GENE TECHNOLOGY ETHICS AND COMMUNITY CONSULTATIVE COMMITTEE (GTECCC) DISCUSSION PAPER: ENVIRONMENTAL ETHICS AS IT RELATES TO GENE TECHNOLOGY IN AUSTRALIA

Summary

This paper arises out of discussions by the Gene Technology Ethics and Community Consultative Committee, which provides advice on ethical issues and on matters of general concern to the community to the Gene Technology Regulator in relation to genetically modified organisms, and its predecessor, the Gene Technology Ethics Committee.

In reflecting on what people think about gene technology, the question arose as to what people think about the potential harms (or benefits) of gene technology for the environment, and what our duties are toward the environment. We then broke this issue down into two interrelated questions: (1) what ethical values do members of the public hold with regard to the environment, and (2) what does the *Gene Technology Act 2000* (the main set of laws which governs gene technology in Australia) say with regard to these values?

The first question has proven extremely difficult to answer, given the current state of information about what values people actually hold. We do know from philosophical literature on the subject of environmental ethics that there is a range of possible views and positions which therefore are reviewed in this paper. From this, it is clear that there is widespread disagreement about how much protection to give to the environment and at what cost to other values which we view as important.

This paper also outlines the relatively limited treatment of environmental ethics and values within the *Gene Technology Act 2000* , including how environmental protection should be defined, or even how we should define the environment itself. Hence it is clear that the *Gene Technology Act 2000*, as with much of environmental law, is not based on a clear, coherent set of ethical values. This paper has revealed that there should be ongoing investigation of community values in this area, and feedback of this information in the future as the *Gene Technology Act 2000* is implemented and revised.

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- The members of the environmental ethics working group-Ms Judy Jones *ex officio member,* Associate Professor Rachel Ankeny and Associate Professor Vaughan Monamy. and
- Chair of GTECCC-Professor Don Chalmers.

Background to paper

At the 10th meeting of the Gene Technology Ethics Committee (GTEC: 15 November 2005) a working party was formed to examine various ethical approaches to gene technology with an emphasis on how environmental ethics is distinct from medical ethics. GTEC deemed this issue to be a high priority as the Gene Technology Act (2000) *looks at the protection of the environment but, at that time, GTEC had not considered exactly what that statement meant (Minutes of 10th meeting).*

Two secondary questions were posed:

(1) What can ecocentric ethics bring to gene technology? and

(2) What status do environmental goods have in ethics?

A discussion paper was prepared by Vaughan Monamy that addressed both these questions so that GTEC could use it as a basis for determining how environmental ethics differed from medical ethics.

Following discussion in early March 2006, GTEC asked the Working Party (originally Assoc. Prof. Monamy and Assoc. Prof. Rachel Ankeny but with the addition of Ms Judith Jones) to further examine issues on two levels:

- *GTEC's duty as defined by the Act, and*
- *The wider context of environmental ethics as it related to gene technology.*

To this end, Judith Jones added a substantial section to the draft paper. The committee also suggested that the Working party investigate the value of the document in terms of supporting the National Framework for the Development of Ethical Principles in Gene Technology (National Framework: GTEC 2006).

The draft paper was discussed at the first meeting of the Gene Technology Ethics and Community Consultative Committee (GTECCC) in May 2008. GTECCC agreed that the draft paper should be further developed. At its second meeting (February 2009), after considerable discussion, GTECCC considered the paper in its current form to be complete for the primary purpose of providing information to the Regulator and members of GTECCC. The paper was presented at the Australasian Association of Bioethics and Health Law conference, Adelaide, July 2010 where comments on the paper were invited.

What follows is the revised draft that takes into consideration input from conference attendees and from subsequent discussion between the authors Judy Jones, Rachel Ankeny and Vaughan Monamy.

The Objectives, Scope and Organisation of this Paper

This paper seeks to:

1. Examine the main schools of philosophical thought and other approaches to environmental ethics which may be applicable to gene technology and
2. Examine environmental ethics currently applicable to the *Gene Technology Act 2000* and to implementation of the Act.

Since each of these enquiries is potentially vast, boundaries have been set. Part One provides an overview to various approaches in environmental ethics which raise issues related to a range of gene technology activities (including what may be outside the current scope of the *Gene Technology Act 2000*, which is primarily anthropocentric in its focus). Part Two commences with interpretation of section 56 which creates the primary statutory obligation on the Gene Technology Regulator not to issue a licence unless satisfied as to risk management. From this flows consideration of other core concepts of the *Gene Technology Act 2000*, such as the Object of the Act (section 3), the definition of 'environment' and other key concepts within the legislation. It also considers the Risk Analysis Framework (RAF: April 2009) as a core document of relevance to implementation of the *Gene Technology Act 2000* (primarily intentional release). This analysis can be expanded subsequently to include other aspects of the *Gene Technology Act 2000* and implementation if desired.

