second opportunity for public submissions, in fact the only opportunity in the vast majority of instances, arises following the preparation of the risk assessment and risk management plan.⁵⁸ Following consideration of the submissions on the risk assessment and risk management plan, any policy principles or guidelines issued by the Ministerial Council⁵⁹ and the suitability of the proposed licence holder,⁶⁰ but not specifically the precautionary principle, the Regulator decides on the issue of a licence and conditions thereto.⁶¹

There have been 13 licences for dealings involving intentional release issued under the Act while there are 24 deemed licences under the previous regime which will expire on 20 June 2003. Under the new Act there has been just one licence issued for the commercial release of a crop which is for Bollgard II cotton (DIR 12/2002).

GM Canola Applications

⁵³ *Gene Technology Act 2000*, s 49.

⁵⁴ *Gene Technology Act 2000*, s 49(2).

⁵⁵ *Gene Technology Act 2000*, s 50.

⁵⁶ *Gene Technology Act 2000*, s 51.

⁵⁷ Office of the Gene Technology Regulator, *Risk Analysis Framework for Licence Applications to the Gene Technology Regulator* (January 2002) p 15.

⁵⁸ *Gene Technology Act 2000*, s 52.

⁵⁹ The Ministerial Council is established under Part 6 of the Gene Technology Agreement between the Commonwealth, States and Territories consisting of representatives of each party. *Gene Technology Act 2000* s 10. An application must be refused if it would be inconsistent with a Ministerial Council policy principle *Gene Technology Act 2000* s 57.

⁶⁰ *Gene Technology Act 2000*, s 56 & 57.

⁶¹ *Gene Technology Act 2000*, s 55-65.

Of the 13 licence applications before the Regulator at the time of writing the most controversial of these applications are the two seeking the commercial release of GM Canola.⁶² The applicants are the multi-national companies Monsanto Australia Ltd and Bayer CropScience Pty Ltd. Both applications relate to the release of canola which is resistant to the companies' brand name herbicides. Monsanto markets a herbicide under the commercial name Roundup, hence the name of its GM canola being Roundup Ready canola. The Bayer canola is resistant to its herbicide, Liberty. The controversy centres on, amongst other issues, the possibility of the spread of the canola to non-GM crops which has received world-wide publicity as a result of Monsanto's successful prosecution of the Canadian farmer, Percy Schmeiser.⁶³ Schmeiser was found to have breached Monsanto's patent when he saved seed from his own crop of canola and sowed it the following year. The subsequent crop was found to have a component of Roundup Ready canola which apparently came about through spillage or cross-pollination. The Court accepted that Schmeiser had not deliberately obtained and planted any Roundup Ready canola. There is the fear amongst Australian farmers that because of the manner in which canola cross pollinates, that they will be subject to similar claims as Schmeiser faced. Another fear is that Australian producers who produce GM-free or organic crops, will find it very difficult to maintain their status and markets once the GM crops are commercially released. A key issue for non-GM farmers will be the segregation of GM and non-GM crops if the licences should be granted. There are also other issues such as the costs of certifying GM free crops, who should bear those costs⁶⁴ and liability if GM crops should contaminate non-GM crops.⁶⁵

The context of decisions under the Act should be borne in mind when the likely outcome of these applications is considered. As stated at the outset, the Act does not consider economic impacts and appears to favour the introduction of GM technology rather than take a neutral position. This is based on the statement in the object of the Act that risks are able to be managed⁶⁶ and that the Act provides an efficient and effective system for the application of the technology.⁶⁷ In the case of GM canola those opposing its introduction would seem to have valid arguments based on overseas experience, but the majority of matters are ones which the Regulator would say are outside the ambit of consideration being fundamentally economic or market issues rather than risks to human health and safety and the environment.

It is therefore unsurprising, given this background, that the Regulator has released for public submissions the Risk Assessment and Risk Management Plan (RARMP) for Bayer's application (DIR021/2002) indicating that it is proposed to issue a licence in respect of the application.⁶⁸ It is made very clear in the RARMP that issues such as segregation of crops, marketability and trade implications do not come within the ambit of the assessment.⁶⁹ The justification of that position is stated as follows:

Considerable media and written communication has focussed on the possible impact of commercial release of GM canola on non-GM crops and markets eg. the status of Australian grain exports. It is important to note that the evaluation of trade, marketing and cost/benefit issues have been intentionally excluded from the *Gene Technology Act 2000* assessment

⁶² Office of The Gene Technology Regulator, DIR 020/2002 & DIR 021/2002 at <http://ogtr.gov.au/ir/index.htm> viewed 7 February 2003.

