australian network of environmental defender's offices

Review of the *Gene Technology Act 2000*

15th July 2005

The Australian Network of Environmental Defender's Offices (ANEDO) consists of nine independently constituted and managed community environmental law centres located in each State and Territory of Australia.

Each EDO is dedicated to protecting the environment in the public interest. EDOs provide legal representation and advice, take an active role in environmental law reform and policy formulation, and offer a significant education program designed to facilitate public participation in environmental decision making.

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Introduction

The *Gene Technology Act 2000* ("*GTA 2000*") provides for an independent review of the Act after four years.[1] The Minister must table a copy of the report of the review in Parliament by the 21st June 2006. The Act further provides that the review is to be "of the operation of this Act, including the structure of the Office of the Gene Technology Regulator".

This submission is on behalf of the Australian Network of Environmental Defender's Offices Inc (ANEDO). This year marks 20 years of EDO in Australia, and an important part of our work is making submissions to improve legislation at state and federal levels. ANEDO has an office in every state, and therefore would be interested in participating in on-going consultation or hearings that may be undertaken regionally as part of this review process over the next 12 months.

This paper is divided into 7 parts in response to the Terms of Reference. First, it looks at the **scope of the *GTA 2000***, and considers the adequacy an appropriateness of current key definitions.

Second, the paper examines whether the regulatory framework is appropriate and effective in **achieving the object** of the legislation. This involves discussion of effectively implementing the precautionary principle and the principles of ecologically sustainable development (ESD).

Part Three looks at the **operation of the *GTA 2000*** in light of the object and framework. We look at three main aspects of operation: the role of the Office of the Gene Technology Regulator (OGTR); consultation provisions; and compliance and enforcement provisions. Regarding consultation, we examine the opportunities for public consultation in the *GTA 2000*, as well as consultation with the specific advisory bodies established under the Act. We consider whether the composition of the advisory bodies is appropriate, and whether the functions conferred upon them are both appropriate and being carried out. In this review, we consider whether the operation of the various bodies could be improved. Regarding compliance and enforcement, the submission considers

how the monitoring and enforcement provisions of the *GTA 2000* have been implemented, and consider issues of liability and implications for third parties. For example, we consider whether common law actions for nuisance or negligence are sufficient to protect non-GM farmers or the broader environment from contamination by GMOs.

Part Four of the paper discusses the **regulatory burden and risk assessment**, and focuses on a review of those provisions of the *GTA 2000* that apply to dealings in GMOs. We consider each class of dealing under the Act to see how many approvals have been granted and whether the assessment regime for applications is appropriate. Particular attention is given to dealings that involve the intentional release into the environment. With a particular focus on the impact of the dealing upon the environment, we consider whether the criteria for risk analysis and assessment is appropriate and whether the risk management plans adequately deal with the prevention of harm to the environment. This part also reviews the types of conditions that have been imposed and critiques whether they are appropriate for mitigating potential impacts.

In Part Five, we examine the **interface with other systems** and the role of the Ministerial Council in co-ordinating a nationally consistent scheme for dealings in genetically modified organisms.

Part Six looks at whether the effectiveness of the Act and whether the OGTR is equipped to deal with emerging technologies and **changing circumstances.**

Finally, Part Seven lists **recommendations** for reforming the Act and regulatory structure.

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[1] *Gene Technology Act 2000 s 194.*

Part 1 – Scope of the *Gene Technology Act 2000*

1.1 Scope of the *GTA 2000*

The regulatory scheme imposed by the *GTA 2000*:

- defines GMOs;[2]
- establishes the independent office of the Gene Technology Regulator ("Regulator") to administer and make decisions under the legislation;
- establishes committees from which the Regulator can request advice;[3]
- prohibits people from dealing with GMOs without relevant licenses or approvals;
- establishes a scheme to assess the risks to human health and the environment associated with dealings with GMOs; and
- creates a centralised, publicly available database of all GMOs and GM products approved in Australia.

Essentially, the *GTA 2000* regulates all dealings with live, viable GMOs and also GMO products that are not regulated by existing regulators. The dealings covered by the Act include research, manufacture, production, propagation, commercial release and import of GMOs.[4] The Act does not regulate matters that are concerned with products containing GMOs (as opposed to the organisms themselves) that are already covered by other agencies. This is discussed further in Part 5.

Evidence from the Office of the Gene Technology Regulator suggests that the process of regulation is operating in a timely and cost effective manner, with most applications being dealt with by the Regulator within 90 days.[5] However, meeting time deadlines is not a true indicator of the quality of the assessment and decision making process.

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[2] As any organisms which are modified by gene technology or inherit particular traits from an organism which has been modified by gene technology.
[3] being the Gene Technology Technical Advisory Committee; the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee.
[4] See definition of "deal with" in *Gene Technology Act 2000 s 10*.
[5] See quarterly reports at www.ogtr.gov.au/pubform/reports.htm.

There are two key issues that arise regarding the scope of the *GTA 2000*. First, whether having many different agencies[6] responsible for the regulation different aspects of gene technology undermines the effectiveness of the system to achieve the objects of the Act. Second, whether it would be better to adopt a nationally comprehensive and integrated regime regulating all aspects of gene technology – or as Anton describes it, a "one-stop-shop" model.[7]

In relation to the first question, a number of people have expressed the view that the segregated approach to assessment has led to deficiencies in the operation of the risk analysis and risk management process, particularly where environmental impacts and risks are concerned.[8] This process is discussed in more detail in Parts 4 and 5 of this paper, however, it is worth noting at this stage that by relying upon other agencies to assess different risk elements of a dealing with a GMO, based upon criteria that does not necessarily have any environmental protection basis, certain risks may not properly be considered at all.

In relation to the second question, the Senate Community Affairs Reference Committee (CARC), observed that it would be preferable for the adoption of a streamlined process involving a single approval from one regulator, rather than the piecemeal approach being proposed. Further, such an approach would provide greater transparency and certainty for both those in the biotechnology industry and also members of the public. Under a more comprehensive model, all GMOs and GM products would be regulated by a single agency or through a centralised process, regardless of whether the GMO or GM product was also a therapeutic good or an agricultural chemical. This would allow for the adoption of consistent objectives for the regulation of GMOs and ensure that compatible criteria was applied when assessing risk. In our opinion, this position remains valid.

The goal of establishing a nationally consistent scheme is discussed further in Part 5.

1.2 Definitions

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[6] For example, Food and safety Australia and New Zealand (FSANZ), Therapeutic Goods Administration (TGA), and the Australian Quarantine and Inspection Service (AQIS).

[7] D Anton "Submission to the Senate community Affairs References Committee in the matter of the Inquiry into the Gene Technology Bill 2000" (21 October 2000).

A key issue relevant to the effectiveness of the *GTA 2000* is whether the current definitions, in particular the limitations on relevant dealings, operate as a fetter on the Act's effectiveness. The terms "GMO"[9] and "deal with"[10] are narrowly defined in section 10 of the Act. Anton has noted that the terms GMO could be expanded to encompass "any biological entity capable of replication or transfer of genetic information ... in which the genetic material has been altered in a way that does not occur naturally."[11] Furthermore, the Western Australian Environmental Defender's Office has argued that the ability of the Regulator to declare organisms not to be GMOs undermines the protection the community expects from the *GTA 2000*.

In relation to dealings with GMOs, Anton[12] and Lin Jin Tsui[13] both note that the definition of "deal with" in section 10 of the Act could be improved by extending it to exports of GMOs, the deliberate dealing with products derived from GMOs and the marketing of GM products. However, these changes could only be given effect to if the

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[8] For example: Lawson *op cit.*

[9] ***genetically modified organism*** means:

(a) an organism that has been modified by gene technology; or

(b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or

(c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

(d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or

(e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

[10] ***deal with***, in relation to a GMO, means the following:

(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;

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).

[11] D Anton "Submission to the Senate community Affairs References Committee in the matter of the Inquiry into the Gene Technology Bill 2000" (21 October 2000).

[12] A Lin Jin Tsui "Australian Regulation of Gene Technology: Impacts on Biodiversity" (2004) 1 Macquarie Journal of International and Comparative Environmental Law.

[13] *Ibid.* p.101.

GTA 2000 operated comprehensively, taking on the powers and functions of other agencies to regulate those aspects of GMOs (discussed further below).

In relation to the object of protecting the environment, some confusion arises as to the scope of the environment being protected and the particular values of that environment that are considered important in the Regulator's decision making process. The definition of "environment"[14] under the Act lacks a clear focus – be it on the biodiversity values of the natural environment or on the wider agricultural values of rural land. By comparison, the definition of "environment" in the *Environment Protection and Biodiversity Conservation Act 1999* (C'th) ("*EPBC Act 1999*") encompasses (a) ecosystems and their constituent parts, including people and communities; (b) natural and physical resources; (c) the qualities and characteristics of locations, places and areas; and (d) the social, economic and cultural aspects of (a), (b) and (c). This definition goes beyond that contained in the *GTA 2000* insofar as it expressly refers to the relationship between people and communities and the environment and also social, economic and cultural aspects of ecosystems, resources and places.

It is curious, given the close proximity between the preparation of the *EPBC Act 1999* and the *GTA 2000*, that different definitions were adopted. Clearly the Parliament intended the scope of the environment in the *GTA 2000* to be limited, but for what reason? We have assumed that references to economic factors within the broader meaning of environment have been excluded on the basis that it relates to marketing matters which are beyond the scope of the Act. However, matters such as the long-term and short-term economic, environmental, social and equitable considerations are clearly at the forefront of public concern about gene technology. For example, concerns about the risk and the impact of crop contamination by GMOs are regularly raised by groups such as Organic Farmers and the Grain Harvesting Board. Yet these matters appear to be excluded from deliberations under the *GTA 2000* due to the limited definition of "environment".

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[14] ***environment*** includes:

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

Both Tranter and Tsui argue that the "environment" that the Regulator considers should include those areas where non-GMO crops may be grown as those areas meet the description of "a location, place or area" notwithstanding that they may be a homogenous area with limited biodiversity values.[15] However, the Regulator is loathe to impose conditions which address those impacts, such as requiring buffer zones.

An example of this approach is found in the Regulator's Statement of Reasons for the grant of approval to Monsanto Australia Limited for commercial release of RoundUp Ready canola into the environment.[16] At paras 15-17 and 196 of the Statement of Reasons, the Regulator sets out her understanding of the term "environment". Whilst she accepts a broad definition of environment, the Regulator concludes at para 17 that

> "economic impacts, such as the costs of crop segregation for marketing purposes and generally, risks to agricultural production and sustainability of farming systems do not come within the definition of the term environment in the Act. Accordingly, in considering this application, I approached the task of identifying risks posed by or as a result of gene technology on the basis that it does not cover economic matters such as the national or regional or sectoral economies or markets. Further, I have approached the process on the basis that it does not require me to identify risks relating solely to the monetary costs of gene technology for individuals or groups of farmers."

In other words, the Regulator clearly rejects the adoption of an assessment process based upon a broad concept of ecologically sustainable development.

Similarly, in relation to an application to release transgenic cotton into the environment, the Regulator failed to consider the broader ecological effects of such a release (except weediness and crossbreeding) when determining to approve the release of the GMO.[17]

In summary, the *GTA 2000* adopts a risk management approach to regulating gene technology, but the ability of that framework to protect the environment more broadly (including effects on humans, communities and biodiversity) is only of marginal effect due to the limitations imposed by the definitions in the Act and the matters to which the Regulator can turn her mind when assessing applications for dealings with GMOs. Accordingly, if the object of the *GTA 2000* includes "protecting the environment" from

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15 Tranter, M ""A system under strain: The Regulation of Gene Technology" (2003) 2 National Environmental Law Review p.32at 35.
16 Licence DIR020/2002.
17 Lawson *op cit.*

risks posed by GMOs, then it is our opinion that this part of the object is not adequately being addressed.

