

Review of the *Gene Technology Act 2000 (Cth)*
Submission from the
Gene Technology Ethics Committee (GTEC)

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Submission from the Gene Technology Ethics Committee (GTEC)

Professor Don Chalmers (Chair)

This submission comments on the following terms of Reference

Scope of Act

1. Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act including:
 - a) consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered.
 - b) the definitions in the Act, including of the environment, and the need for the definition of other terms, including health.

Act Achieving objects

2. Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate

Operation of the Act

4. Review the consultation provisions of the Act including:
 - a) their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide.
 - b) the functions and roles of the statutory advisory committees
 - d) the stakeholders included in consultations for various applications under the Act

Regulatory Burden

6. Examine whether compliance and administrative costs, including information requirements, for organisations working in gene technology are reasonable and justified compared to the benefits achieved and possible alternatives to legislation.

Interface with other systems

9. Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies, including regulatory gaps and areas needing consistency and harmonization of provisions.

Changing Circumstances

10. Examine emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances.

Changes to the legislation

11. Recommended amendments to the Act (including consideration of those recommendations made by State or Territory Parliamentary Committees), or alternatives to legislation, which improve the effectiveness, efficiency, fairness, timeliness and accessibility of the regulatory system.

A. Preamble

The National Biotechnology Strategy (NBS), which outlines the Government's vision for biotechnology, aims to ensure that "consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment" (National Biotechnology Strategy, 2000, p.7). The *Gene Technology Act 2000* (Cth) was introduced as a measure to ensure that human health and safety and the environment are safeguarded whilst the research and commercial development objectives of the NBS are achieved. The system of regulation imposed by the Act should therefore be seen as part of a broader set of objectives that the Government has for the success of biotechnology in Australia.

The *Gene Technology Act 2000* (Cth) has an apparently simple object, "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". (GT Act s 3). The Act, and its operation through the Office of the Gene Technology Regulator (OGTR) and the Gene Technology Regulator, was intended as a 'gap-filler'. In other words, it would operate in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products, such as AVPMA, FSANZ, TGA, AQIS, and NICNAS. Additionally, some supervision of ethical practice in scientific establishments is left to committees that work under auspices other than the OGTR, such as human research and animal ethics committees. However, significant matters of risk assessment and risk management of GMOs that are not covered by these other schemes and committees do rest with the OGTR. In addition, there is an unstated but real need to consider the cumulative impact of the regulatory system on the research and development of GMOs in a manner consistent with the vision enunciated in the NBS.

GTEC's view is that two key aspects of the NBS need to be addressed more explicitly by the Act and the operations of the OGTR. These are "raising public awareness and informing community dialogue" and "consideration of ethical issues" (NBS, pp.7-8). GTEC acknowledges that Biotechnology Australia has a public awareness program but we believe that the OGTR can make a significant contribution to public awareness of the regulation of biotechnology in Australia and, in particular, to addressing some of the social and ethical concerns expressed by the public. GTEC also believes that ethical issues need to occupy a more central place within the regulatory system and that the two statutory committees, GTEC and GTCCC, have the potential for a greater role in considering those aspects of the operations of the OGTR that bear upon social and ethical concerns relevant to the operations of the Act and to the regulation of gene technology in general.

B. Summary of Activities and Role of GTEC: 2001 - 2004 Advice to the OGTR and the Regulator

Development of Ethical Guidelines in Relation to Genetically Modified Organisms

In the first triennium, at the request of the Regulator, GTEC commenced work on the development of a set of ethical guidelines (values and principles) in relation to genetically modified organisms. These draft Guidelines have been discussed with other ethics committees and government agencies, then revised in response to that consultation.

Extent of Ethical Considerations in Applications

GTEC considered the need for a survey of Institutional Biosafety Committees (IBCs). The purpose of the proposed survey was to determine the extent of ethical review for all types of

applications for genetic modification work in relation to plants and animals. Towards the end of the first triennium it was decided that the work was not to be progressed at that time.

Other Advice

At the request of the Regulator, GTEC also worked on a range of ethical issues falling within the purview of the new regulatory system. This led to working papers on:

- The ethical aspects of risk including multiple facets of managing risk ethically
- Release of Information and Notification under the *Gene Technology Act 2000*.
- Ethical Issues Arising from the Genetic Modification of Animals (including animal welfare considerations)
- Ethical Issues Associated with Transkingdom Gene Transfer
- "GMOs, Lay Understandings and civic ethics"
- " A history of ideas about environmental precaution"

A number of these GTEC papers have been considered by GTTAC and GTCCC.

A GTEC working paper entitled *Managing Risk Ethically* provided expert advice to the OGTR and the Regulator throughout the process of revision of the *Risk Analysis Framework* during 2003 - 4. The paper's emphasis on considering the broader context in which risk analysis takes place is referred to throughout this submission. Amendments to the *Risk Analysis Framework* (OGTR, 2005, 2nd Edition) reflect the integration of ideas and themes raised in *Managing Risk Ethically* into the revised *Risk Analysis Framework*.