Why Consider Environmental Ethics in Relation to the *Gene Technology Act 2000* ?

The *Gene Technology Act 2000* is sometimes viewed simply as another example of a statutory scheme that provides for environmental protection. However, closer comparison of the *Gene Technology Act 2000* with other regimes for environmental impact assessment reveals that the *Gene Technology Act 2000* has some fundamentally different features when compared to other environmental laws that are also aimed at (different forms of) risk regulation. This raises a very important question; are the features of the *Gene Technology Act 2000* so fundamentally different to the features of mainstream environmental risk regulation that the *Gene Technology Act 2000* ought to be considered to express a unique environmental ethic or a unique set of values, at least for an 'environmental law'?

The lack of articulation of the values embedded in environmental laws

One important point to note at the outset is that environmental laws, since the 1970s, have operated without a precise or consistent articulation or statement of either the

values embedded in those laws or the motivation behind their enactment. Moreover, even when the values are *prima facie* apparent, the values may perhaps be in conflict and only resolved by decision-makers exercising discretionary powers.

Furthermore, much environmental law scholarship (and scholarship on the *Gene Technology Act 2000* is no exception) has focussed on the content and operation of those laws with only scant attention paid to the values or any environmental ethic underlying them. Tarlock (2004) considered that "…there is no longstanding social consensus about the central question of modern environmentalism – the 'correct' human stewardship relationship to the natural world" (Tarlock, 2004, pg. 223).

Disagreement exists on how much protection to give the environment and at what cost to other values (Flournoy, 2003). It has been argued (e.g., Flournoy, 2003) that there are good reasons for pursuing a refinement of our understanding of the ethical bases for environmental law including assistance with public decision-making where there are ethical choices to be made.

1.0 REVIEW OF ENVIRONMENTAL ETHICS RELEVANT TO GENE TECHNOLOGY

> Environmental Ethics is not a muddle; it is an invitation to moral development… An ecological conscience requires an unprecedented mix of science and conscience, of biology and ethics."
>
> Rolston (1991)

1.1 Preamble

What follows is an introduction to some recognised approaches to environmental ethics. Despite a longer history of ethical consideration of human's relationship and duties to their environment, it is clear that many people and society as a whole have become increasingly concerned over the past 50 years about environmental issues. Societal values are often rapidly changing and are sometimes difficult to identify accurately, let alone articulating ethical theories or foundations that might underlie these values. Few data are available to assess the Australian public's views on their preferred environmental philosophy particularly as it applies to a contested domain such as gene technology, although there are some public opinion polls relating to specific issues such as the surveys conducted by the now defunct Biotechnology Australia (see http://www.biotechnology.gov.au). It could be argued that there has been a general shift away from viewing humans as separate from and dominant over the natural world, an approach that echoes economic approaches which see the

environment as a resource to be managed and used, but it is unclear how widespread such a change has been or what the implications of such an approach are, particularly for gene technology.

Hence the main question that remains is the perspective or point of view from which environmental values are to be assessed. Most ecocentric approaches to environmental ethics oppose outright the use of gene technology outside of the human biomedical sphere. Nonetheless it is critical to include these perspectives in any comprehensive discussion of environmental ethics in order to have these views on the table for consideration as, for instance, there may still be underlying values that can be articulated which are not incompatible with the generally anthropocentric approach to environmental ethics contained in the *Gene Technology Act 2000*.

The *Gene Technology Act 2000* seems to presuppose the somewhat uncontroversial assumption that curiosity and subsequent invention are core aspects of human culture. Historically, we have often looked for efficiencies and better ways to utilise the natural world to our benefit, and as will be outlined below, this is in accordance with more traditional, anthropocentric approaches to the environment.

1.2 Scientific Background Relevant to Environmental Ethics

The modern environmental sciences (and principally ecology) draw upon many well-established scientific disciplines (e.g., physics, geology, biology, chemistry, mathematics, and palaeontology). The environmental sciences seek patterns in ecosystems from which predictions can be made, and base conclusions about future changes on data collected at a single point in evolutionary and ecological time (our present) or interpreted from the past but recognising the importance of understanding successional processes (e.g., plant and animal successions in a time of variable fire regimes).

Modern environmental sciences demonstrate empirically that most species (all but the most resilient) require healthy functioning ecosystems if they are to survive, and hence it is critical to have a clear approach to fostering such ecosystems. All species modify their local environment in some way (e.g., release of phenols by pine trees to stop germination of other plant species, beavers building dams, coral polyps creating giant reefs). However, unlike the vast majority of species, humans modify the environment on a global scale. For example, humans currently have found uses for 95% of biological resources that sequester energy as sunlight (plants) or derive their energy from those plants (animals). All human beings require, among other things, access to food, water

and shelter, and the resources required to achieve these needs must come from the natural world. Resources in the natural world are finite when viewed in the time scales in which humans utilise them.