Discussion relating to consideration of other impacts under the Act is included in Part 2, and the process for consideration of ethical issues is dealt with in Part 3. Further discussion of the scope of the Act to deal with emerging technologies is covered in Part 6.

Part 2 – Is the Regulatory Framework appropriate to achieve the object?

2.1 Object of the *GTA 2000*

The object of the *GTA 2000* is expressed as being:

> "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 genetically modified organisms."[18]

In the Second Reading Speech for the Bill, Senator Ian Campbell identified the role of the Gene Technology Regulator as having "the sole purpose of protecting the health and safety of the community and protecting the Australian environment by identifying and managing risks posed by or as a result of genetically modified organisms."[19]

The above statements expressly acknowledge that GMOs may pose a risk to both human health and the wider environment and that those risks must be assessed and managed appropriately. The question is therefore whether or not the scheme imposed by the Act is appropriate to assess and manage those risks.

At this point it is important to note the dual risks that influence the operation of the *GTA 2000*. First, the risk to human health and safety, and second, the risk to the environment. The success of the *GTA 2000* in achieving the object of protecting human health and the environment is contingent upon a clear scientific understanding of the risks that GMOs pose. During debate on the Bill, Senator Sherry identified some of the risks associated with GMOs as including:

- introducing unidentified allergens into GM foods;
- contamination of traditional or organic crops by neighbouring GM crops;
- the inability to eliminate a GMO once it is released and found to have an adverse impact;
- the increased environmental damage due to increased use of chemicals;

[18] *Gene Technology Act 2000 s 3.*
[19] Hansard, 30 August 2000 p.16961.

- increased environmental competitiveness of GMOs, creating weeds, in the case of plants, or pests in the case of animals;
- insect resistant crops affecting non-target insects; and
- transfer of genes for herbicide tolerance from GM crops to related species resulting in herbicide resistant weeds.

As will be seen from the discussion in Part 4 below, it is questionable whether the Regulator's process for considering risk, in particular relying upon assessments done by other agencies, is sufficiently rigorous and independent to achieve the object of the *GTA 2000*.

The *GTA 2000* explicitly includes principles to guide how the regulatory framework is to achieve the object of the legislation. Section 4 provides that:

> **Regulatory framework to achieve object**
> The object of this Act is to be achieved through a regulatory framework which:
> (aa) 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; and
> (a) provides an efficient and effective system for the application of gene technologies; and
> (b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.
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> Note: Examples of the schemes mentioned in paragraph (b) are those that regulate food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods.

Similarly, Part 2 Division 4 of the *GTA 2000* is devoted to "Provisions to facilitate a nationally consistent scheme" including a policy role for the Ministerial Council. This is discussed further in Part 5.

This part examines whether the regulatory framework is currently achieving implementation of the precautionary principle.

2.2 The Precautionary Principle and Ecologically Sustainable Development

It is clear from the Second Reading speeches and parliamentary debates that there was significant public concern about the risks associated with gene technology, in particular the risks associated with cross contamination, and an acknowledgement that those

concerns must be taken seriously.[20] Importantly, many people consulted on the Bill advocated for the adoption of a "precautionary" approach to decision making under the scheme. As noted, this was given effect to in section 4 (aa) of the *GTA 2000*.

The wording adopted in section 4(aa) of the *GTA 2000* reproduces the definition of the "precautionary principle" from the 1992 Rio Declaration.[21] However, the term "cost effective" has been left out of most pronouncements of the "precautionary principle" in Australian environmental law.[22] In other words, for the most part, risk assessment is a technical question. However, under the *GTA 2000* risk is balanced with economic factors and where mitigation is expensive then measures to protect the environment will not be taken.

The *GTA 2000* purports to be an Act to protect the Australian environment. However, unlike other Federal (and State) laws for environmental protection, there is no mention in the objects or principles of the Act to give effect to the principles of ecologically sustainable development (ESD) more broadly.

It is interesting to note that, in contrast to the *EPBC Act*, which expressly requires that the Minister takes the precautionary principle (and other principles of ESD) into account when making decisions under that Act, the *GTA 2000* does not require the same level of consideration by the Regulator when determining whether or not to approve dealings.

Lin Jin Tsui argues that although biodiversity protection may be implied from the object of the *GTA 2000*, it would be greatly improved if the protection, conservation and maintenance of biological diversity against threats posed by GMOs were an explicit object of the Act.[23] This approach was rejected by the Senate when deliberating on the Bill, along with the suggestion that the Bill should refer explicitly to operating in accordance with the principles of ESD. It is our understanding that the Senate was of the opinion that the aim of protecting the environment, and the use of the precautionary principle to achieve that end was sufficient. However, in the absence of an appropriate

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[20] see for example Hansard 6 November 2000 at p.19191 (per Senator Foreshaw) and Hansard 6 November 2000 19195 (per Senator Sherry).

[21] Principle 15 "Rio Declaration on Environment and Development" United Nations (12th August 1992).

[22] Intergovernmental Agreement on the Environment (1992) Clause 3.5.1 - see discussion in M Tranter "A question of confidence: an appraisal of the operation of the *Gene Technology Act 2000*" (2003) 20 EPLJ 245 at 247.

framework to consider matters such as the conservation of biodiversity and the social and economic impacts of gene technology, it is clear that other aspects of ESD are not being addressed.

Lawson has argued that the Regulator has failed to consider the broader ecological effects of releasing GMOs into the environment. His conclusions were based on a review of the data and analysis considered by the Regulator in determining whether to approve the release of GM cotton strains into the environment.[24] He states:

> Some data was available to illustrate 'low' toxicity levels for mammals, birds, vertebrates, non-target invertebrates and soil biota, and 'low' pollen distribution rates, but there was no ecological data presented about community studies, succession studies, ecosystem analysis, population dynamics or organism-environment relationships. Significantly, some data was presented which hinted at likely environmental consequences for 'ecosystems', which suggested that the released GMOs might have significant effects on the environment with the potential to be threats of serious or irreversible environmental damage, albeit long term ecological effects (with possible intergenerational consequences)…. Failure to consider the broader possible ecological consequences is a significant oversight."

These findings suggest that the Regulator did not adopt a precautionary approach when considering the transgenic cotton applications or at least, did not properly weigh these factors.

Similarly, in relation to the Monsanto Roundup Ready canola application (discussed above), it is clear the Regulator excluded considerations of long-term and short-term economic, social and equitable considerations when assessing the application.

The *GTA 2000* is a half-way house; it is partly an Act about biotechnology and biosafety and partly about environmental protection. As a consequence, little guidance is provided to the Regulator with ESD principles unevenly imbricated into the framework of the Act. This imbalance is compounded as the Regulator is arguably more experienced in dealing in matters relating to biotechnology and biosafety than biodiversity.

In summary, it is clear that a number of important principles of ESD are not being considered by the Regulator when assessing licence applications, in particular, broader impacts on biodiversity and also the economic and social implications of decisions.

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[23] Lin Jin Tsui *op cit* at p.99.

[24] C Lawson "Risk Assessment in the Regulation of Gene Technology under the *Gene Technology Act 2000* (C'th) and the Gene Technology Regulations 2001 (C'th)" (2002) 19(3) EPLJ 195 at p.208-216.

Clearly the Government's claim that having regard to "the environment" would encompass consideration of ESD principles, has not been borne out. Furthermore, there is a strong argument, based upon Lawson's critique that the Regulator is struggling to apply the precautionary principle when making her decisions.

In our opinion, this regulatory failure is due to the related factors, the *GTA 2000* itself does not fully imbricate ESD principles into its structure, and scant guidance is provided. The *GTA 2000* needs to integrate ESD principles into its decision-making framework and apply these consistently with existing environmental laws and concepts, in order to fully achieve its object.

Part 3 – Operation of the Act

In relation to the Terms of Reference 3-5, we now examine the following:

- Structure and Effectiveness of the Office of the Gene Technology Regulator
- Consultation provisions of the *GTA 2000*
    - Public consultation
    - Advisory Committees
- Compliance and Enforcement under the *GTA 2000*

3.1 Structure and effectiveness of the Office of the Gene Technology Regulator

The Regulator is an independent statutory office holder appointed by the Governor General (upon the advice of the Minister for Health). The roles of the Regulator are multi-faceted and include liaising and regulatory functions, providing information and advice, monitoring, research and ancillary functions.[25]

Performance of Statutory Functions

The Regulator is required to prepare annual reports to the Minister and which are to be laid before Parliament.[26] In addition, the Regulator must prepare Quarterly Reports to the Minister[27] and may also prepare additional reports to Parliament about any matter relevant to the Regulators functions.[28] During the period in which the Act has been operational, no annual reports have been prepared, however, Quarterly Reports appear to have been prepared in accordance with the Act. Some additional reports have also been commissioned by the OGTR, including research reports and reports on investigations into non-compliance.[29]

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[25] *Gene Technology Act 2000 s 28* further provides that the Regulator has the power to do all things necessary or convenient to be done for or in connection with the performance of the Regulator's functions.
[26] *Gene Technology Act 2000 s 136.*
[27] *Gene Technology Act 2000 s 136A.*
[28] *Gene Technology Act 2000 s 137.*
[29] See: http://www.ogtr.gov.au/pubform/reports.htm.

From a review of the Quarterly Reports, it would appear that the Regulator is technically performing those functions relating to licence application assessments.[30] The Regulator and her Office regularly conduct or support research into certain aspects of gene technology and engage, through conferences and meetings with international bodies to monitoring developing practices. The Regulator has also issued guidelines to assist applicants for licences, covering such things as requirements for certification of containment facilities, good industrial practice and transportation of GMOs.[31] However, there is a lack of qualitative reporting available to the public. Meeting time deadlines is not a true indicator of the quality of the assessment and decision-making process.

For more robust information, ANEDO recommends that the OGTR be required to prepare annual reports that detail the social (including ethical), economic and environmental aspects of the operation of the Regulator ("triple bottom line" reporting).

One aspect of the Regulator's performance that appears to be unclear is how well her Office is harmonising risk assessment within and amongst other agencies and whether agency consultation is limited only to the referral of licence applications or whether more broad cooperation exists. The reliance placed on other agencies to carry out aspects of risk assessment is discussed in Part 5. Of note at this point is the question of how that reliance affects the perception of independence of the Regulator.

Independence

Importantly, the office of the Regulator is expressly stated to be independent and not subject to direction from anyone in relation to the decision to grant or refuse a licence or the conditions that may be imposed on a licence. The independence of the Regulator is a critical component of the scheme both in terms of the operation of the Act and the broader public perception of the office. Section 120 of the *GTA 2000* requires the Regulator to disclose to the Minister, all interests (pecuniary or otherwise) that could conflict with the performance of his or her functions. Commentators, such as the

[30] Notwithstanding the failure to properly consider elements of the precautionary principle, as noted in Part 1.1.
[31] Supra note 52.

Australian Centre for Environmental Law, have expressed the view that this provision is not wide enough to ensure independence and that any person who has had an interest in a regulated entity (being an entity that carries out dealings with GMOs) should be precluded from holding office. ANEDO supports the broadening of the conflict clause.

In terms of the structure of the OGTR, commentators have argued that the independence of the Regulator would be strengthened if the office was held by more than one person. In fact, the CARC made a recommendation that the position be held by three people.[32] ANEDO supports this recommendation.

Current perceptions of the OGTR have been shaped by the failure of the OGTR to prosecute breaches and properly use offence provisions, and the failure to determine that proposed dealings will have a significant impact due to the failure to fully assess all environmental impacts.

Further discussion of the OGTR's specific functions is included in Part 3.3 dealing with compliance and enforcement, and Part 4 which examines dealings and risk assessment.

[32] CARC report.