⁶³ *Monsanto Canada Inc v Schmeiser* 2001 FCT 258, confirmed in the Full Federal Court *Schmeiser v Monsanto Canada Inc* 2002 FCA 309 at <http://decisions.fct-cf.gc.ca/fct/2002/2002fca309.html> viewed 25 November 2002.

⁶⁴ Hain et al, n 11 at 176.

⁶⁵ L McIntosh, "Liability for loss of Biodiversity caused by the release of Genetically Modified Organisms" (2002) 4 *National Environmental Law Review*, 40.

⁶⁶ *Gene Technology Act 2000*, s 3.

⁶⁷ *Gene Technology Act 2000*, s 4(a).

⁶⁸ Office of the Gene Technology Regulator, *Risk Assessment and Risk Management Plan, Commercial Release of Genetically Modified Canola (DIR 021/2002) Consultation Version*, (April 2003) p10.

⁶⁹ Office of the Gene Technology Regulator, n 68, p12.

process.⁷⁰

The proposed licence conditions do not address the matter of the buffer zones but leave it to industry bodies as well as the applicant itself to suggest those.⁷¹ The recommended buffer between GM and non-GM canola is 5 metres.⁷² It is not the purpose of this paper to address the scientific arguments relating to the cross pollination of canola but some of the research indicates canola pollen can move as far as 2.6 kilometres.⁷³

It is clearly outside the scope of the legislation for the Regulator to consider the economic viability of the use of GM crops compared to more traditional farming, but a main concern of the opponents of GM crops is the costs of segregation and certifying their crops as being non-GM. A narrow reading of the Act leads to the conclusion that these are economic matters and therefore not the Regulator's concern. However, a wider reading might conclude differently. If the issue was examined from the point of view of the effect the GM crop might have on an aspect of the environment, that is non-GM crops, then this is an environmental concern. "environment" is defined in the Act as:

- (a) ecosystems and their constituent parts; and
- (b) natural and physical resources; and
- (c) the qualities and characteristics of locations, places and areas.⁷⁴

Commercial non-GM crops may be regarded as part of an ecosystem, albeit a relatively short term part, or the cultivation of non-GM crops might be viewed as a quality or characteristic of a location, area or place where they are grown. Such interpretations would bring non-GM crops and their sites within the Act's definition of environment.

There is also further support for more attention being paid to buffer zones in the RARMP in that the Act specifically states that in determining the issue of significant risks to the health and safety of people or to the environment the Regulator must have regard to:

- provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment; and
- the potential for spread or persistence of the GMO or its genetic material in the environment.⁷⁵

The RARMP for the Bayer canola application did address this issue and recognised:

- the ability of canola to outcross at low levels over considerable distances
- the ability of canola seeds to remain dormant in the seedbank and germinate as volunteers and
- the fact that segregation procedures proposed by the industry may limit mixing of GM and non-GM seed to low levels but may not limit it entirely.⁷⁶

Taking account of these matters the RARMP concluded that "the risks are considered low to

⁷⁰ Office of the Gene Technology Regulator, n 68, p121.

⁷¹ Office of the Gene Technology Regulator, n 68, p121-123.

⁷² Gene Technology Grains Committee, *Canola Industry Stewardship Protocols*, (20 December 2002) p10.

⁷³ R Norton, *Conservation farming systems and canola*, (University of Melbourne, 2003) p23.

⁷⁴ *Gene Technology Act 2000*, s 10. This definition is the same as that in the EPBC Act (s 528) except for the omission of social, economic and cultural aspects.

⁷⁵ *Gene Technology Act 2000*, sections 49(2)(c) & (d).