1.3 Overview of Environmental Philosophies

Numerous environmental philosophies exist and differ primarily in the centrality afforded to the human versus the non-human world. Anthropocentric approaches view it as permissible that the natural world be used for human ends, and view nature as in some sense instrumental to those ends. Ecocentric philosophies recognise the natural world as being important for its own sake, and hence having intrinsic value separate from its potential uses by humans. There are advocates for the ethical recognition of ecosystems regardless of whether they are of instrumental value to humans or not. One shared concern among most environmental philosophies is whether the natural world can continue to sustain all of humanity indefinitely given current exponential population growth, present resource use, and lack of effective waste management.

1.3.1 Anthropocentric approaches

Historically, there has been a widely-held view in the Western tradition that as the only legitimate moral agent, the human is the measure of all things. Its foundations can be traced to the Old Testament and Judaism, and even further to Aristotelian and Stoic discourse, and these beliefs were incorporated into Christianity and later in humanism.

According to this view, humans are divine (or at least special) and all other beings have a lower status. Humans are considered worthy of special consideration (moral and otherwise) because of any number of reasons (e.g., personhood, advanced self-consciousness, ability to gain knowledge about the world). As moral agents, humans have responsibilities with regard to the environment in general and certain other species in particular. This is evidenced in discussions about human well-being and stewardship, dominion and responsibility.

This relationship between humans and the environment is anthropocentric. In other words, since moral values are exclusive to humans, value can only be attributed (e.g., to the environment) because it is recognised by humans. Within this perspective, there are three rough categories for describing the relationship between humans and their environment: domination, co-operation and conservation (the discussion that follows draws closely on Fisher 2003).

The strongest among the anthropocentric approaches, which arises out of the Greek and Judeo-Christian philosophies described above, holds that humans should be able to treat nature as they see fit, for instance as a resource to be utilised, and without any moral judgements being attached to such actions except inasmuch as they might affect moral agents (i.e., other humans). Humans may be able to modify and transform nature, according to more radical approaches, or may only be able to use nature as it is given, under some conservative views. The resonance with economic perspectives is obvious, inasmuch as use and even exploitation of the environment as a resource is permitted.

A second anthropocentric approach sees humans' role as one of steward, which does place some limits on permissible actions. Stewardship can range from caring for the environment but also modifying it in order to improve it, which may be a relevant consideration for gene technology. Although the environment is acknowledged to have value and hence some sense of responsibilities toward nature is implicit, humans are still the central focus.

Certain forms of an ethic of conservation can be considered as a third approach to anthropocentrism. This is typically attributed to the conservationist Aldo Leopold (1949) who claimed that the environment was being abused because of private interests and ownership of land should be vested in the community. We should treat and use our environment with respect, and a so-called 'land ethic' grounded in both the laws of nature and the conception of community interest, allows recognition of the complex relationship between humans and their environment while still allowing humans to use and modify the environment. (Certain ecocentric views also derive from Leopold's philosophy as will be discussed below.)

In summary, within all anthropocentric views, human impacts on the natural world are morally right if they have consequences that are favourable to human well-being or if they implement (or defend) fundamental human rights. It is to humans that all duties are owed, and our duty of care to aspects of the natural world is contingent on furthering human goals including values and rights.

1.3.2 Ecocentric and other non-anthropocentric approaches

Ecocentrism and other non-anthropocentric approaches challenge anthropocentric ethics by re-defining the boundaries of ethical obligation to include species, ecosystems, or even the biosphere as subjects of moral relevance. Some environmental

philosophers have argued for the expansion of our moral sphere beyond the biota to include our planet as a whole and, in a few instances, the entire universe (Nash, 1990).

At their core, these approaches share the fundamental idea that humans should not be considered above or outside the natural world. Instead, there is acknowledgement that ascribing moral relevance to healthy functioning ecosystems will ensure the survival and fulfil the evolutionary potential of most species (including humans without giving primacy to their well-being). They often make reference to values including interdependence, spiritual harmony, and extensionalism (i.e., the treatment of the environment as persons for the attribution of rights and other legal purposes).