3.2 Consultation Provisions

3.2.1 The functions and roles of the statutory Advisory Committees

The *GTA 2000* provides for the establishment of three advisory committees, namely, the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Community Consultative Committee (GTCCC), and the Gene Technology Ethics Committee (GTEC). These committees have been established to provide expert advice to the Regulator and the Ministerial Council in overseeing the legislative scheme. These are discussed in turn.

Gene Technology Technical Advisory Committee

The role of the GTTAC is to provide scientific and technical advice on issues including:

(a) gene technology, GMOs and GM products;
(b) applications made under this Act;
(c) the biosafety aspects of gene technology;
(d) the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products, and the content of such principles, guidelines and codes.[33]

The committee comprises a Chairperson, appointed by the Minister, and up to 20 part-time members who have expertise in a broad range of scientific disciplines.[34]

The current composition of GTTAC emphasises agricultural and medical expertise, with no member having ecological expertise. ANEDO recommends a member be appointed[35] with ecological expertise, otherwise this knowledge gap could lead to certain issues not being fully considered.

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[33] *Gene Technology Act 2000 s 101.*
[34] *Gene Technology Act 2000 s 100*; sub(5) molecular biology; ecology; plant, microbial, animal or human genetics; virology; entomology; agricultural or aquacultural systems; biosafety engineering; public health; occupational health and safety; risk assessment animal biology;; clinical medicine; biochemistry; pharmacology; plant or animal pathology; botany; microbiology; immunology; toxicology; an area specified by the regulations for the purposes of this paragraph. There is also a requirement that at least one representative on the committee is a member of each of the ethics committee and the community consultative group, and that a lay person who is not required to have scientific expertise is also appointed. In addition, the Minister may appoint one or more expert advisors to the committee on a needs basis.
[35] After consultation with the states, Regulator, and relevant stakeholders as required by s100(4).

The *GTA 2000* provides that the Regulator must consult with the GTTAC in relation to the risk assessment and risk management plans for dealings which involve the intentional release of a GMO into the environment. However, such consultation is not mandatory where intentional release is not contemplated. ANEDO recommends that the matters that the GTTAC can advise upon should be expanded to cover all aspects of dealings that may pose a significant risk to human health or the environment and all licence applications.

Gene Technology Community Consultative Committee

The GTCCC was established to provide advice to the Ministerial Council and the Regulator on the following:

> (aa) matters of general concern identified by the Regulator in relation to applications made under this Act;
> (a) matters of general concern in relation to GMOs;
> (b) the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the content of such principles, guidelines and codes.[36]

Similar to the GTEC, the GTCCC is comprised of up to 12 part time members appointed from a wide variety of backgrounds.[37] The appointment process is governed by the same procedure, involving consultation with the States, the Regulator and appropriate scientific, consumer, health, environmental and industry groups.[38]

The expectation behind establishing the GTCCC was to ensure that the Ministerial Council and the Regulator remained in touch with the opinions and views of the community (for example, consumer groups, environmental groups and industry groups) in relation to issues relating to GMOs. It was further expected that the GTCCC would provide advice on the most appropriate ways to consult and engage with the public in relation to matters of general concern about GMOs. During the CARC review of the Bill, it was argued that the GTCCC should have a greater role in relation to specific dealings with GMOs, such as being consulted in relation to licence applications.

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[36] *GTA 2000 s 107.*
[37] *Gene Technology Act 2000 s 108(3)* - environmental issues; consumer issues; the impact of gene technology on the community; issues relevant to the biotechnology industry; issues relevant to gene technology research; public health issues; issues relevant to primary production; issues relevant to local government; issues specified by the regulations for the purposes of this paragraph.
[38] *Gene Technology Act 2000 s 108(2).*

However, this was rejected by Parliament. The functioning of the GTCCC has attracted criticism for example, regarding the lack of time to consider significant proposals, and divisions between representatives.[39] Given the limited opportunities for public consultation and participation (described below) it is important that the GTCCC has a strengthened role.

Gene Technology Ethics Committee

During consultation on the GTA 2000 various stakeholders argued successfully that ethical issues should be considered separately from the consideration of scientific and technical issues by the OGTR. The GTEC was then established to provide advice to the Ministerial Council and the Regulator on the following:

(a) ethical issues relating to gene technology;
(b) the need for, and content of, codes of practice in relation to ethics in respect of conducting dealings with GMOs;
(c) the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.[40]

The GTEC is comprised of 11 part-time members representing specialist ethical disciplines,[41] with similar appointment processes to the GTCCC, and requirements, for example for a member with expertise in medical research.

An ethics advisory committee is unique amongst not only Australian advisory committees, but also internationally within the gene technology regulatory regimes.[42] The inclusion of such a committee is therefore a positive aspect of the gene technology scheme. However, the input of the ethics committee into broader policy documents is limited to policy principles only and not codes of practice or guidelines. To date, there have been no policy principles developed which relate to ethical matters.

[39] GTCCC membership expired 8th October 2004, appointment process ongoing currently.
[40] *Gene Technology Act 2000 s 112.*
[41] *Gene Technology Act 2000 s 111(5)* - ethics and the environment, health ethics, applied ethics; law; religious practices; population health; agricultural practices; animal health and welfare; issues of concern to consumers in relation to gene technology; environmental systems.
[42] Senate Inquiry Report p.135.

In the absence of an ethics policy principle, the Regulator is unable to refuse a licence on the basis that a dealing is contrary to such a principle.[43]

In addition, ethics would appear to have a somewhat marginalised role in risk assessment and licensing decisions. As Rogers notes, the risk assessment process in the *GTA 2000* does not include assessment of the ethical aspects of each dealing with a GMO.[44] Furthermore, the deliberations of the GTEC do not directly affect licensing decisions unless a policy principle is developed.

The Committee has played a limited role to date, with communiqués publicly available on the OGTR website and only two submissions recorded.[45] ANEDO recommends strengthening the role of this Committee and making the development of an ethics policy principle a priority.

3.2.2 Stakeholder Consultation: Public Consultation and Participation under the *GTA 2000*

The issue of gene technology is a dynamic and controversial public issue. While public consultation provisions are common place in Australian environmental law, it is imperative to ensure that robust consultation provisions are activated where there is uncertainty over contentious issues.

In NSW, many environmental statutes contain comprehensive public participation provisions. Increasingly, however, consideration needs to be given to using such public participation effectively, given limited community capacity. As the NSW Department of Environment and Conservation (DEC) has recently recognised in the context of licence reviews, there is a need to actively ensure proper public participation in environmental decision-making beyond simply meeting the formal requirements of the legislation. Such an approach recognises the complexities of public participation in an increasingly technical, difficult and time-consuming operating environment. Recent practice has

[43] section 57 *Gene Technology Act 2000*.
[44] N Rogers "Seeds, Weeds and Greed: An Analysis of the *Gene Technology Act 2000* (C'th) Its effect on property rights, and the legal and policy dimensions of a constitutional challenge" (2002) 2 Macquarie Law Journal 1 at p.9.
[45] Submissions on the Draft Guidelines on Xenotransplantation Research: www.ogtr.gov.au/committee/gtec.com.

demonstrated that mechanisms for public participation need to be better managed to ensure the best possible environmental outcomes. This is particularly relevant to the technical issues surrounding gene technology.

The *GTA 2000* provides for public participation in decisions affecting the regulation of GMOs in four main areas. First, in providing input into certain decisions relating to the determination of whether or not to grant a licence for a dealing with a GMO. Second, in providing input into policy principles and other administrative matters such as the terms of the risk assessment and risk management framework. Third, by allowing limited opportunities for third parties to seek administrative review of decisions of the Regulator; and fourth, by maintaining publicly available registers of information about license and dealings.

When the Bill was before Parliament and the Senate CARC, there was much debate about the extent to which the public would be involved in scrutinizing decisions of the Regulator. Given the levels of public interest and concern about GMOs, a number of individuals and organisations called for greater transparency within the Bill in order to promote public confidence in gene technology.[46] Provisions were introduced which gave effect to the public participation mechanisms referred to above, however, many other opportunities for enhancing public participation, such as incorporating third party objector rights were not adopted.

The value of public consultation has been recognised internationally[47] as a fundamental tenet of achieving ecologically sustainable development, and it is essential that the federal government reflect this in their legislation.

Quality of information available to public

A number of commentators have expressed concern about the quality and extent of information available to the public, and whether the opportunities provided under the *GTA 2000* framework provide a "meaningful opportunity" for public consultation about specific circumstances and general policy development.

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[46] ACEL submission to CARC; Hansard 6 November 2000 p.19191 per Senator Foreshaw.

[47] For example, the European *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental matters* (Aarhus Convention) 1998.

Chin notes that the key providers of information in relation to gene technology are the CSIRO, consumer organisations, universities and schools. Much of the information about gene technology is conveyed to the public through the media and does not necessarily reflect the true nature of the information. The way in which information has been reported to the public has been criticised and described as "overly sensationalist and lacking in substance and depth."[48]

As noted, quarterly and additional reports are publicly available on the OGTR website, as well as public registers listing dealings; however the public does not have access to all the information, for example where commercial in confidence provisions operate. This is discussed further below.

Consultation about Dealings

The scope for public submissions about specific licence applications is highly confined. Section 49 of the *GTA 2000* requires the Regulator to issue a public notice and receive submissions in relation to a particular licence application where the licence would involve the intentional release of a GMO into the environment,[49] and where the Regulator is satisfied that at least one of the dealings under the licence application might pose a significant risk to the health and safety of people and the environment.[50]

Therefore consultation with the public is only available to one particular dealing, dealings involving intentional releases, and only then at the instigation of the Regulator. The ANEDO recommends that there should be broader scope for public participation, namely in relation to other types of dealings like exempt dealings, notifiable low risk dealings, and entries on the register.

Tranter idenitifies the short-sightedness of public consultation provisions in that there is no provision for consultation beyond the initial stages when the Regulator is considering

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48 Chin G, "Role of public participation in the genetically modified organisms debate" (2000) 17(6) Environmental and Planning Law Journal 519 at 522.
49 *Gene Technology Act s 48.*
50 *Gene Technology Act s 49(1) and (3).*

whether to issue the licence.[51] There is no scope for consultation and participation if, for example, a party seeks to vary or change an existing licence. This was one of the aspects which was raised as an area to be addressed by Labour during the second reading speech debates.[52] ANEDO recommends that public consultation go beyond initial stages, and for example, be revisited where a party wishes to amend or vary a licence.

Consultation about Policy Principles, Risk Assessment and Management Planning

The scope for consultation on policy principles is limited under the *GTA 2000*. Section 22 of the Act sets out that policy principles are to be developed in consultation with select bodies, including the GTTAC, the Regulator, the GTCCC, the GTEC, Commonwealth and State agencies, and regulatory committees, industry groups, environmental, consumer and other groups that the Ministerial Council considers to be appropriate. This indicates that the Ministerial Council has discretion as to the breadth of the consultation on the basis of what is "appropriate". The ANEDO recommends that it be mandatory for the Ministerial Council to consult with peak environment groups regarding policy principles, risk assessment and management planning.

Given that the Council has only issued one policy principle to date and only met twice, it is questionable whether the level of consultation envisaged in the Act has been adhered to by the Council.