⁷⁶ Office of the Gene Technology Regulator, n 68, p 24.

negligible and therefore do not require specific licence conditions.”⁷⁷

It has been argued that when making decisions in favour of the use of GMOs, the Regulator must have decided that:

...to sanction some releases that pose some risk requires a conclusion that the likely benefits, whatever they might be, justify the risk of an adverse event....⁷⁸

However, it has been stated clearly by the Regulator in interpreting her role under the Act that:

The risk assessment will be transparent, objective and scientifically based. It is purely based on risk, not on a balance of risk and benefit.⁷⁹

While this statement seems clear, in the context of the Act's emphasis on management of risk, it ultimately requires a subjective decision by the Regulator determining when the risk is too great or at what point the risk is manageable. At the same time the Regulator must have regard to the precautionary principle militating against taking risks which may threaten serious or irreversible environmental damage. As indicated non-GM crops and the locations where such crops are grown come within the definition of environment and the precautionary principle has some application to the manner in which GM crops may affect such crops and locations.

In the context of this canola application, the issue of the required buffer zone is a specific matter which is required to be addressed under the Act. The assessment of level of risk must be made within a framework which takes account of all relevant matters. The risk of contamination of non-GM crops is such a relevant matter which should be assessed against acceptable industry standards for certification of such crops. The assessment of a manageable risk should be guided by that criteria rather than a finding that the risk is “low to negligible” made within a scientific vacuum.

PUBLIC PARTICIPATION

One method of engendering public confidence in a regulatory system is to provide the opportunity for public participation whereby a process is accepted as transparent and inclusive. The desirability of public participation received international recognition in the Rio Declaration.⁸⁰ The typical types of participation may be through the opportunity for public submissions or more liberal standing rules to enforce breaches of the regulations and to appeal decisions. The *Gene Technology Act* allows only limited public participation.

Public Submissions

As indicated previously there is only one type of dealing with a GMO on which public submissions may be made. This arises in connection with dealings which would involve intentional release of the GMO into the environment.⁸¹ Such dealings may allow two opportunities for submissions: firstly, on the application,⁸² and secondly, on the risk assessment and risk management plan prepared by the Regulator.⁸³ The first opportunity for public submissions is not automatic but dependent on the regulator being satisfied that the proposal poses a significant threat to the health or safety of people or to the environment.⁸⁴ The Regulator has sought submissions at the application

⁷⁷ Office of the Gene Technology Regulator, n 68, p 24.

⁷⁸ Lawson, n 17 at 203.

⁷⁹ Office of the Gene Technology Regulator, n 57 p 15.

⁸⁰ Rio Declaration, Article 10.

⁸¹ *Gene Technology Act 2000*, s 49 and 52.

⁸² *Gene Technology Act 2000*, s 49

⁸³ *Gene Technology Act 2000*, s 52.

⁸⁴ *Gene Technology Act 2000*, s 49(1).

stage only in relation to the commercial release of Bollgard II cotton which received its licence on 23 September 2002.⁸⁵ It would have been thought that the canola applications for commercial release would receive a similar treatment and have an initial round of public submissions.

None of the other types of dealings: exempt dealings, notifiable low risk dealings, dealings not involving intentional release and entries on the Register, provide any opportunity for public input. While this is reasonable for exempt dealings and notifiable low risk dealings given the prescriptive nature of the regulations, there is an argument for some public input in relation to some types of dealings not involving intentional release (DNIR) and entries on the register. As previously mentioned, the recent importation of GM corn was dealt with as a DNIR and this seems an inappropriate category given the magnitude and nature of the dealing. An entry on the Register is the final approval giving totally unrestricted release of a GMO. While it could be argued that such a listing would only take place after a GMO has been licensed and assessed for a period, there is some benefit, for the sake of both transparency and to ensure that the listing process is balanced, in incorporating public submissions into the process.

In a similar vein, there is no public submission rights available should there be a proposal to vary an existing licence. This may not be a consideration if the power was available to the Regulator to only reduce the activity licensed, but the Regulator has specific authority to extend the scope of the licence.⁸⁶ Once again accountability and transparency would be enhanced by requiring public notice and the opportunity for submissions if there was an intention to increase the extent of a dealing under a licence. Alternatively, the regulator should not have the authority to extend the licence but only to reduce its scope.