Inherent in any discussion of ecocentric ethics is a denial of human superiority. This is often motivated by asking two questions: "What is the morally relevant difference between humans and non-human organisms (usually interpreted to mean other vertebrates)?" and "If there are no morally relevant differences, then why do we treat non-human organisms/animals and humans so differently?" Failure to agree on answers to this question leads to discussion about expanding the moral sphere to incorporate moral consideration of all animals and plants (e.g., Schweitzer's (1965) *Reverence for Life*), ecosystems (e.g., Taylor's (1981) *Respect for Nature*), ecosystems and the energetic systems that ensure biotic survival for all species including humans (e.g., Leopold's (1949) *Land Ethic*, Naess's (1973) *Deep Ecology*, Warren's (1990) *Ecofeminism*, and Fox's (1995) *Transpersonal Ecology*), and ultimately, the entire cosmos (e.g., Nash's (1990) *Rights of Nature,* Berry's (1999) *Viable Human*).

1.3.2.1 Animal Ethics

Adherents to animal-centred approaches to environmental ethics usually cite Peter Singer's 'equality of consideration of interests' principle as applied via preference utilitarianism (Singer 1975). In short, this approach expands the principle of the 'greatest good for the greatest number' to count some types of non-human animals among those beings given moral standing. Singer (1975), for instance, limits his moral consideration to organisms considered by science to be sentient, and argues the division where sentience begins to be somewhere between an oyster and a crab. Tom Regan (1983) attributes moral worth to beings based on them being 'subjects-of-a-life,' and considers mentally-normal mammals older than one year of age to be such beings. It is the subject-of-a-life that is worthy of moral consideration inasmuch as it has inherent value; in order to respect such beings, they must be given rights.

1.3.2.2 Ecocentric Ethics

Ecocentric ethical approaches focus on moral obligations which humans owe to plants, animals, and micro-organisms to promote their well-being for their own sake because of their intrinsic value. Additionally, moral recognition may be given to the connections between ecosystems upon which biota rely, or the networks which link various individuals within the ecosystem or environment. Ecocentric ethics tend to branch from a brief statement by Leopold (1949) that claimed that, "… a thing is right when it tends to preserve the integrity, stability, and beauty of the biotic community. It is wrong when it tends otherwise." Many ecocentric philosophies will also incorporate some type of mysticism and/or spiritualism.

1.3.2.3 Global Ethics

Global ethics focus on the moral consideration of the planet as a whole with prominent advocates including Rockefeller (1992), Lovelock (1995) and Berry (1999). The Gaia theory is the most readily recognised of these environmental philosophies. Gaia theory proposes that our planet is a living being capable of maintaining its own health and well-being through a complex pattern of equilibria and disequilibria. Scientific aspects of Gaia theory emphasise the interconnectedness of all biological and non-biological systems. Spiritual aspects of Gaia theory advocate a reverence for the entire planet and for affording her appropriate moral status.

1.3.2.4 Cosmological Ethics

Cosmological ethics ascribe moral worth to all organic and inorganic matter in the universe(s). Energy fields that sustain life (and non-life when it manifests itself as matter rather than energy) are also relevant in any discussion of cosmological ethics. There is usually discussion of pantheism and/or panentheism (Harrison 1999) in cosmological ethics. Recognition that the universe became self-aware through human consciousness is reflected in the writings of Nash (1990) and Berry (1999) who both argue for the moral importance of the cosmos.

1.4 Implications and Discussion in Relation to Gene Technology

Those who take a generally anthropocentric view toward environmental ethics are less likely to oppose gene technology than those coming from an ecocentric position. For many who take an anthropocentric perspective, gene technology can be viewed as another tool which either resembles previous low-tech means of modifying nature or which differs from earlier technologies in that it has the potential to rapidly create new strains of living organisms that may impact on ecosystems. Where there is community

concern, ethical consideration has tended to focus on consequentialist and deontological arguments, such as intrinsic objections to genetic modification and/or risk assessment, which make reference to potential harms (and/or lack of benefit) for humans. More acceptable uses of gene technology seem to be those that promise numerous direct benefits for human health, including humane use of animals (principally mice) for experimentation which is viewed by many as an inescapable necessity (though this is debated by many animal rights scholars and activists).

Ecocentric approaches share in common an emphasis on the moral value of non-human species and their ecosystems. Radical ecocentrism as well as many forms of global and cosmological ethics might well hold that nature should never be altered or modified, particularly for human benefit alone, in which case all forms of gene technology (and much plant breeding) would be morally impermissible. Less radical advocates of ecocentrism would likely argue that equality of consideration ought to be given to non-humans and ecosystems to various extents. So, for instance, as it is morally wrong to interfere with the welfare, behaviour, or rights of a human without first obtaining consent, so too should non-human animals and other organisms be given at least equality of consideration. As consent cannot be granted by any non-humans, many would hold that genetically-modified organisms should not be created or released into the natural world. A more liberal position might allow some form of substituted judgment or legal mechanisms for protection of such organisms and the environment, but such a position would often generate institutional mechanisms that would cause collapse into an anthropocentric perspective (an exception might be Stone's (2010) proposal for mechanisms for recognising and enforcing legal rights of natural objects).