Public Registers and Access to Information

Under section 138 of the *GTA 2000*, the Regulator maintains a record of all GMO and GM product dealings. The record contains information about the name of the licence holder, persons covered by the licence, the dealings authorized by the licence and the GMO to which the licence relates, any licence conditions and the dates of issue and expiration for the licence.[53] Certain information which is declared to be "commercial in confidence" does not need to be recorded. In addition, the Regulator maintains a GMO

[51] See Tranter *op cit* at 254.
[52] See Hansard, Senate, Monday 6 November 2000 at 19195.
[53] The *Gene Technology Regulation 2001* sets out the matters to be noted on the register.

register for notifiable low risk dealings.[54] The Regulator must allow any person to inspect any part of the GMO record or register.[55]

Tsui suggests that, despite this provision enabling public access to the contents of the GMO register, the *GTA 2000* should operate inversely, namely on the presumption that the public is able to access all information, and not confined to information determined by the Regulator to be included on the GMO register.[56]

The Regulator can declare that particular information is of a commercially sensitive nature and confidential, where disclosing the information or making it publicly available would be likely to diminish or destroy the value of that information.[57] The scope for making a declaration is broad, as the Act only provides that the Regulator cannot make a declaration where "the public interest in disclosure outweighs the prejudice the disclosure would cause to any person"[58] or if the information relates to locations where field trials of GMOs are taking place.[59] Tsui suggests that the Regulator's ability to declare that information is commercially sensitive and consequently confidential is one way in which the *GTA 2000* limits the accessibility of relevant information to the public.[60] Tsui recommends that information should only be declared confidential commercial information if the applicant for the declaration is able to rebut this presumption by demonstrating that the declaration would not create a significant risk to human safety, the environment or biodiversity.[61]

With regard to information concerning the location of trial sites, section 185 (2A) provides that

> The Regulator must refuse to declare that information is confidential commercial information if the information relates to one or more locations at which field trials involving GMOs are occurring, or are proposed to occur, unless the Regulator is 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.

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54 *Gene Technology Act 2000 s 77 and 78.*
55 *Gene Technology Act 2000 s 138 and 81.*
56 See Tsui *op cit* at 108.
57 *Gene Technology Act s 184 and 185.*
58 *Gene Technology Act s 185(2).*
59 *Gene Technology Act s 185(2A).*
60 See Tsui *op cit* at 108.
61 Ibid.

> Note: This means that, in general, information about sites where dealings with GMOs are occurring will be required to be disclosed under sections 54 and 138, unless the Regulator is satisfied that disclosure would involve significant risks to health and safety.

However, much information on trial sites is not publicly available. This inhibits the publics' ability to assist the Regulator by reporting suspected breaches.

Third party appeal rights

The *GTA 2000* contains a right of appeal in relation to decisions made under the Act.[62] The review mechanism under the Act allows for internal review,[63] a review by the Administrative Appeals Tribunal ("AAT"),[64] and an appeal to the Federal Court under the *Administrative Decisions (Judicial Review) Act 1997* (*ADJR Act)*.[65]

Each of these types of appeal can only be made by an "eligible person" as defined in the table in section 179 of the *GTA 2000* or the *ADJR Act*. Eligible persons will ordinarily be applicants for licences, licence holders, applicants for certification or accreditation or holders of such certification or accreditation. The definition of eligible person is therefore highly confined. There is no extended scope for an appeal by a third party, for example, regarding variation of a licence or certification, or suspension or cancellation of a licence or certification.[66]

Essentially, the only opportunity for third party review of a decision under the *GTA 2000* is to seek administrative review of a decision by the Regulator to issue a licence or approve dealing. The grounds for such an appeal are limited to very narrow grounds of administrative law, including: error of law; denial of procedural fairness; denial of natural justice, taking into account irrelevant considerations or failing to consider relevant considerations; bias and manifest unreasonableness. These grounds are primarily determined by reference to the Regulator's published Statement of Reasons for decision and are extremely difficult to challenge.

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62 Part 12 Division 2.
63 *Gene Technology Act 2000 s 181.*
64 *Gene Technology Act 2000 s 183.*
65 *Gene Technology Act 2000 s 183A.*
66 *Gene Technology Act 2000 s 179.*

The lack of provision for third party appeal rights under the *GTA 2000* is a "significant shortcoming."[67] During the debate on the Bill and the Senate CARC review, many parties called for wider standing provisions to be included in the Act, particularly in light of the extended standing provided for under the *EPBC Act 1999* and what was perceived as best practice for environmental legislation.[68] Industry and the Interim Office of the Gene Technology Regulator were not supportive of such provisions on the basis that such standing would give rise to vexatious appeals and would add delays to the assessment process. Further, they believed the opportunity for public consultation in respect of licence application would give the public a sufficient opportunity to comment upon proposed dealings.

The CARC committee was of the opinion that the Bill unfairly discriminated against third parties wishing to appeal the grant of a licence and was against the public interest and likely to undermine public confidence in the system.

In addition to establishing a cause of action for judicial review, standing of third parties is also difficult to establish. In administrative review actions under the *ADJR* Act in the past, conservation groups have been able to establish standing as "aggrieved parties" if they can demonstrate that they have actively campaigned in relation to a particular issue. Similarly, individuals who may be directly affected by a decision, such as neighbouring farmers, may also be able to establish standing. Notwithstanding the Court's approach, standing is nevertheless a hurdle which has to be overcome. In contrast, the presumption of standing in the *EPBC Act 1999* is for conservation groups or individuals who have campaigned on a particular issue in the preceding two years.[69]

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[67] Tsui ALJ, "Australian regulation of Gene Technology: impacts on biodiversity" (2004) 1(1) Macquarie Journal of International and Comparative Environmental Law 95 at 108.

[68] See ACEL submission to CARC, & Hansard 7 November 2000 p.19297 per Senator Crowley.

[69] Extended standing for judicial review under the *EPBC Act 1999* - section 487.

(1) This section extends (and does not limit) the meaning of the term person aggrieved in the Administrative Decisions (Judicial Review) Act 1977 for the purposes of the application of that Act in relation to:

(a)a decision made under this Act or the regulations; or

(b)a failure to make a decision under this Act or the regulations; or

(c)conduct engaged in for the purpose of making a decision under this Act or the regulations.

(2) An individual is taken to be a person aggrieved by the decision, failure or conduct if:

(a)the individual is an Australian citizen or ordinarily resident in Australia or an external Territory; and

(b)at any time in the 2 years immediately before the decision, failure or conduct, the individual has engaged in a series of activities in Australia or an external Territory for protection or conservation of, or research into, the environment.

(3) An organisation or association (whether incorporated or not) is taken to be a person aggrieved by the decision, failure or conduct if:

To date, no legal challenges have been brought by third parties. The ANEDO recommends that the *GTA 2000* should contain provision providing "open standing" for internal, merits and judicial review of any decision under the Act.[70]

3.3 Enforcement and compliance

The ANEDO submits that current levels of enforcement and compliance monitoring are neither effective nor appropriate. The OGTR website currently lists only 2 reports of investigations into non-compliance at past-trial sites in Tasmania. In contrast, Greenpeace Australia-Pacific has compiled a list of 36 separate breaches of the *GTA 2000*. There have been no prosecutions under the *GTA 2000* to date. Issues of liability for contamination remain unresolved.

Investigation and Monitoring

The Regulator has powers of investigation and inspection, more specifically to appoint investigators and issue search warrants to authorise an inspector to enter and monitor premises.[71] Monitoring powers are extremely broad and include searching, inspecting, examining, taking measurements and photographs of things within the premises, and operating equipment on the premises. The Regulator also has emergency powers to deal with dangerous situations.[72]

The monitoring and compliance section of the OGTR has developed and continues to update protocols to assist organisations and parties interested in the process by which the

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(a)the organisation or association is incorporated, or was otherwise established, in Australia or an external Territory; and
(b)at any time in the 2 years immediately before the decision, failure or conduct, the organisation or association has engaged in a series of activities in Australia or an external Territory for protection or conservation of, or research into, the environment; and
(c)at the time of the decision, failure or conduct, the objects or purposes of the organisation or association included protection or conservation of, or research into, the environment.
(4) A term (except person aggrieved) used in this section and in the Administrative Decisions (Judicial Review) Act 1977 has the same meaning in this section as it has in that Act.

[70]The standing test is not only relevant to seeking injunctions, it is also applicable to the process of seeking judicial review of any decision or failure to make a decision by the Regulator[70]. For the purposes of this discussion, it is interesting to note that in addition to applicants, the only other persons with standing to seek a review of a decision (on its merits) under the *GTA 2000* are the States.

[71] *Gene Technology Act 2000 s 150, 151.s and s153.*

Office carries out its functions. As a general rule, the OGTR conducts routine monitoring visits to a minimum of 20% of the filed trial sites involving GMOs each year. A minimum of 5% of the current sites and 5% of the post harvest sites are monitored each quarter. The OGTR also engages in spot checks on sites, and at times, that are considered to be higher risk. Similar levels of monitoring occur at contained facilities. ANEDO suggests that the percentage of sites monitored be increased due to the serious environmental and health implications that breaches could have.

The Quarterly Reports issued by the Regulator provide details of the monitoring, auditing and compliance activities carried out by the Regulator in each quarter. Some of the results from these reports are disturbing. For example, breaches of conditions occurred at 21 post-harvest GM canola sites in Tasmania in 2001. After studies were conducted to determine the seriousness of the breaches, it was decided that the risk to human health and safety and to the environment from gene flow and out-crossing to nearby brassicaceous plants was negligible. In order to address the monitoring conditions, the Regulator decided to reduce the area to be monitored for future dealings.[73] This is an unacceptable approach.

Often it is difficult for regulators to be aware of all breaches of licence conditions or other activities that would constitute a breach of their legislation. In these circumstances members of the public are able to play an important role in notifying the Regulator if they have concerns about how licensees are operating. The difficulty with the *GTA 2000* is that much of the information about the location of trial sites is not publicly available, therefore it is difficult for the public to play a role in monitoring compliance. ANEDO recommends that this deficiency be addressed by increasing public access to information and increasing levels of monitoring.

Offence Provisions

The *GTA 2000* has a number of offence provisions, many of which are strict liability offences.[74] An offence can be an aggravated offence if the offence causes or is likely to cause significant damage to the health or safety of the environment.[75]

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[72] *Gene Technology Act 2000 s 158.*
[73] Quarterly Report for period 1 July to 30 September 2003 p.23.
[74] See *Gene Technology Act 2000 ss33, 34, 35 and 37.*

Section 33 of the *GTA 2000* provides for offences relating to unlicensed dealing with a GMO, with penalties of 50 to 200 penalty units. To date, there have been no proceedings commenced for a breach of section 33 of the *GTA 2000*.

In relation to offences of non-compliance with a GMO licence, section 34 of the *GTA 2000*, provides that the holder of a GMO licence must not contravene the Act intentionally or recklessly; with provision that each day a breach continues a person is potentially liable for the maximum penalty which includes 2000 penalty units or imprisonment. To date, there have been no proceedings commenced by the Regulator for a breach of section 34 of the *GTA 2000*.

Offences regarding breaches of conditions of a GMO licence are established under section 35. As noted, Greenpeace has compiled a list of 36 breaches of licences issued under the *GTA 2000* and also the previous regime monitored by the Interim Office of the Gene Technology Regulator. Some of the breaches include non-compliance with post harvest monitoring requirements; GM plants being found seeding in exclusion zones; buffer zones not being complied with; escape of GMO from trial sites; spillage of GM seed during transportation; research being undertaken not in certified facility; burial of GMO post harvest without complying with sterilisation requirement; and non compliance with storage requirements. In all reported or investigated instances of breaches, the Regulator required steps to be taken to mitigate against and remedy the breach. However, even in what appear to be more serious breaches, such as toxic GMOs being found off site or the spillage of 15kg of GM cotton during transport, the offence provisions were **not** triggered. In some instances, the Regulator has expressed the view that "the environmental risks [of the breach] were negligible". Regardless of the risk, the mere fact that licence holders are not strictly complying with conditions is serious. The preferred course of action of the Regulator when dealing with breaches is to direct the licence holder to take steps to remedy or mitigate any harm caused by the breach. More serious sanctions need to be utilised to provide an effective deterrent.

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[75] *Gene Technology Act 2000 s 38*. In order to prove an aggravated offence, the prosecution must prove that the person who committed the offence: (a) intended his or her conduct to cause significant damage to the health and safety of people or to the environment; or (b) was reckless as to whether that conduct would cause significant damage to the health and safety of people or to the environment.