Restraining Orders

The Act provides that the Regulator and “any other aggrieved person” may obtain an injunction to restrain any conduct which would be an offence against the Act.⁸⁷ The term “aggrieved person” is not defined in the Act and therefore the threshold question of standing must be addressed. The term “person aggrieved” as used in the *Administrative Decisions (Judicial Review) Act 1977* has been the subject of judicial interpretation and it is assumed that the cases relating to the definition of that term will have applicability to “aggrieved person” as used in this Act. However, despite considerable judicial consideration of “person aggrieved”, as well as the related one “special interest”, the outcome of any analysis remains subject to the exigencies of each case. More than one judge has described the present state of interpretation of the phrase as being in a state of “transition” or “flux”.⁸⁸

For a person to satisfy the test of a “person aggrieved” a material interest would naturally suffice. An example in this context would be a neighbour’s right to enforce the condition of a licence for a required buffer zone. However, in the absence of such a material interest, an applicant must show that its interest is more than “a mere intellectual or emotional concern”⁸⁹ thereby distinguishing the interest from that which “any member of the public has in upholding the law”.⁹⁰ This restriction has particular application to interest groups who must show a concern greater than “a mere intermeddler or busybody”.⁹¹ Relevant factors are the length of time the organisation has been concerned with

⁸⁵ Office of the Gene Technology Regulator, *Gene Technology Regulator Refuses Commercial Release of GM Cotton in Northern Australia But Gives Approval Elsewhere*, Media Release, 23 September 2002.

⁸⁶ *Gene Technology Act 2000*, s 71(3)(c).

⁸⁷ *Gene Technology Act 2000*, s 147.

⁸⁸ *North Coast Environment Council Inc v Minister for Resources (No 2)*(1994) 36 ALD 533 at 542 or (1994) 127 ALR 617 at 627; *Right to Life Association (NSW) Inc v Secretary, Commonwealth Department of Humane Services and Health* (1995) 128 ALR 238 at 254.

⁸⁹ *Australian Conservation Foundation Incorporated v Commonwealth* (1980) 146 CLR 493 at 530; 28 ALR 257.

⁹⁰ *Australian Conservation Foundation Incorporated v Commonwealth*, n 89 at 526.

⁹¹ *United States Tobacco Co v Minister for Consumer Affairs* (1988) 83 ALR 79 at 86.

the activity,⁹² its recognition by government through funding and participation in government policy making,⁹³ and the extent to which the organisation's interests coincides with the object of the legislation.⁹⁴ The outcome of a person or organisation's standing based upon a weighing up of these factors is not clear cut.

Comparison may again be made with the EPBC Act in that "interested persons" may apply for injunctions under that Act. However, the EPBC Act goes on to define interested persons, inter alia, as individuals who have engaged in protection, conservation and research into the environment in the 2 years before the incident or, in the case of an organisation, has as its objects the protection, conservation or research into the environment and being engaged in such activities.⁹⁵ This has avoided argument in relation to standing under that Act.⁹⁶ By leaving standing to the judicial tests as this Act does, creates uncertainty, expense and inhibits accountability.

Appeals

The Act specifically provides that applicants, licence and certification holders and those applying for information to be confidential may apply for an internal review of a decision as well as apply for a merits review to the Administrative Appeals Tribunal (AAT) of the decision.⁹⁷ The Act describes these persons who may apply as "eligible persons" and the appealable subject matter as a "reviewable decisions". Thus, a merit review appears not to be available to non-applicants making submissions on applications and risk assessments and risk management plans, nor to persons who may have a more immediate interest in a dealing, such as neighbouring property owners or interest groups. Similarly, there are no appeal rights available to applicants or anyone else about a decision to include a dealing in the GMO Register.⁹⁸

The *Administrative Appeals Tribunal Act 1975* itself allows a much wider range of persons to appeal being those "whose interests are affected by the decision."⁹⁹ That Act goes on to define organisations which have interests affected as those whose objects or purposes relate to the matter of the decision¹⁰⁰ which is even wider than the EPBCA's standing for an injunction.¹⁰¹ The question arises as to whether this wider definition could be availed by others such as neighbours and interest groups to obtain a merits review. Section 183 of the *Gene Technology Act*, which allows the appeals by eligible persons, is prefaced by "Subject to the *Administrative Appeals Tribunal Act 1975*..." and there is no provision which expressly excludes appeals by other persons. However, the argument against such wider opportunities for appeal rights strikes fairly obvious initial counter argument by the simply application of basic methods of statutory interpretation, such as: "expressio unius est exclusio alterius" - express inclusions, implied exclusions - and "leges posteriores priores contrarias abrogant" - the provisions of the primary act, the *Gene Technology Act*, impliedly overriding the provisions of the more general Act - the *Administrative Appeals Tribunal Act*. Appeals by persons other than those nominated in the Act are likely to fail for lack of standing.