2.0 THE *GENE TECHNOLOGY ACT* 2000 AS AN AUSTRALIAN ENVIRONMENTAL RISK ASSESSMENT REGIME: UNIQUE STATUTORY FEATURES AND IMPLIED VALUES

2.1 Methodology

2.1.1 A method for determining the underlying ethic of environmental laws

The general method for discovering the underlying environmental ethic of any piece of environmental legislation is statutory interpretation of the language of the statute and regulations. Analysis of statutory language to discover an environmental ethic involves a range of legal and non-legal tasks *viz* (i) legal analysis in the form of statutory

interpretation but also (ii) elaboration of values embedded within that language from which (iii) plausible justifications are derived (Flournoy, 2003).

Determination of an environmental ethic within a regulatory regime is also not limited to an analysis of statutory language. Rather, determination of the ethics and values expressed through social institutions involves consideration of not only statutory sources but also mechanisms of implementation including guidelines, operational manuals and exercise of discretionary powers.

2.1.2 A method for determining the environmental values underpinning the Gene Technology Act 2000

Following this general method, the method adopted in this paper to consider values underpinning the *Gene Technology Act 2000* is to analyse statutory language of the Act itself and also to examine values that emerge from the law in action, as implemented within discretionary frameworks in public administration (such as reflected in the Risk Analysis Framework, [RAF]), April 2009).

Subjecting the wording of the entire *Gene Technology Act 2000* and the Gene Technology Regulations, the implementation procedures and the actions of the Office of the Gene Technology Regulator (OGTR) to analysis would be an immense project. Consequently, a single primary operative section, section 56 has been selected as a preliminary starting point for analysis of the values underpinning the Act.

Section 56 is a very important section as it creates the primary statutory obligation on the Regulator not to issue a licence unless satisfied as to risk management. Interpreting this important section of the Act, in context, requires consideration of other core concepts of the *Gene Technology Act 2000*, such as the Object of the Act (section 3), the definition of 'environment' and other key concepts within the legislation. This analysis also considers the RAF (April 2009) as a core document of relevance to implementation of the *Gene Technology Act 2000*. The inquiry could be expanded to consider individual Risk Assessment and Risk Management Plans (RARMPs). Other sources that could be considered as part of an expanded inquiry are the historical context (including the operation of the Genetic Manipulation Advisory Committee and impetus for regulatory reform), the explanatory memorandum to the *Gene Technology Act 2000* and documented public consultation both prior to enactment of the *Gene Technology Act 2000* and also as part of the review of the Act (2005 - 2006). Since all of these sources are highly relevant to determining the values and motivation behind the legislative

scheme, and have not yet all been incorporated, the statutory analysis that follows should be regarded as a starting point.

2.2 Analysis

2.2.1 Section 56, Gene Technology Act 2000

Section 56 (1) provides:

> "The Regulator must not issue the licence unless the Regulator is 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:
> (a) the health and safety of people; and
> (b) the environment."

The thematic structure of the analysis that follows picks up on the fundamental elements of Section 56 which are:

- What can decision-makers consider? What is included and excluded from the Regulator's consideration?
- the definition of "environment", and
- the obligation "to protect", and
- the obligation to "manage risk."

The latter three elements namely "environment", "to protect" and "manage risk" appear not only in section 56, but are also duplicated in section 3, the Objects of the Act.

> "Section 3: Object of Act
>
> The object of this Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs."

2.2.2 What can decision-makers consider? What is included and excluded from consideration?

One notable feature of mainstream environmental law (such as in environmental impact assessment) is that economic and social considerations are consistently placed in direct

competition with environmental objectives (including for example in some conceptions of ecologically sustainable development). The *Environment Protection and Biodiversity Conservation Act 1999* (the '*EPBC Act'*) makes it mandatory for the decision-maker to consider the economic and social impact of a development as well as environmental considerations.[1]

In contrast, section 56 of the *Gene Technology Act 2000*, consistent with the remainder of the *Gene Technology Act 2000*, does not allow consideration of economic and social considerations in decision-making by the Gene Technology Regulator when issuing a licence. This means that issues relating to trade and benefits of gene technology are outside the scope of the Act. This is clearly expressed in the RAF (April 2009, page 16) which states: "…Certain issues, such as impacts on trade, social and cultural effects, as well as benefits that may be derived from gene technology or food labelling, are outside the scope of the analysis."