Injunctions

If a party is about to engage in conduct which would be an offence against either the *GTA 2000* or *Gene Technology Regulations 2001* the Regulator or an aggrieved person can make an application to the Federal Court for an injunction.[76]

As noted above, when drafting the *EPBC Act 1999,* Parliament expressly extended the definition of an "aggrieved person" beyond the *ADJR Act 1977* definition,[77] for example to include a person who has engaged in protective or research activities regarding the environment. ANEDO submits that such an approach would have been preferable in the *GTA 2000* as there are a number of public interest groups which campaign on genetic engineering issues that may struggle to meet the more limited test. The ANEDO submits that an open standing provision should be included to allow "any person" to bring an injunction.

Liability for damage

The *GTA 2000* contains stringent offence provisions relating to the intentional release of a GMO into the environment without a licence or not in accordance with licence conditions. However, the Act does not impose liability upon GMO licence holders for damage caused to the environment or biodiversity as a result of an authorised release of a GMO. As such, the only liability that may arise in these circumstances is in relation to common law offences of trespass, nuisance and negligence.[78] The applicability of these offences has not yet been tested in Australian Courts, however, in Canada the Supreme Court accepted submissions from lawyers for Monsanto that a farmer whose crops had been contaminated by GMOs from a nearby site was in breach of patent law because his crops contained the GMO and were not licensed to do so.[79]

McIntosh reviews the elements of each of the causes of action of trespass, negligence and nuisance and reaches the conclusion that it would be unlikely that licence holders would ever be found liable under the common law regime – in many instances the

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[76] *Gene Technology Act 2000 s 147.*
[77] Section 3.
[78] See discussion in McIntosh L "Liability for loss of Biodiversity caused by the release of Genetically Modified Organisms" (2002) NELA Review p.40.

defence of statutory authority (as a result of compliance with a licence issued by the Regulator will defeat a claim). However, as McIntosh notes, even if a GMO licence holder were found liable, compensation for loss of biodiversity would rarely be available as damage to the environment, and biodiversity in particular, is inherently very difficult to quantify [as] the law has not yet developed a mechanism to place a monetary value on the loss of a species, let alone species diversity.[80]

Accordingly, there is a need to develop appropriate statutory provisions that protect individuals and the environment from the unforseen or unintended consequences of the release of GMOs into the environment. In States such as NSW and the ACT stakeholders have lobbied for the inclusion of liability provisions in their State gene technology legislation. However, due to the limitations on States' powers in relation to GMOs (most State Acts only dealing with moratoriums) Parliaments have been unwilling to adopt such provisions. The ANEDO submits that a framework to provide appropriate strict liability provisions and for compensation for loss or damage as a result of unforseen consequences relating to licensed dealings, be developed as a matter of priority.

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[79] *Monsanto Canada, Inc. v. Schmeiser* 2004 SCC 34 (CanLII)
[80] *Ibid.* p.44.

Part 4 – Regulatory burden versus Risk

This part reviews the system of approvals and the application of regulatory requirements commensurate to the level of risk.

4.1 Dealings and Risk assessment

It is necessary for the upcoming review of the *GTA 2000* to carefully consider whether the process of categorising and licensing dealings adequately assesses the full range of risks involved, in accordance with the object of the Act. This is not merely a legal question, but scientific, ethical, and inevitably political. The Government's expressed wish to develop an advanced and profitable biotech industry, must not be at the expense of a genuine precautionary approach and full risk assessment.

Part 4 of the *GTA 2000* prohibits all dealings with GMOs unless the dealing fall within the four types of exceptions outlined in the Act. The first 3 exceptions are:

- *exempt dealings* – generally those conducted in secure facilities, involving experiments not known to be harmful to humans;[81]
- *notifiable low risk dealings* - are those involving GMOs that have been assessed over time as posing low risks provided certain risk management conditions are met,[82] and
- *registered dealings* – which can be undertaken by any person, subject to the conditions imposed on the dealing by the Regulator, provided that the dealing is notified on the Register.[83]

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[81] A range of exempt dealings are set out in the *Gene Technology Regulations 2001*. The dealings contemplated by the Regulation are the type of dealings typically conducted in laboratory facilities, such as experiments with naked DNA, bacterial and yeast systems or somatic modifications of mature animals using genes not known to be harmful to humans. All exempt dealings must be conducted in a secure, closed environment and must not involve the intentional release of the GMO into the environment (clause 6).[81] An exempt dealing can be carried out within notifying the Regulator.

[82] NLRDs must be conducted within a facility certified to be at least Physical Containment PC 2 (s75), appropriately supervised within an Accredited Organisation, and if the GMO is to be transported, it must be in accordance with the Regulator's "Guidelines for the Transport of GMOs." The *GTA 2000* precludes NLRDs being released into the environment (s74(2)). There are currently five types of NLRDs (clause 12 and Schedule 3, Part 1). These are essentially those dealings that do not result in an organism being able to seed (for plants), or otherwise involves hosts or vectors that cannot cause disease in human beings, animals, plants or fungi. Dealings are not NLRDs if they are described in Schedule 3 Part 2 identifies those dealings of a higher risk to human health or the environment as a result of the toxicity of the organism, the potential for infection or the volume of GMO produced.

[83] *Gene Technology Act 2000 s 76.* Most of the dealings that are listed on the Register are those that would ordinarily require a licence to be issued. However, due the Regulators determination that the risks posed

The ANEDO recommends that the criteria for dealings to qualify under these 3 exemptions should be revisited and assessed commensurate to the potential level of risk. This is necessary as a part of better implementation of the precautionary principle (as discussed above). This is also of particular importance in the absence of liability provisions for contamination.

4.2 Licensed dealings

The fourth exception to part 4 is for licensed dealings. These may be:

- involving the intentional release of GMOs
- not involving intentional release of GMOs.

The Regulator or her delegate can issue licenses for both circumstances,[84] however, the risk assessment procedure for each category is slightly different, with dealings involving intentional release into the environment being more rigorous and requiring additional scrutiny and public consultation.

(a) Dealings involving the intentional release of a GMO into the environment

There are two types of intentional release dealings: those that pose a significant risk to health and safety of people or the environment, and those that do not pose such a risk.[85] A number of commentators have indicated that the intentional releases of GMOs attract much public attention and raise contention, because the licences available allow for the commercial release of GMOs at a level that has the potential to impact significantly on the environment, either by causing contamination or inducing a loss in biodiversity.[86] Accordingly, the framework for assessment applied by the Regulator needs to be thorough and rigorous.

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by the dealing are minimal, the dealing does not need to be licensed to protect the health and safety of human health and the environment (s79).

[84] *Gene Technology Act 2000 s 55.*

[85] *Gene Technology Act 2000* Division 4 of Part 5 deals with applications for licences involving the intentional release of a GMO into the environment.

[86] See Tranter M, *op cit* at 250-251.

Where the risk to health and safety of people or the environment is not significant, the Regulator is nevertheless required to prepare a risk assessment and risk management plan and consult widely on those instruments. Where the risk may be significant, a preliminary investigation of the risk, again involving public consultation, is also undertaken.

There are currently 54 recorded dealings involving intentional releases: 29 current licenses; 12 licenses which were previously operative but which have now been withdrawn; 7 licenses which have been surrendered, and 6 licenses which are conditional on "post harvest monitoring" (2 of which are current).[87]

Dealings that may pose significant risks to the health and safety of people or the environment

The Regulator must publish public notices if satisfied that a dealing proposed to be authorised by the licence may pose significant risks to the health and safety of people or to the environment.[88]

Section 49(2) lists relevant considerations that the regulator must have regard to in determining what may determine significant risk.[89] Consideration of environmental risks is arguably limited to the potential for dissemination, persistence and spread of a GMO into the environment. This means that the secondary aspects of environmental risk, such as the likelihood of competition with non-GM varieties and longer term environmental impacts, are not currently considered.[90] The ANEDO recommends that factors for consideration be broadened to include more comprehensive and long term environmental impacts.

To date, the Regulator has not determined that any proposed dealings are likely to have a significant impact on human health and safety or the environment, despite considering almost 50 applications for licences to deal with GMOs. We note, however, that in relation to the application by Monsanto for the commercial release of roundup ready

[87] http://www.ogtr.gov.au/gmorec/ir.htm.
[88] *Gene Technology 2000 s 49.*
[89] the properties of the organism to which the dealings relate; the expected effect, of genetic modification that has occurred, or will occur; provisions for limiting the dissemination of the GMO in the environment; the potential for spread or persistence of the GMO or its genetic material in the environment; the extent or scale of the proposed dealings; and any likely impacts of the proposed dealings on health and safety.
[90] Lawson *op cit.*

canola the Regulator nevertheless invoked the dual public consultation process due to public perception of the risks posed by the GMO.

Risk Assessment

The Regulator is required to make a comprehensive risk assessment of each application involving the intentional release of a GMO into the environment. The Explanatory Memorandum to the Bill stated that the risk assessment would:

- Identify any hazards to public health and safety of the environment [associated with] the dealing, based upon objective information;
- Estimate the probabilities of hazards occurring; and
- Estimate the risk that is a function of the above factors.[91]

The Regulator describes the general process that she undertakes as identifying the elements that pose risk, analysing their likelihood and the significance of impacts, their management, and communication about them to the applicants, stakeholders and the broader community.[92]

Section 51(1) of the *GTA 2000* identifies the matters that the Regulator must take into account as part of the risk assessment process. This is supplemented by criteria set out in the Regulation. Also, the Regulator has released a Risk Assessment Framework to clarify the way in which she will consider matters relating to risk.[93]

The statutory guidance and framework provide that risk assessment is a scientific process that does not take into account political or non-scientific aspects of an application to deal with a GMO into account. However, notwithstanding this objective and scientifically based assessment process, it is still difficult to determine, with any certainty, that an activity poses "no risk" or "an insignificant risk."[94] As Lawson notes, the term "risk" conveys inherent uncertainty about the proposed dealing. Therefore, the exercise of quantifying risk is contingent upon decisions relating to the probability of an adverse

[91] Explanatory Memorandum to the Gene Technology Bill 2000 p.63.
[92] Risk Analysis Framework for Licence Applications before the Office of the Gene Technology Regulator (January 2002) p. 11.
[93] Risk Analysis Framework for Licence Applications before the Office of the Gene Technology Regulator (January 2002) p. 20-26.

event occurring, the magnitude of the adverse effect if it occurred and the weight of public perception that a particular adverse effect will be unacceptable.[95] This is particularly true when the subject matter under consideration involves novel or new technology. Furthermore, a low risk does not have the same meaning or potential outcome, in terms of impact upon health, safety or the environment, as a zero risk. The Framework expressly states that it is general in its application and does not attempt to classify risk.[96] Accordingly, that final determination of the level of risk is extremely subjective.

It is noted that the matters identified in section 51(1)(a) to (g) of the *GTA 2000* do not require consideration of economic or financial issues associated with the introduction of GM crops. However, for many, particularly farmers who are seeking to maintain GM free status for their crops, the potential exposure to economic risk as a result of releasing a GMO into the environment may be significant. This notwithstanding, as Tranter notes, the context in which decisions are made under the Act must be borne in mind when the likely outcomes of applications are considered. For example, when dealing with the commercial release of a GM crop, the key issue for non-GM farmers (and also the broader community) is what will happen if the GMO escapes the area in which it supposed to be contained. From a farmer's perspective, the need for segregation, to ensure that non-GM crops can achieve certification, and issues of contamination are very real risks.[97]

As noted in Part 1 above, a number of commentators have argued that the term "environment" should either be redefined by reference to the *EPBC Act*, or that a broad interpretation to the term should be adopted to enable the Regulator to consider the risks posed by contamination to adjoining agricultural crops. However, the Regulator has declined to adopt such an interpretation.[98]

During the Senate review of the Bill, the CARC considered the relationship between the risk assessment framework and the process for environmental impact assessment (EIA) under the *EPBC Act 1999*. The CARC Report referred to submissions by ACEL, ACF,

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[94] Lawson , *op cit* p.202.
[95] Lawson *op cit* p.201.
[96] Risk Analysis Framework for Licence Applications before the Office of the Gene Technology Regulator (January 2002) p. 1.
[97] Tranter *op cit* p.252-3.
[98] See for example, Statement of Reasons – Monsanto Licence Application 020/2002 for roundup ready canola 2003.