If there are no third party appeals in the first instance, there is the possibility that if an "eligible person" did appeal to the AAT under the Act, then others interested could apply to be joined in the

⁹² *North Coast Environment Council Incorporated v Minister for Resources* n 88 at 552.

⁹³ *Australian Conservation Foundation Incorporated v Minister for Resources* (1989) 19 ALD 70; and *North Coast Environment Council Inc v Minister for Resources*, n 88.

⁹⁴ *Alphapharm Pty Ltd v SmithKline Beecham (Australia) Pty Ltd* (1994) 121 ALR 373; and *Right to Life (NSW) Inc v Secretary, Commonwealth Department of Human Services and Health*, n 88.

⁹⁵ *Environment Protection and Biodiversity Conservation Act 1999*, s 476(6) & (7).

⁹⁶ *Booth v Bosworth* 2000 FCA 1878 (13 December 2000); and C. McGrath, "Casenote: Booth v Bosworth" (2001) 18 EPLJ 25.

⁹⁷ *Gene Technology Act 2000*, s 179 & 183.

⁹⁸ *Gene Technology Act 2000*, s 78.

⁹⁹ Section 27(1).

¹⁰⁰ *Administrative Appeals Tribunal Act 1975*, s 27(2).

¹⁰¹ *Environment Protection and Biodiversity Conservation Act 1999* s 475(7).

appeal. In *Re Control Investments Pty Ltd and Australian Broadcasting Tribunal (No 1)* (1980) 3 ALD 74, the primary act, the *Broadcasting and Television Act 1942*, specifically provided that only applicants could appeal to the AAT and excluded the broader appeal standing provision of the *Administrative Appeals Tribunal Act 1975* discussed above, of a person whose interests are affected.¹⁰² An application to be joined in the applicant appeal was brought by a range of other persons including the Australian Labor Party. Davies J in the AAT ordered that other parties could be joined who were not applicants under section 30(1)(c) (now 30(1A)) of the *Administrative Appeals Tribunal Act 1975*. Thus the way is open for other persons to apply to be joined in “eligible person” appeals to the AAT under the *Gene Technology Act* and argue a matter such as the granting of a licence on the merits. As mentioned previously the opportunity for interest groups to seek involvement is assisted by the wider standing provisions for such groups under the *Administrative Appeals Tribunal Act 1975*.¹⁰³

There has been only one appeal to the AAT under the Act and that was in relation to a decision by the Regulator to reject an application for a declaration that two site locations in Western Australia were commercial in confidence. The appeal was discontinued.

Judicial Review

Decisions under the Act may be reviewed under the provisions of the *Administrative Decisions (Judicial Review) Act 1977*. The standing under that Act is determined by the phrase “person aggrieved” which was discussed in the earlier section on restraining orders. Standing to make an application for judicial review will depend on the factors outlined in the preceding section. Naturally, being only a review of process rather than on the merits, the outcomes, generally speaking, are limited.

STATE MORATORIUMS ON GM CROPS

The “nationally consistent scheme for the regulation of certain dealings with GMOs by the Commonwealth and the States”¹⁰⁴ faces its greatest threat through the States imposing or proposing to impose moratoriums on the commercial release of GMOs within their jurisdictions. Tasmania has recently announced a further 5 year moratorium which will be in place until 30 June 2008. The returned Labor government in New South Wales has promised a three year ban. South Australia has a bill presently in abeyance to designate the State GM free,¹⁰⁵ while the Western Australian Government proposes a five year moratorium to be given legislative force.

The constitutional validity of such State action is worth examining. The constitutional basis of the *Gene Technology Act* is stated to be the corporations power, the trade and commerce power and powers ancillary thereto.¹⁰⁶ It is interesting to note that the external affairs power does not provide a basis although there is an international instrument, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, but Australia is not a signatory to it. The main focus of that Protocol is the “safe transfer, handling and use of living modified organisms.....specifically focusing on transboundary movements.”¹⁰⁷ From that respect it would only partially cover the field intended to be covered by the *Gene Technology Act*. However, the other bases of Commonwealth power are acknowledged and valid sources¹⁰⁸ but because of doubts relating to the applicability of the Act to individuals, State instrumentalities and universities, a co-operative approach has been

¹⁰² *Broadcasting and Television Act 1942*, s 119A(2).