GTEC Submissions

GTEC also made submissions in response to the:

- National Health and Medical Research Council's (NHMRC) release of *Draft Guidelines and Discussion Paper on Xenotransplantation*
- *Draft Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*(7th Edition)
- Australian Health Ethics Committee (AHEC) paper *Animal-to-human transplantation research: How should Australia Proceed?*
- *NHMRC Draft Australian Code for Conducting Research - 2004*
- *NHMRC National Statement on Ethical Conduct in Research Involving Humans*
- *Victorian Biotechnology Ethics Advisory Committee "Statement of ethical principles for biotechnology"*

Through the observer on GTEC from the Animal Welfare Committee (AWC) GTEC has commenced involvement with the development of *Guidelines for the Creation, Breeding, Care and Use of Genetically Modified Animals for Scientific Purposes*.

C. Comments on Specific Terms of Reference

Scope of the Act

Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act including:

- 1. a) consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered;**

Economic, marketing and trade, cultural and social impacts

The scope of the Regulator's considerations is limited by the object of the Act (GT Act, s 3), among other things, and by what the Regulator may have regard to in preparing a risk assessment and risk management plan ("RARMP") (GT Act, s 51) and in making her determination (GT Act, s 56 (1) and (2)). These provisions limit the Regulator's considerations to protecting "the health and safety of people, and to protect the environment" by "identifying risks", "managing risks" and regulating dealings (see especially GT Act, ss 3 and 56 (1)). Under the current GT Act, the Regulator is precluded by the Act from considering economic, marketing and trade issues when issuing licences.

This narrow scope of the GT Act contrasts with the more expansive scope of other environmental regulatory regimes, particularly the environmental impact assessment regimes such as the *Environment Protection and Biodiversity Conservation Act 1999* ("EPBC"). EPBC has more expansive objects that include economic and social matters within notions of sustainability (see EPBC s 3(1) and s 3A(a)) and makes economic and social matters mandatory considerations (EPBC, s 136). Within EPBC this potentially sets up the 'triple-bottom line' competition between environmental and economic and social matters that is familiar in sustainability debates. Although potentially moderated by sustainability, these features of environmental impact assessment regimes have previously been noted for potentially giving primacy to social and economic objectives over environmental protection (see Bates, G. (2002) *Environmental Law in Australia* (5th ed), p 112 – 4, and especially p 128; see also Farrier, D. (1999) "Factoring biodiversity conservation into decision-making processes: The role of the precautionary principle", in *Perspectives on the Precautionary Principle* (Harding, R. and Fisher, E. (eds) (Federation Press: Sydney) chap 6, at p 106 -107). GTEC considers that one possible negative consequence of this (EPBC) regulatory design, is that, under a regime with expansive objects and considerations, the potential high economic benefits of a new development can outweigh the objective of environmental protection, allowing a decision-maker to permit a development on social and economic grounds even though it might pose considerable environmental harm.

The current narrow scope of the GT Act, combined with the science-based or evidence-based provisions in the remainder of the statute, provides a risk-based assessment of the potential effects of a genetically modified organism. GTEC strongly supports a primarily science-based determination as the outcome of the regulatory risk analysis conducted by the OGTR – with two important qualifications.

- (i) economic, marketing, trade, social and cultural matters (for example) need to be considered by other (non-OGTR) agencies or institutions
and

- (ii) *the wider context of the risk analysis (a term that is explained at p. 5 of this submission)*, should be more fully taken into account by the OGTR, in the course of conducting risk analysis.

GTEC notes that in relation to (i) consideration of marketing etc issues, the GT Act does create an intergovernmental mechanism (GT Act, s 21(aa)) that has provided for a separate decision (and separate legislation) prohibiting commercial release of genetically modified organisms in some Australian jurisdictions. This inter-governmental mechanism may not be entirely satisfactory from all perspectives (for example it may appear contradictory to a nationally consistent scheme to regulate gene technology, GT ACT s 5) but it does provide a clear separation between the regulatory process of scientific risk analysis and the consideration of marketing issues. GTEC affirms the advantage of this separate analysis of risk. GTEC notes the potential for this or like mechanisms to provide for an analysis of risk separate from the assessment of other impacts of gene technology.

Recommendation 1: Object of the GT Act (s 3) and Risk Analysis Scope of GT Act (ss 51 and 56)

GTEC recommends that the GT Act should continue to give primacy to considerations of human health and safety and to the environment. Therefore these sections of the Act should remain unchanged.

Recommendation 2: Consideration of economic, marketing, trade, cultural and social impacts

GTEC supports the current exclusion of economic, marketing, trade, cultural and social impacts from the decision-making process in relation to GMO applications.

Recommendation 3: The Wider Context of Risk Analysis

GTEC recommends that the wider ethical and social context of risk ought to be recognised and considered in risk analysis.