HSI and WWF that argued that without an appropriate EIA process, the Bill would not achieve its objective of protecting the environment and that important environmental matters could be overlooked.[99] In addition to a call for a stronger link between the Bill and the *EPBC Act 1999*, some groups called for a greater role for the Minister for the Environment, including the ability to veto a dealing that posed a significant risk to the environment. These matters were not adopted by Parliament, leaving the Minister for the Environment with only a consultative role.

The ANEDO submits that the role for the Minister for the Environment be strengthened (including a right of veto) and that the *GTA 2000* be made more consistent with EIA under the *EPBC Act 1999*.

Management Plans

Once risk is assessed, the next stage is to identify the options and strategies for managing the risk through a risk management plan. This step, of itself, indicates that the *GTA 2000* scheme does not seek to avoid all risk, but rather to identify risks and manage them. As Lawson notes, a certain amount of risk will be acceptable.[100] However, this leads to tensions between the scientific decision as to what the level of risk is and a more political decision as to whether that risk is "acceptable" on the basis that it can be managed.

Section 51(2) of the *GTA 2000* identifies the matters that a risk management plan must take into account, and section 50 sets out consultation requirements.[101]

From a review of the Quarterly Reports prepared by the Regulator and the Communiqués issued by the GTTAC, it would appear that it is actively providing advice to the Regulator about licence applications, in particular ways to facilitate the approval of licences subject to conditions which would mitigate risks. Whilst the Regulator is not required to consider the advice of the GTCCC, the Committee is nevertheless reviewing contentious applications and providing feedback to the Regulator. For example, in relation to the applications for the commercial release of GM canola, the Committee resolved to advise the Regulator that

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[99] CARC Report p.99.
[100] Lawson *op cit* p.202.
[101] Section 52 of the *GTA 2000* also requires the Regulator to notify the public of the preparation of a risk assessment and risk management plan and invite submissions on the content of those documents.

> "the GTCCC expresses concern that a state of community unreadiness exists concerning the risk to the environment of the commercial release of GM canola, so significant that the applications should be declined at this time".[102]

In practice, the risk assessment and risk management plan process operate in tandem. As such, the Regulator (or her delegate) will prepare the risk assessment and risk management plan concurrently and then once comments are received from other Government agencies and the public, a decision about the grant or refusal of a licence will be made. The fact that the Regulator oversees all three steps in the assessment processis cause for concern. In particular, it may be difficult for the Regulator to make an objective or independent decision in relation to risk, if she has drawn up the management plan which is proposed to facilitate the carrying out of the activity. Arguably this function compromises the independence of the Regulator.

A further concern is that the risk management process is established to manage acceptable risks, but what is acceptable tends to be measured by standards within the Biotechnology industry (non-GM farmers and environmentalists taking a preferred no risk stance). Lawson expresses the view that, in light of the Government's express policy to develop a biotechnology industry, there is likely to be significant political and commercial pressure on the Regulator to release GMOs into the environment unless there is overwhelming evidence of likely harm. The difficulty here is that the research on the impacts of the release of these "new" organisms is very limited, and impacts which may arise over generations of the organisms are not well understood.

Case study: Bollgard II and Bollgard II Roundup Ready cotton

Lawson has carried out a thorough review of the Regulators assessment approach to the applications for the intentional release of Bollgard II and BollgardII/Roundup Ready cotton and in many regards found the assessment lacking. In that instance, the Regulator determined that there were not likely to be additional risks to public health and safety or the environment arising from the genetic modification of Bollgard II and Bolgard II/Roundup Ready cotton varieties because *inter alia* the varieties were not likely to prove any more toxic or allergenic than conventional varieties of cotton; their risk of developing as a weed was low and not likely to be greater than conventional cotton; the likely transfer on introduced genes to other organisms was low and unlikely to pose a risk to human health or the environment; and the risk of development of target insect resistance to key proteins was low.[103] However, as Lawson notes, the concept of "low risk" is laden with value judgements about what level of risk is acceptable. Adopting such

[102] Gene Technology Community Consultative Committee Meeting 20 February 2003 – Communiqué p.4
[103] Lawson *op cit* p.206.

an approach is, in Lawson's opinion, contrary to the notion that the Regulator' decision should be objective and scientifically based.[104] Lawson is also critical of the paucity of scientific evidence upon which the Regulator based her decision, in particular where no or insufficient evidence was before her. This is particularly relevant in relation to environmental impacts beyond weediness and transfer of genetic material to non-target species, for example, considering the long term ecological consequences of releasing a GMO into the environment. In his opinion, there should be consideration of broader issues relating to community studies, succession studies, ecosystem analysis, population dynamics or organism-environment relationships.[105]

The following recommendations have been made in relation to improving the risk assessment process:[106]

- requiring rigorous environmental impact statements (similar to requirements under the *EPBC Act 1999*) before and after the release of GMOs into the environment to properly assess those individuals and groups in society that are likely to suffer the adverse effects of consequent damage;
- considering suitable insurance against loss or damage to the broader society, including individuals and third persons as a result of releasing GMOs into the environment;
- considering ESD as part of the decision making process for release of GMOs into the environment – and balancing environmental and economic factors in relation to the adoption of gene technology;
- carrying out rigorous cost-benefit analysis that addresses, in economic terms, short term advantages versus "low risk" of long term loss and damage; and
- increasing the funding for research directed to improved risk assessment – especially towards research that considers the long term ecological and intergenerational impacts to improve understanding about unforeseen consequences.[107]

These conclusions are broadly supported by the ANEDO, along with a requirement that a final RARMP must be prepared by the OGTR after the draft risk assessment, in which submissions are directly responded to (as is required for EISs).

(b) Dealings not involving the intentional release of the GMO into the environment

[104] Lawson *op cit* p.207.
[105] Lawson *op cit* p.200.
[106] Lawson *op cit* p214.
[107] Lawson *op cit* p.214

Dealings that do not involve the intentional release of a GMO into the environment are typically those dealings being carried out in laboratories and similar venues. As Tranter notes, the vast majority of the 170 or so licences that have been issued relate to human, animal or plant research.[108] Notwithstanding their containment, they still may pose a significant risk to human health and safety and the environment, should they inadvertently be released.

The risk assessment and risk management plan process for these dealings is similar to that outlined above for intentional releases of GMOs, however there are three significant differences. First, section 47 of the *GTA 2000* does not require public input into the risk assessment and risk management plan process. Second, the Regulator may, but is not required to, consult with the States, the Advisory Committee, other agencies or other persons the Regulator considers appropriate. Third, if consultation does occur, it is only in relation to the risk assessment and risk management strategy and not in relation to the issue of the significance of risk.

In relation to the absence of public participation, the ANEDO recommends that public confidence in facilities where genetic research are occurring would be enhanced if the public had the opportunity to provide input into the risk management framework, particularly those residents who live in close proximity to the facility.

Case study: Hunter Grain Pty Ltd licences

Tranter uses the two licenses issued to Hunter Grain Pty Ltd for the importation of corn and soybeans from the United States which were likely to contain GMOs as an intriguing example of how the provisions of the *GTA 2000* for dealings not involving the intentional release of a GMO into the environment can be abused. The potential GM grains were unloaded from a bulk carrier, the Ocean Emperor, in Brisbane, Newcastle and Melbourne and were then contained, subject to treatment to eradicate the risk to the GMO persisting in the environment, in bulk handling facilities at the respective ports. The *GTA 2000* is silent in relation to the types of facilities that can be certified for containment,[109] however, it is clear from the explanatory memorandum to the *GTA 2000* that it was anticipated that this category of dealing would take place in research laboratories, and not quasi commercial facilities.[110] Tranter notes additional problems that arose with this dealing in relation to: the operational arrangements between the Regulator and AQIS in managing the shipment; the actual containment of the grain whilst being unloaded; and the delay by the Regulator in making information about the licence and its conditions publicly available within a reasonable timeframe.

[108] See Tranter *op cit* at 249.
[109] Schedule *Gene Technology Regulation 2001* – item 1.1.4.
[110] Tranter *op cit* p 249.

This case study indicates a need for a much broader scope of the Regulator's authority, particularly in relation to the handling and storage arrangements for GMOs.

Licences

As noted above, the Regulator may grant a licence for dealings with a GMO.[111] The *GTA 2000* identifies relevant factors that the Regulator must consider when deciding whether it is appropriate to issue a licence[112] and the circumstances in which the Regulator is required to refuse to issue a licence. Expressly, the Regulator must not issue the licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in such a way as to protect: the health and safety of people; and the environment.

Additionally, the Regulator must not issue the licence if the Regulator is satisfied that issuing the licence would be inconsistent with a policy principle in force or unless the Regulator is satisfied that the applicant is a suitable person to hold the licence.[113]

As noted above, only one policy principle has been issued to date, relating to the imposition of moratoriums. Stakeholders have queried whether a decision by the Regulator to issue a licence for commercial release of a GM crop in circumstances where States have expressed a clear view that they do not want those plantings to occur is inconsistent with the Policy Principle. The Regulator's view is that an applicant would still be required to obtain an exemption from the relevant moratorium before planting could occur, therefore granting licence is not inconsistent with the principle.[114] Whilst this may be the strict legal position, an approval by the Regulator at a Commonwealth level is no doubt very persuasive in pressuring State governments to issue exemptions, as it is difficult to rely on issues of risk in refusing them.

In relation to the requirement that a licence holder be a "fit and proper person", two points arise. First, to date, the Regulator has not brought any prosecutions against

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111 *Gene Technology Act 2000 s 55, 56 and 57*. Once granted, a licence is valid for the period specified in the licence, or otherwise, until cancelled or suspended by the Regulator (s59).

112 *Gene Technology Act 2000 s 56(2)*- (a) if a risk assessment has been prepared under section 50 in relation to those dealings—the risk assessment; (b) if a risk management plan has been prepared under section 50 in relation to those dealings—the risk management plan; (c) any submissions received under section 52 in relation to the licence; (d) any policy guidelines in force under section 23 that relate to: (i) risks that may be posed by the dealings proposed to be authorised by the licence; or (ii) ways of managing such risks so as to protect the health and safety of people or to protect the environment.

113 *Gene Technology Act s 21*.

114 Statement of Reasons for Licence 020/2002.

persons for breaches of the *GTA 2000*. Usually when considering a person's competency to hold a licence the reference point will be their performance in the field in which the licence operates. In the absence of prosecutions relating to breaches of gene technology and related legislation, it would *infer* that all participants in the industry are "fit and proper". The *GTA 2000* does in fact go further than an industry test of competency. Section 58(1)(b) of the Act extends the reference criteria to revocations or suspensions of licences held under any Commonwealth, State or foreign laws relating to the health and safety of people and the environment. Such a test is extremely broad and it is open for concerned persons to argue that certain companies are not fit and proper based upon their records in other areas of regulation and even other countries. For example, Monsanto has recently been found guilty of paying bribes to officials in order to get approvals for GM products in Indonesia.[115] Such a conviction will be relevant when considering future applications made by that company in Australia.