¹⁰³ *Administrative Appeals Tribunal Act 1975*, s 27(2).

¹⁰⁴ *Gene Technology Act 2000*, s 5.

¹⁰⁵ *Gene Technology (Temporary Prohibitions) Bill No. 60 of 2002*.

¹⁰⁶ *Gene Technology Act* section 13 and the *Constitution* 51(i), (xx) and (xxxix).

¹⁰⁷ Cartagena Protocol on Biosafety, Montreal 2000, Article 1.

¹⁰⁸ Corporations power, eg. *Trade Practices Act 1975*; trade and commerce power - *Murphyores Inc Pty Ltd v Commonwealth* (1976) 136 CLR 1; 38 LGRA 224; 9 ALR 199; 50 ALJR 570.

adopted in the Act with each State intended to adopt mirror legislation.¹⁰⁹ Notwithstanding the desire for corresponding legislation and reservations about the extent of Commonwealth power, the Act enables the Governor-General to “prescribe” state laws.¹¹⁰ It appears that the intended effect of this prescription is to render the State law ineffective to the extent it is inconsistent with the *Gene Technology Act*.¹¹¹

Consider the situation of State legislation which prohibits the commercial release of a GMO in that State and a biotech company which has a licence from the Regulator authorising the Australia-wide commercial release of the same GMO. The State legislation might either be prescribed by the Governor-General under section 16(2) of the Act or the biotech company may challenge the validity of the State law. In either circumstance the validity of the Commonwealth power under section 51 would be examined to determine if it will prevail and the State law found to be inconsistent under section 109 of the Constitution. As stated above, the Commonwealth legislation is firmly based in well accepted areas of Commonwealth power. The Commonwealth legislation authorises a person to “deal with” the GMO, which includes selling and cultivating it.¹¹² It is suggested that only in a very narrow range of situations would the State prohibition be effective: state instrumentalities, some non-incorporated farming entities not engaging in interstate trade.

In any event, the constitutionality of State moratoriums appears set to become a moot point. The Act provides that a Ministerial Council set up under the intergovernmental Gene Technology Agreement may issue policy principles on certain topics which are binding on the Regulator.¹¹³ The listed topics include recognising State designated non-GM crop areas for market purposes.¹¹⁴ Following its first meeting on 24 May 2002 the Ministerial Council started work on such a policy principle “to provide constitutional certainty for GM/GM-free designated areas under State and Territory legislation”.¹¹⁵ The policy principle is expected to be released for consultation in the near future. It should be noted that while the Act provides for consultation on policy principles, it does not specifically prescribe public consultation.¹¹⁶

The upshot of this is that the so called national regime with respect to new commercial releases of GMO crops, could well be limited to only two States, Victoria and Queensland.

CONCLUSION

The use of gene technology is an issue with no shortage of proponents and critics. The successful use of the technology requires that both consumers and industry have confidence in the system which assesses the technology and proclaims it safe for public release. This is most evident in its application to food and food crops. This desire to win public confidence in the assessment process required that the *Gene Technology Act* have credibility. This was acknowledged in the formulation of the Act:

.....lack of credibility (particularly in relation to the assessment and management of GMOs for release into the environment) may harm the ability of industry to market GMOs and GM products assessed as safe.¹¹⁷

¹⁰⁹ Explanatory Memorandum, n 44 clause 13 p 15. The Gene Technology Agreement provided, p6 clause 9, that such corresponding legislation commence by 31 December 2001. Only Queensland, South Australia and Victoria have passed the mirror legislation.

¹¹⁰ *Gene Technology Act 2000*, s 16(2).

¹¹¹ Explanatory Memorandum, n 44, clause 12, p 51.

¹¹² *Gene Technology Act 2000*, s 10.

¹¹³ *Gene Technology Act 2000*, s 21 & 57(2); Gene Technology Agreement, section 13.

¹¹⁴ *Gene Technology Act 2000*, s 21(1)(aa)(ii).

¹¹⁵ Gene Technology Ministerial Council Communiqué, 24 May 2002.

¹¹⁶ *Gene Technology Act 2000* s 22.

¹¹⁷ Explanatory Memorandum, n 44, p 13.