It was also noted in the earlier version of the RAF (November 2007, para 46) that extensive stakeholder consultation "…made it clear that the community wanted the regulatory system to focus exclusively on the evaluation of risks to human health and safety and the environment. This was to prevent economic considerations (eg, cost-benefit analyses, market access and agricultural trade implications), from compromising the regulatory system's focus upon the scientific evaluation of risks and the protection of human health and safety and the environment". When compared to all other environmental laws this feature of the *Gene Technology Act 2000* is a significant privileging or elevation of environmental values over economic and social benefits and values.

2.2.3 Definition of "environment"

What is the environment that the Regulator is obliged to consider and "protect"?

The starting point is an examination of the text of the *Gene Technology Act 2000* and the text of the RAF (April 2009). Statutory interpretation of "environment" for the purposes of the *Gene Technology Act 2000* is assisted by inclusion of a definition within Section 10 of the Act which states:

> "Environment includes:
> (a) ecosystems and their constituent parts; and
> (b) natural and physical resources; and

[1] See for example, the *Environment Protection and Biodiversity Conservation Act 1999* (Cth), section 136(1)(b).

(c) the qualities and characteristics of locations, places and areas."[2]

The RAF (April 2009) provides some examples of environmental components that will be considered in environmental risk assessment. On pg. 5, following discussion of the definition of the environment, it is noted:

> "Risk to the environment includes consideration of effects on biotic and abiotic components of the environment".

Biotic components include reduced "biodiversity" and abiotic components include "soil, water, or air".

So far, there is nothing remarkable about this characterisation of the environment when compared to other environmental regulation (including the *EPBC Act*) – many of which refer to biodiversity in similar terms. But what kind of bio-diverse environment is envisaged?

One of the common assumptions made about environmental policy and law is that it seeks to protect and maintain the environment in a pristine 'natural' or unmodified (by humans) state. However, closer scrutiny of general environmental policy and law reveals that it seeks to satisfy a range of competing social, economic and environmental interests – and ultimately only provides limited environmental guarantees.

Arguably, the *Gene Technology Act 2000* also does not use the pristine environment as its reference point for protection. Indeed, the *Gene Technology Act 2000* refers, in its definition, to "natural and physical resources" expressly acknowledging that in the *Gene Technology Act 2000*, as in other environmental law statutes, the environment is a resource. Furthermore, on a globe populated by seven billion people it is very difficult to find an unmodified environment – and Australia is no exception. While it is of course a question of degree, one only needs to consider increased atmospheric carbon dioxide levels or increased seasonal UV levels due to the hole in the ozone layer over the Antarctic to appreciate how difficult it is to find an environment that remains unmodified by human activities. This policy and regulatory landscape is a very important context when considering the environmental ethics or philosophy that underpin provisions of the *Gene Technology Act 2000*.

[2] As noted in the RAF (April 2009, para 43) this definition is less inclusive than the definition of the environment contained within the *Environment Protection and Biodiversity Conservation Act 1999* (Cth). That definition includes social, economic and cultural matters whereas they are not included here under the *Gene Technology Act 2000*. This point has been discussed above.

2.2.3.1 The Relevance of the Agricultural Environmental Baseline to the meaning "Environment" within the Gene Technology Act 2000

In the preceding section it was noted that much of the environment is modified by humans. One such modified environment is the agricultural environment. This is an important 'environment' or context for the purposes of the *Gene Technology Act 2000* because many current gene technology applications for intentional release, such as genetically-modified cotton and genetically-modified canola, do have distinct agricultural applications.

Agricultural activities are relatively unregulated in Australia – at least in terms of direct regulation. Landowners have historically had a free choice as to any agricultural enterprise adopted – although, indirectly, some forms of regulation may have a large bearing. For example, at State level, the siting of intensive agriculture such as feedlots will invoke development approvals and pollution controls; growing of irrigated crops will invoke water licensing regulation; and land clearing will require development approval. At the Federal level the Australian Pesticides and Veterinary Medicines Authority regulates insect resistant genetically-modified organisms as agricultural products ('plant pesticides') and considers product efficacy (i.e., the emergence of insect resistance). If regarded as a "matter of national environmental significance" the activity would need Federal approval pursuant to the *EPBC Act*. So, although there is some indirect regulation and also some properties are managed more sustainably than others, environmental regulatory obligations are limited and the agricultural environment is, generally speaking, a highly modified environment.

What then, does the *Gene Technology Act 2000* suggest as the relevant baseline environment? Section 15 AA of the *Acts Interpretation Act 1901* (Cth) permits recourse to the purpose section of a statute to assist with interpretation of a provision (such as section 56). In section 3 (Object of Act) the *Gene Technology Act 2000* refers to the risks "posed by or as a result of gene technology".