Licence conditions

All licences issued to date contain both general and specific conditions. The general conditions relate to matters such as the duration of the licence, the details of the licence holder, the identity of the project supervisor, and a description of the dealing authorised by the licence. Specific conditions will depend upon the type of GMO, the venue in which the dealing is taking place and the risks associated with that dealing.

Examples of specific conditions that have been imposed include requiring bee-proof cases being placed over the location in which GM white clover was being grown[116] and requiring licence holder to carry out research on gene flow and environmental impacts including those impacts relating to feeding GM cotton seed to stock and the effectiveness of the isolation zone in preventing gene flow from the GMOs to conventional cotton and native Gossypium species detected in the [50m] isolation zone.[117]

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[115] www.abc.net.au/news/ 2005.
[116] Licence DIR 047/2003 issued to DPI (Vic) for field evaluation of GM white clover resistant to infection by alfalfa mosaic virus.
[117] Licence DIR 012/2002 as varied 24 December 2004 to Monsanto Australia Ltd for commercial release f Roundup ready cotton.

Lin Jin Tsui has submitted that it would be more effective for conditions that gave effect to measures set out in a management plan to be imposed on a licence. Additionally, conditions that required a regular review of the licence (similar to that provided for in the *Protection of the Environment Operations Act 1997* (NSW)); continual monitoring and evaluation of risk, annual reporting requirement and the provision of financial bonds or assurances that could be called upon should a dealing cause harm to human health or the environment.[118] Conditions such as these would assist in better protecting biodiversity values, but would also allow greater scrutiny of a licence holder's performance against its conditions, particularly if the reports submitted were made publicly available. Lawson has also argued for conditions that require the licence holder to submit information (during and after the dealing has occurred) about matters such as harm to other organisms, adverse effects on ecosystems; limits of dissemination or persistence of the GMO; selection advantage of the GMO compare to related organisms and other organisms in any ecosystem; interactions between the GMO and the environment that may not have been available at the time of the application; human errors resulting from the release of the GMO (transport, site containment etc); elements of the concept of ESD; and how effective the use of modelling data has been.[119] The ANEDO is supportive of these measures.

Arguably, some of the more recent conditions imposed upon licence provide a more stringent framework for compliance. However, there remain serious questions about the extent to which conditions are being met. We note that the Regulator has not suspended any licences as a result of breaches to date that we are aware of. Breaches of conditions are discussed in Part 3.3.

[118] Tsui *op cit* p.107
[119] Lawson *op cit* p. 212

Part 5 - Interface with other systems

5.1 A nationally consistent scheme

Section 5 makes it clear that the *GTA 2000* is only a component of a nationally consistent scheme for the regulation of only certain GMO dealings.[120] This was adopted by the Commonwealth, the States and Territories in the Gene Technology Agreement 2001 ("Agreement").

The Commonwealth lacks express Constitutional power to deal with GMOs specifically or the environment more generally. Accordingly, it must rely upon the Constitutional power provided by section 51(xx) to regulate corporations and other entities engaged in interstate or overseas trade and commerce.[121] In order for the Commonwealth to cover the field in relation to the regulation of GMOs (for example, where individuals are involved) it was necessary for the States and Territories to agree to implement corresponding State laws that provided for the carrying out of functions and the exercise of powers by the agencies established by the *GTA 2000*.[122] This has now been done by all States and Territories.[123] However, there remain significant tensions between the Commonwealth and States in relation to the commercial releases of GMOs into the environment and the role that States play in relation to economic issues relating to the marketing of GMOs.

Policy Principles developed by the Ministerial Council (discussed below) allow States to designate areas for preserving the identity of non-GM crops or GM crops for marketing purposes.[124] Almost all States have enacted legislation that imposes moratoriums, of varying duration, on the cultivation of GM crops within their territory.[125] However, exemptions may be granted on a case by case basis in some instances. As a result of moratoriums being declared, there have only been a limited number of trials involving

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120 Part 2 Division 4 of the GTA 2000 is devoted to "Provisions to facilitate a nationally consistent scheme" including a policy role for the Ministerial Council.

121 For a general discussion on the Constitutional power to enact GMO legislation – see McIntosh, L "The Regulatory Framework –*Gene Technology Act 2000* (C'th) and the Gene Technology Bill 2001 (WA)" paper presented at CCWA conference 10 October 2002.

122 *Gene Technology Act 2000 s 16.*

123 *Gene Technology Act 2001* (Vic); *Gene Technology Act 2001* (SA) *Gene Technology Act 2001* (NSW) etc.

124 *Gene Technology Act s.21(1)(aa).*

the commercial release of a GMO into the environment, notwithstanding that the Regulator may have approved those dealings.

The ability for States to preserve the right to restrict dealings with GMOs was an important concession when negotiations were being held in relation to the terms of the Bill. However, as debates around the State Moratorium Acts have shown, the power of States to prevent dealings with GMOs in their territories is extremely narrow. For example, NSW can only allow restrictions on cultivation of GM food crops (although recent amendments now allow for the State to impose additional conditions on handling, for example, storage and transport of the food crop).

A question that arises in relation to the relationship between the Commonwealth and the States and Territories is therefore how appropriate is a cooperative national legislative scheme for the regulation of GMOs now and into the future when the moratoriums expire? Clearly, for industry, a nationally consistent framework provides certainty when making investment decisions. However, the commercial release of GMOs is primarily operating in relation to agricultural crops. Each State and Territory is responsible for its own laws relating to land use and planning, environmental protection and the regulation of agriculture. These laws may, in certain circumstances, purport to limit the ability of companies to activate a Commonwealth approval. If they are inconsistent with the Commonwealth law, there is a presumption that, once the moratoria are no longer in place, the *GTA 2000* will override the State laws restricting commercial releases.[126]

The ANEDO recommends that a procedure be established for when moratoria expire.

5.2 Interface with other agencies

The Act does not regulate matters that are concerned with products containing GMOs (as opposed to the organisms themselves) that are already covered by other agencies. These agencies include:

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[125] *Plant Quarantine Act 1997* (Tas); *Gene Technology (Temporary Prohibition) Act 2002* (SA); Gene Technology (GM Crop Moratorium) Act 2003 (NSW); OTHERS.. - these moratoriums range between 3 – 5 years.
[126] Commonwealth Constitution s 109.

- Food and Safety Australia & New Zealand ("FSANZ") – which deals with food safety and labelling issues;
- the Therapeutic Goods Administration ("TGA") - which deals with medicines and drugs;
- the Australian Quarantine and Inspection Service ("AQIS") – which deals with customs and imports; and
- the National Registration Authority for Agricultural and Veterinary Chemicals ("AGVET") – which deals with other chemicals.

Each of these matters is governed by specific legislation and individual agency regulators.[127]

Under the *GTA 2000* scheme, a framework for cooperation and consultation amongst the relevant regulatory agencies has been established. Existing regulatory agencies are required to request advice from the Regulator and to (merely) consider that advice when making decisions about GMOs or products containing GMOs.

It is important to note that the statutory enactments that establish FSANZ, AGVET and the TGA do not operate as environmental legislation. The Acts do not contain objectives which refer to environmental protection or the principles of ecologically sustainable development (ESD). As such, there is arguably a lack of synergy between the *GTA 2000*, which has at least a pseudo environmental focus, and the other Acts, which are focused upon health and safety concerns.

As well as requiring the Regulator to comment upon decisions made by other agencies, those agencies are also required to consult with the Regulator when she is considering applications for licenses to deal with GMOs. The efficacy of this process is discussed in Part 4 relating to risk assignment. However, at this point it is worth reiterating the fact that the matters that the other agencies consider when determining risk do not necessarily align with those matters which would ordinarily be considered a significant risk to the environment and biodiversity.

Commentators, such as Bennett and Williams, have described the regulation of gene technology in Australia as "a patchwork of laws and regulatory agencies"[128] and the *GTA 2000* as a "gap filler".[129] This issue was raised as a concern prior to the passage of the *GTA 2000*. The Democrats, and others, expressed a preference for

> "a one stop shop for gene technology regulation – not a replication of a mega regulatory body …. But a body which does not cause unnecessary complications and increasingly theoretical delineations between GM products with the development of this technology."[130]

The current situation has been described by some as a bureaucratic, complex and confusing regime, which allows for regulatory gaps, duplication and loop-holes, and which encourages non-compliance.[131] However, as the Explanatory Memorandum accompanying the Bill identified, the rationale behind this approach was that it would "minimise the regulatory burden on industry by adopting a sliding scale or regulatory oversight based on risk".[132] The inadequacies of the current risk assessment process are discussed in Part 4.

5.3 The Ministerial Council

It was hoped that issues of coordination and consistency would be addressed by the Gene Technology Ministerial Council ("Council"), as established pursuant to the Gene Technology Agreement. The role of the Council is to provide broad oversight and coordination of the regulatory framework and guidance on matters of policy that underpin the legislation. The Council's responsibilities include issuing policy principles,[133] policy guidelines[134] and codes of practice[135] to govern the activities of the Regulator and the operation of the scheme; and appointment, oversight, and review functions. The

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127 see *The Agricultural and Veterinary Chemicals (Administration) Act 1992* and *Agricultural and Veterinary Chemicals (Code) Act 1994*; the *Australia New Zealand Food Authority Act 1991*; *the Industrial Chemicals (Notification and Assessment) Act 1989*; the *Therapeutic Goods Act 1989*.
128 B Bennett & G Williams "Gene Technology Regulation: An Overview of the Act and the Penalties for non-compliance" (2001) 12(5) Australian Product Liability Reporter 69, at 70.
129 B Bennett & G Williams "Gene Technology Regulation: the Australian Approach" (2001) 1(2) Biotechnology Law and Policy Reporter 29.
130 Hansard 7 November 2000 p.19293 (per Senator Stott Despoja).
131 see A Lin Jin Tsui "Australian Regulation of Gene Technology: Impacts on Biodiversity" (2004) 1 Macquarie Journal of International and Comparative Environmental Law 95 at 98 & associated footnote references 35-41.
132 Explanatory Memorandum to the Gene Technology Bill p.25.
133 *Gene Technology Act 2000 s 21.*
134 *Gene Technology Act 2000 s 23.*
135 *Gene Technology Act 2000 s 24.*

Agreement provides for the meeting arrangements (such as representatives, quorum and procedure) for the Council.[136]

The Council comprises the Commonwealth Minister for Health and Aged Care and a Minister representing each State and Territory. At present, the State Ministers are drawn from the portfolios of Health, Agriculture and Primary Industries. None of the Environment Ministers are represented on the Council.[137] Consequently, the current composition of the Council does not provide the broad ranging disciplines advocated by some commentators.

The Council meets on an ad hoc basis, although it was intended that such meetings would occur at least once a year. The Council met in May 2002 and July 2003, and 2005.[138] In circumstances where the Council meets so infrequently, it is difficult to see how it can operate effectively. As the comments below show, many of the functions of the Council have not been exercised. It is acknowledged that these functions are discretionary, for example developing codes of practice, yet the intent of the Act was clearly that such supporting policy documents would play a role in gene technology regulation.

Policy Principles

Policy principles may be issued in relation to ethical issues, recognising areas (if any) designated under State law for the purpose of preserving the identity of GM crops or non-GM crops for marketing purposes, and other matters prescribed by regulation (which may relate to matters other than human health and safety or the environment).[139]

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136 Gene Technology Agreement Clauses 17-25.

137 During the Senate CARC inquiry, submissions were received from a number of stakeholders arguing for particular representation on the Council. However, due to the fact that gene technology impacts upon a wide range of portfolios, the Committee took the view that it was important that Ministers were aware of the broader issues relevant to gene technology and that they approach their role on the Council as a multi-faceted one.