The *Gene Technology Act* espouses appropriate objects in protecting the health and safety of people and to protect the environment but these objectives are then weakened by the implication that the risks can be managed to take advantage of the technology.¹¹⁸ This attitude is given eloquent expression by the then Minister, Dr Michael Wooldridge in his second reading speech:

This bill demonstrates that it is possible to effectively regulate risks associated with technology. For Australia to lose the benefits of this technology when we are able to manage those risks would be an irresponsible and insupportable step for government to take.¹¹⁹

The Act has been said to exclude any consideration of economic or marketing implications. This may be interpreted as confining the Regulator's role to an examination of only the scientific issues relating to GMOs. However, the scientific assessment of risks should be related to what are regarded as the risks in the industry, which in turn may have some relationship to economic or marketing factors. The very narrow reading of the Act, as illustrated by the Risk Assessment and Risk Management Plan for Bayer's application for the commercial release of GM canola, does not instil public confidence that the outcomes provided by the Act fulfil its object in protecting the environment, in this particular case, non-GM canola and the ability to grow such crops in areas or locations. This aspect of assessments under the Act should be clarified.

The other criticism of the objects of the Act is the lack of emphasis on the precautionary principle. In the international instrument on Biosafety, the Cartagena Convention, the principle is given primary emphasis in the first article.¹²⁰ It appears in this Act as a method by which the object might be achieved¹²¹ but this was not included in the original formulation of the bill but only by way of an amendment. The precautionary principle is not incorporated into the decision making process in the same way as it is in the EPBC Act.¹²²

Public participation is a means whereby public confidence in the system can be engendered but the Act allows only limited scope for public submissions and there are no merit appeal rights available to the public or other interested parties. Furthermore, standing for injunctions to restrain a breach of the Act is based on more restrictive common law grounds¹²³ and lacks the greater certainty and breadth of standing under the EPBC Act.¹²⁴

Public information is aided under the Act through the publication of extensive material on the Office of Gene Technology Regulator's website. The Act requires that information concerning licences be made available by way of a GMO Record¹²⁵ and the website is an appropriate vehicle for this information to be displayed. At this stage, however, it does not appear that the Regulator has been able to make all the required information on licence conditions available.

The manner in which importations of GM grain are dealt with is a further concern in relation to the structure and administration of the Act. The treatment of the importation of thousands of tonnes of GM corn in the same manner as a dealing involving laboratory tests on organisms is not a satisfactory situation. While it may be that the parties do not propose an intentional release of the GMO, the Hunter Grain incident shows that the handling of thousands of tonnes of grain in ships, bulk handling and storage facilities and the land transport of the grain allows a greater opportunity for an unintentional release than handling a GMO in confined facilities. A process for dealing with such applications under the Act which allowed an opportunity for public submissions rather than a

¹¹⁸ *Gene Technology Act 2000*, s 3.

¹¹⁹ Dr M Wooldridge, n 1, p 18105.

¹²⁰ Cartagena Convention, n 93, Article 1.

¹²¹ *Gene Technology Act 2000*, s 4(aa).

¹²² *Environment Protection and Biodiversity Conservation Act 1999*, s 391.

¹²³ *Gene Technology Act 2000*, section 147.

¹²⁴ *Environment Protection and Biodiversity Conservation Act 1999*, section 476.

¹²⁵ *Gene Technology Act 2000*, s 138.

process that presently allows a dealing of that magnitude, risks and controversy to proceed without any public notice, would be more desirable.

Administratively, such dealings have also presented a problem with the Australian Quarantine and Inspection Service not co-ordinating with the Regulator and some importations taking place without the knowledge of or permits from either entity.

The final and potentially most serious challenge to the gene technology regime is the disintegration of the national scheme. Four of the six states have indicated that they will impose or have already imposed a moratorium on the commercial release of GMOs. Such reversion to differences between States would add costs, complicate regulation and be the antithesis of the “efficient and effective regulatory system” envisaged by the Gene Technology Agreement.¹²⁶

In its short life the “comprehensive, independent and accountable”¹²⁷ regime originally envisaged has not been forthcoming. This has come about through some inherent deficiencies in the regulatory scheme outlined above. The issue of GMOs, their use and development has been identified as of great importance for Australia. The *Gene Technology Act 2000* is a fundamental component of this and, despite its short life, requires modification if it is going to adequately fulfil its role and engender the confidence of sections of industry and the public which the new technology requires to deliver the promised benefits.

¹²⁶ Gene Technology Agreement, Recital B(a).

¹²⁷ Dr M Wooldridge, n 1, p 18104.