As noted in the RAF (April 2009; page 19):

> "In particular, the Regulator identifies risks posed by or as a result of gene technology by using comparative risk assessment methodology. Therefore risks posed by a particular GMO need to be considered in relation to the parent organism in the receiving environment. For example, non-GM crop species already present risks to the health of people (for example, gluten in wheat or

allergens in soybeans or peanuts) or to the environment (for example, some pasture species have a degree of weediness). These risks associated with the parent organism form part of the baseline against which the GMO is assessed to determine whether gene technology has increased the level of risks or poses additional risks."

Because genetically-modified organisms are currently being released in agricultural environments, a number of agricultural examples will be utilised to illustrate the scope of the *Gene Technology Act 2000* and OGTR deliberations.

(a) Agricultural Sustainability

Cotton has been grown for several decades in the Australian agricultural sector in an unmodified form (subject, of course, to modification through traditional plant breeding) (see further 'The Biology and ecology of cotton (*Gossypium hirsutum*) in Australia' (OGTR website). Current agricultural practices, including, for example, the use of insecticides in cotton growing have detrimental environmental impacts, having a detrimental impact on non-target species. Insecticide use and consequently its negative environmental effect will be changed by the growing of genetically-modified cotton (cotton containing an insecticide). In addition, the mere fact that cotton crops are grown at all, e.g., irrigated cotton, have a significant environmental impact. This is starkly illustrated by the example of the environmental effects of growing any type of irrigated cotton in the Murray-Darling Basin. Arguments have been made that the OGTR should look at the environmental impact of cotton growing *per se* rather than simply the environmental impact of genetically-modified cotton. However, such an approach to the *Gene Technology Act 2000* would not be consistent with the assessment of risks that are "…posed by or as a result of gene technology…" as required by the *Gene Technology Act 2000* (s 3).

(b) Harmfulness to other Organisms – target and non-target

Does the *Gene Technology Act 2000* oblige the protection of native invertebrates or other native organisms such as plants as part of the ecosystem or environment it seeks to protect? What if a genetically-modified organism has a detrimental effect on native species (e.g., native invertebrates that are considered pests to agriculture)? Indeed, in some agricultural applications of gene technology the aim of the genetically-modified organism, such as an insecticidal agricultural plant, will be the mortality of such invertebrates. Furthermore, what if the genetically-modified organism that has an

indirect detrimental effect on native species, e.g., native vertebrates (birds) that feed on the invertebrates? Is such 'collateral damage' part of the risk to the environment that has to be managed or avoided?

Thus, statutory interpretation of the definition of the "environment" assisted by Section 3 of the *Gene Technology Act 2000* (and as interpreted by the OGTR in the RAF (April 2009)) suggests that the agricultural environmental baseline or environmental 'status quo' is very relevant. This is also a pragmatic and consistent approach. First, it seems reasonable to recognise that the current environment is an environment that has been modified by humans. Secondly, as noted above, elevation or tolerance of agricultural values is consistent with the philosophy underpinning other forms of well-accepted environmental regulation.

2.2.4 Obligation "to protect"

- Statutory Guidance in the *Gene Technology Act 2000*

Another important feature to expand our understanding of the ethical bases or values embedded in the *Gene Technology Act 2000* is the obligation "to protect" the environment. Mandatory statutory provisions prevent the Regulator from issuing a license unless satisfied that risks can be managed in a manner that will "protect …the environment" (sections 56 (1) and also 51(2) (a)). "Protect" is not defined in the Act.

In the absence of a definition of "protect" within the *Gene Technology Act 2000* recourse to a dictionary for the purposes of statutory interpretation is permitted (*State Chamber of Commerce v Commonwealth (1987) 163 CLR 329* at 348). The Australian Oxford Dictionary (1999) defines "protect" as "keep safe; defend; guard". But what does this mean in terms of statutory environmental protections?

What does the notion "to protect" require? Is this protection offered by the regime(s) protection of the species, ecosystem or community or of individuals of the species, ecosystem or community? Again, comparison with other environmental laws is useful as a starting point.

- *Comparisons with the* EPBC Act.

Regardless of the fact that the word "protection" is contained in the title to the *Environment Protection and Biodiversity Conservation Act 1999,* the level of protection that this statute can provide is arguable. This is because, as noted above, the decision-maker under the *EPBC Act* is not only authorised, but is required, to take into account economic and social considerations as well as environmental matters.

But the legislation does provide indirectly a higher level of protection for some individuals – those that are members of threatened or endangered species or communities. Regulatory regimes, such as the *EPBC Act* (and equivalent legislation in all States and Territories) do recognise the so-called threatened or endangered species or ecological communities, and these 'species' or 'communities' may be given a higher level of protection. And, if the species or community is threatened, then the individuals of the species or community (or the individual communities) will be protected in order to protect the species or community.