138 The 2004 meeting was postponed until March 2005 as a result of the federal election in late 2004.

139 Gene Technology Agreement Clause 6(d)(I); *Gene Technology Act 2000 s 2.1* The process for issuing policy principles involves the Ministerial Council consulting with relevant Commonwealth, State, industry and community organisations, including the advisory committees (s 22). After this consultation, the Council may adopt the principle (however, it is important to note that policy principles are disallowable instruments, and therefore, may be reviewed by Parliament). Once a principle has been adopted, it

The only policy principle currently in force under section 21 of the *GTA 2000* is the *Gene Technology (Recognition of Designated Areas) Principle 2003*. The Policy Principle states that:

> "an area is recognized as a area that is designated for the purposes of preserving the identity of GM crops, non-GM crops, or both GM and non-GM crops , for marketing purposes, if the area is so designated by a State law."

The explanatory Statement to the policy principle states

> "The issuing of the Principle is not intended to derogate from the right of the States and Territories to legislate to designate GM or non-GM areas. Nor is the Principle intended to either endorse or oppose the principle or designating GM or non-GM areas."[140]

States are not required to issue moratoria; however, they have been issued in most States and Territories to date.

Policy Guidelines

Policy Guidelines are advisory and can relate to any matter relevant to the functions of the Regulator. They are not intended to operate as a prohibition or direction. Furthermore, guidelines are not subject to Parliamentary scrutiny in the same way that principles are. The Regulator must simply have regard to the guidelines when deciding whether or not to issue a licence, it is not required to follow those guidelines. In practice, the Regulator will generally act consistently with the guidelines.

In contrast to policy principles, the process that the Council is required to follow when deciding whether to issue guidelines is less prescriptive. The Council is not required to consult with any of the advisory committees or other interested parties but it may do so.[141]

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becomes a relevant matter for consideration by the Regulator when determining whether or not to issue licences under the *GTA 2000 (s57)*.

[140] Gene Technology (Regulation of Designated Areas) Principle 2003 s 5.

[141] The Senate CARC recommended that there be a mandatory requirement for the Council to consult with, at a minimum, the advisory committees before issuing policy guidelines. This would allow for persons with technical expertise to consider the content and efficacy of the guideline. However, this was not viewed as necessary by Parliament.

In practice, the Council has not yet issued any policy guidelines. This may be due to the infrequency at which issues are considered by the Council or because the Council do not consider any matters relating to gene technology regulation to require policy direction.[142]

Due to the comparative lack of regulatory force, we submit that important issues are best dealt with under the consultative policy principle process.

Codes of Practice

The codes of practice contemplated by the *GTA 2000* and the Agreement are those that may be applied by the Regulator as conditions of a licence. The Regulator proposes the appropriate Code, and the Council who issues the Code, which is consulted upon and subject to parliamentary scrutiny.

As with policy guidelines, the Council has not issued any codes of practice under the *GTA 2000*, nor are we aware of any of the committees developing them.

The infrequent meetings, lack of representation from Environment portfolios, and the underutilisation of the guideline and code mechanisms limit the value of the Ministerial Council's role to date. The role needs to be strengthened and more proactive if it is to effectively oversee the regulatory framework and achieve a nationally consistent scheme. For example, the Ministerial Council should be more proactive in issuing policy principles. Also, when the Bill was considered by the CARC, there were a number of submissions calling for the Council to have a power to veto the Regulator's decision on certain licensing issues.

A nationally consistent scheme will not be achieved whilst assessment processes are unclear and inconsistent. As noted, assessments undertaken by FSANZ on food standards or by AGVET regarding pesticides, are done according to different criteria, standards and processes. Not only are there discrepancies between agency assessments, but there is also a danger of assessments falling through the regulatory gaps due to 'buck

[142] We note that the OTGR has issued a number of guidelines including: Guideline for Risk Assessment and Risk Management Framework (January 2002); Guideline for Storage of GMOs (2003-2004); Guideline for Accreditation of Organisations (June 2001); Guidelines for Certification of Facilities / Physical

passing' between agencies and port folios (for example, Health and Agriculture), as has been observed at both state and federal levels.

Unless the assessment of GMOs is coordinated by one body, and the level of comprehensive environmental impact assessment is improved and guaranteed for all relevant dealings and entities, the regulatory framework will not deliver optimal environmental and health outcomes.

The ANEDO requests further opportunity to discuss alternate regulatory models, including centralised coordination of assessment, improved environmental assessment, and an appropriate concurrence role for the states.

Containment Requirements (June 2001); Guideline for Good Industrial Large Scale Practice; and the Guideline for Transportation of GMOs (June 2001).

Part 6 – Changing Circumstances

6.1 Flexibility and emerging technologies

A key issue is whether the current *GTA 2000* regime is flexible enough to appropriately deal with new and emerging technologies. Examples of potential technologies include nanotech and pharmocrop developments. As noted, in light of the Government's express policy to develop a biotechnology industry, there is likely to be significant political and commercial pressure on the Regulator to release GMOs into the environment unless there is overwhelming evidence of likely harm. The difficulty here is that the research on the impacts of the release of these "new" organisms is very limited, and impacts which may arise over generations of the organisms are not well understood.

It is essential that a precautionary approach is taken with regard to emerging technology. As noted, current risk assessment processes fail to fully consider broader environmental impacts, and until this deficiency is addressed, the *GTA 2000* scheme is not fully equipped to deal with emerging technologies.

The ANEDO recommends that there be a specific role for the GTTAC, GTCCC and GTEC to examine emerging technologies, and broad mandatory public consultation before any approvals are granted.

Part 7 – Changes to the legislation

7.1 Recommendations

Part 1: Scope of the Act

Object and definitions

- The definition of "environment" needs to be amended to bring it in line with the definition under the *EPBC Act 1999*, and to ensure the Regulator must also consider agricultural areas where non-GM crops are grown. There need to be specific requirements for assessment stemming from the definition in terms of criteria and benchmarks, and assessment at local and regional scales.
- The term "genetically modified organism" (GMO) should be expanded to encompass "any biological entity capable of replication or transfer of genetic information ... in which the genetic material has been altered in a way that does not occur naturally."
- The definition of "deal with" should be extended to include exports of GMOs, the deliberate dealing with products derived from GMOs and the marketing of GM products. (We note that these changes could only be given effect to if the *GTA 2000* regime involved a more coordinated and comprehensive assessment process).

Part 2: Is the regulatory Framework appropriate to achieve the object?

Precautionary principle and ESD

- The *GTA 2000* should be amended to include a specific object to require decision making and policy formulation under the Act to be in accordance with the principles of ESD.
- Remove the words "cost effective" from the precautionary principle definition, consistent with other Australian environmental legislation.
- The Regulator must be required to consider more broad and long term environmental impacts, as failure to weigh certain factors offends the precautionary principle.

Part 3: Operation of the *GTA 2000*

OTGR

- The OGTR must prepare annual reports as required by section 136, and these must report on the social, economic and environmental aspects of operation and function of the Regulator ("triple bottom line" reporting).
- The expertise of the Regulator should be expanded - 3 person office (as per CARC recommendation).
- The conflict clause in s120 should be broadened to preclude any person with an interest in a regulated entity from holding office.

Advisory Committees

- The matters that the GTTAC can advise on should be expanded to cover all aspects of dealings that may pose a significant risk to human health or the environment, and all licence applications.
- Appoint a member of the GTTAC with ecological expertise, and epidemiology (public health) expertise.
- The GTEC should work with the Ministerial council to develop an Ethics Policy Principle.

Public consultation

- Amend the *GTA 2000* to provide standing to third parties ("any person") to remedy or restrain a breach of the Act.
- Expand the scope for public submissions beyond only those for intentional releases where the Regulator deems a significant risk to health safety or environment exists. Exempt dealings, notifiable low risk dealings and register entries should also be subject to public submissions.
- Consultation should go beyond the initial stages, for example, should be revisited where a party wishes to amend or vary a licence.
- It should be mandatory for the Ministerial Council to consult with the peak environment and community groups regarding policy principles, risk assessment and management planning. Currently the Council need only consult with stakeholders that they "deem appropriate."
- The *GTA 2000* should be amended to provide that information may only be declared commercial in confidence where the applicant for declaration can demonstrate that the declaration would not create a significant risk to human safety, environment or biodiversity.
- A final RARMP must be prepared by the OGTR after the draft risk assessment, in which submissions are directly responded to (as is required for EISs).

Compliance and enforcement

- Increase monitoring to 50% sites per annum due to the serious implications that breaches may have.
- Increase public access to information (for example regarding trial sites) so that breaches may be reported to the Regulator more rapidly, and published.
- Make use of the offence provisions (sections 33 and 34) to provide a stronger deterrent against non-compliance.
- Extend standing so that "any person" can bring an injunction.
- Develop a framework to provide more effectively for compensation for loss or damage as a result of unforseen consequences relating to licensed dealings. This should be developed in conjunction with strict liability provisions relating to both harm and environmental contamination.
- Reporting of breaches should be posted on the website immediately, rather than only in Quarterly Reports.

Part 4: Regulatory Burden versus Risk

Dealings and risk assessment

- Where a dealing poses a significant risk to the environment there should be wide ranging public consultation, even if release into the environment is not intended.

- The OGTR must seek further advice as to whether the criteria to categorise exempt, NLRD and registered dealings remain comprehensive and appropriate in order to better implement the precautionary principle.
- Section 49(2) should be expanded to include impact on non-GMO species and long-term environmental impacts.
- As noted the definition of "environment" needs to be amended to ensure that the Regulator properly considers risks posed by contamination to neighbouring non-GE agricultural crops (section 51(1)(a)). This should include the environment outside cropping areas.
- There needs to be a greater role for the Minister for the Environment, including a right of veto where dealings pose a significant risk of harm.
- There needs to be greater alignment with environmental impact assessment requirements under the *EPBC Act 1999*, with EIA undertaken before and after release.
- The lack of objectivity in the risk assessment process (ie, the Regulator assesses the risk on the plan she has developed) must be addressed.
- Principles of ESD must be integrated into the decision-making process of assessing proposed dealings, including assessment of long term impacts.
- There should be opportunity for public comment (especially in the local area) into risk management plans of genetic research facilities.

Licensing and Conditions

- Conditions giving effect to measures or findings set out in a management plan must be imposed on the licence. (These can be economic to the extent that they respond to or prevent environmental or health impacts).
- There should be a requirement for regular licence reviews (similar to those provided for under the NSW *Protection of the Environment Operations Act 1997*).
- Annual reporting requirements for licences should be triple bottom line reports which are made publicly available.
- The Regulator is not to approve a licence for commercial release where states have a moratorium in place (in accordance with the Policy Principle).
- Any approval for an exemption from a state/territory moratorium should occur before the Regulator considers a licence application.
- Assessment of the suitability of entities to hold a licence should be more rigorous– and not based solely on criminal convictions - including consideration of performance of parent companies (ie, taking into account any overseas breaches).

Part 5: Interface with other systems

A Nationally Consistent Scheme

- Adopt a nationally comprehensive and coordinated regime ensuring more consistent and rigorous environmental impact assessment for a wider range of dealings, and broader considerations for risk assessment.
- Notwithstanding a federally consistent and coordinated approach, it is necessary to confirm an appropriate concurrence model for the States, for example, so that moratoria cannot be undermined by licence approval.
- A procedure must be coordinated and set in place for when moratoria expire.

The Ministerial Council

- Meetings should be twice yearly, and the drafting of guidelines and codes should be a matter of priority.
- Environment Ministers should be represented on the Council.
- The Ministerial Council should produce a Policy Principle on ethics (with input from the GTEC), as a matter of priority.
- The Ministerial Council should have a right of veto over the Regulator's decisions on certain licensing issues.

Part 6 – Changing circumstances

- There needs to be increased funding for best practice risk assessment research, especially as the technology continues to be developed into new areas.
- There must be wide public consultation on emerging technologies, and more rigorous risk assessment and environmental impact assessment (including consideration of long term environmental impacts), in accordance with the precautionary principle.