To obtain this recognition, and higher level of protection, threatened species or ecological communities must be expressly listed or described in a Schedule to the *EPBC Act*. However, listing of a species in this manner does not guarantee its protection or preservation. Rather, the higher level of protection is simply that there will be a higher level of environmental impact assessment prior to making a discretionary decision (which also expressly incorporates social and economic considerations). Thus, the general approach in environmental law is to provide a higher level of procedural scrutiny in the assessment of potential harm for individuals of a threatened species or ecological community. If a community or species is considered to be of sufficient 'worth', then an area will be gazetted as a Nature reserve, National Park or even a World Heritage Area. Creation of nature reserves potentially accords/affords a higher level of protection within these areas. However, the protection of threatened species or ecological communities in off-reserve locations (pursuant to the *EPBC Act*) is never guaranteed since the decision-maker is also required to take economic and social considerations into account in determining management plans for listed species and communities. Thus, the effect of the legislation is that decision-makers conduct a more intense scrutiny of the potential impact of a proposed development on threatened species or ecological communities but the protection of such species/communities is not guaranteed.

The Gene Technology Act 2000 *contains a higher duty of protection when compared to other environmental law statutes*

It is clear that the express obligation to "protect", combined with the exclusion of economic and social considerations from section 56 of the *Gene Technology Act 2000* creates a much higher duty to protect, than is provided by mainstream environmental risk assessment.

The RAF (April 2009) provides considerable insight to the interpretation of environmental protection by the OGTR – and that interpretation is consistent with the general approach in environmental law described above, particularly in relation to differential treatment of individuals versus treatment of species or communities. For example, (p 30) it is noted that:

> "Harm to humans is usually considered at the level of an individual, whereas harm to the environment is usually considered at the level of populations, species or communities."

In terms of values underpinning implementation of the *Gene Technology Act 2000*, this analysis suggests that, consistent with the *EPBC Act*, individual organisms are not valued whereas entire groupings of entities are valued. This is consistent with current regulatory approaches to biodiversity conservation which, as discussed above, focus on habitat and ecosystem protection rather than protection of individuals.

This discussion of the *EPBC Act* serves to highlight how different the *Gene Technology Act 2000* is from mainstream environmental law in a couple of very important ways. The *Gene Technology Act 2000* obliges the OGTR not to take economic and social interests into account (for example, trade related aspects are excluded from consideration). Similarly, the OGTR cannot consider benefits – presumably, also, not being able to consider the environmental benefits of gene technology.

2.2.5 The obligation to "manage risk"

One further difference between the *Gene Technology Act 2000* and mainstream environmental law is that the obligation to manage risk appears prominently in the *Gene Technology Act 2000* and in other risk assessment regimes that originate in the health and agriculture portfolios (therapeutic goods approval, chemicals regulation, quarantine, *etc*) whereas environmental law remains silent on 'risk'. Nonetheless, despite the absence of any express reference to risk in statements of goals or obligations in mainstream environmental law, these regimes are, in effect, managing environmental risk. The significance of this difference between the two 'environmental' regimes deserves further analysis.

Likewise, it should be noted that while the statutory language in the *Gene Technology Act 2000* excludes economic and social considerations, the Act does require the management of risk. All processes of risk analysis require judgments about what is an 'acceptable risk' and this has the potential to inject value-laden judgments. The Risk Analysis Framework to the *Gene Technology Act 2000* does provide some indication as

to the values that have been adopted by the OGTR when assessing and managing the risks of gene technology. This document explains how the risks to human health, safety and the environment are assessed through a comparative methodology which expressly adopts the modified environmental baseline as the relevant environmental reference point (as explained in 2.2.3.1 above).

3.0 Conclusion

As foreshadowed, this represents an initial examination of key statutory language within the *Gene Technology Act 2000* and some contextual documents, for the purposes of gleaning values embedded in the regulatory regime. The inquiry could be expanded in scope to include a more detailed analysis of the RAF and analysis of additional contextual material such as the RARMPs.

The discussion has simply attempted to elicit some of the values underpinning the *Gene Technology Act 2000* and compared them to mainstream environmental laws enacted ostensibly for the purpose of protecting the environment. The *Gene Technology Act 2000* does have some features that make it a much stronger and more 'protective' regime than mainstream environmental law. This is perhaps because some of the features of the regime have originated in the health risk assessment portfolios rather than the environmental portfolio. If the Minister administering the *EPBC Act* decided to destroy the last remaining individual or population of a species by allowing a development on the basis of social or economic considerations it would be within his/her authority to do so. However, the Gene Technology Regulator would not be at liberty either to take these factors into account in making a decision, or to knowingly permit environmental harm as an outcome.

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