Re-examine How Ethical Issues are Considered

Given the narrow scope of the GT Act and of what the Regulator can take into account in conducting a risk analysis and making a decision, what is the role of the Gene Technology Ethics Committee (GTEC) (and indeed the Gene Technology Community Consultative Committee (GTCCC)) within this regulatory regime?

At present GTEC does not routinely consider licence applications for any type of dealing (although some sectors of the public perceive otherwise, according to anecdotal evidence. In particular, the GT Act does not provide for consideration of licence applications by GTEC (s 112) in either the specific way this is provided for in relation to GTTAC (GT Act s 101 (b) and 47(4), 50(b), 51 (1)(d), 51(2)(d), 52(3)) or in the more general manner in relation to GTCCC (GT Act, s 107 (aa)). However, GTEC notes that consultation on specific applications is possible at the Regulator's discretion (GT Act, s 53 (1)) and the statute expressly

contemplates a ‘stopping of the clock’ for the purposes of GTEC’s consideration should the Regulator exercise that discretion (GT Regulation 8 (2)(e)).

Irrespective of the manner of consultation with GTEC (whether about an individual application or in some other form), the inclusion of GTEC within the regime and the exclusion of ethical matters from what the Regulator can consider when preparing a RARMP or when issuing a licence, could create an anomaly, or a source of tension, within the GT Act. A similar argument could be made in relation to GTCCC. While the GT Act appears to provide for Committee based consideration of ethical issues and community consultation, it does not define the relevance of GTEC or GTCCC to specific licence applications. GTEC recommends that the Review Panel take this into consideration in reviewing the GT Act.

At 4(d) below, GTEC comments further, and at length, on the functions and roles of the statutory advisory committees (also in relation to licence applications). At this point in the submission GTEC’s comments are limited to pointing out the apparent anomaly in the Act and stating some general points about GTEC’s role within the scope of the Act.

GTEC perceives that it has a vital role under the Act advising the Ministerial Council, the Regulator and the OGTR, but also the GTTAC, on ethical issues associated with both the environmental context and possible health effects of gene technology, as part of the *wider context of risk analysis* that the Regulator is required to consider under the GT Act. This also includes consideration of issues relating to risk communication (on which the interests and expertise of GTEC and the GTCCC might overlap).

The wider context of risk analysis

During the first triennium of the regulatory scheme, GTEC drafted an information paper entitled “Managing Risk Ethically” that considered the ethics of the risk analysis process and made recommendations about how gaps in knowledge, uncertainty, indeterminacy, attention to process and the basis for judgements about acceptable risk might be incorporated more explicitly into risk analysis and thus address some aspects of *the wider context of risk analysis*. This advice to the Regulator was made available to GTTAC and the OGTR and informed the process of revision of the Risk Analysis Framework (OGTR, 2005, 2nd edition). GTEC considers that while progress has been made on increasing awareness of the wider context of risk analysis, there is scope for further work in this area. This work draws on the expertise of diverse academic fields such as: sociology of risk; risk communication; the design of risk regulation (including precaution); and, public awareness and understanding of science.

This experience of the first triennium of the regulatory scheme informs GTEC’s recommendation that this role of GTEC should be continued and possibly enhanced. The experience also prompts GTEC to suggest that sections 111(5) (composition of GTEC) and 112 (Functions of GTEC) be reviewed to consider the extent to which they authorise GTEC to fully engage with the *wider context of risk analysis*. GTEC notes that this may not require revision of the GT Act (see also comments made in this submission in relation to Term of Reference 4(b) and Recommendation 11).

GTEC notes that the fact that the theme of the *wider context of risk analysis* re-emerges throughout this submission indicates its importance as an integral component to the regulatory regime.

Recommendation 4: A Re-examination of the Functions of GTEC within the context of the Scope of the Act

GTEC recommends that there be consideration of its role, and of sections 111 – 112 to ensure that the composition and function of GTEC is consistent with the scope of the GT Act.

1 b) the definitions in the Act, including of the environment, and the need for the definition of other terms including health

Definition of “environment”

The definition of the “environment” within the GT Act focuses on “ecosystems and their constituent parts” and also the “natural and physical resources” of environments and the landscape. It excludes from the definition of “environment” such matters as “people and their communities”, plus heritage, social, economic and cultural values. GTEC observes that these factors (in addition to the biophysical elements) are included in the definition of the environment within the *Environmental Protection and Biodiversity Conservation Act 1999* (Cth), (s. 528). Their inclusion within the definition of “environment” in the EPBC Act and their exclusion from the definition of “environment” in the GT Act is consistent with the differing objectives and scope of consideration in each statute. Nonetheless, GTEC believes that these additional elements, contained within the EPBC Act and encompassing the concerns of people and communities and the heritage, social, economic and cultural values relating to genetically modified organisms, do need to be considered in the broad framework for decision-making relating to genetically modified organisms. However, GTEC accepts that consideration of values and community should become relevant to the scope of the Act only so far as they relate to the wider context of risk analysis considered by the statutory committees (see Recommendations 2 & 3).

Recommendation 5: Definition of the “environment”

GTEC recommends that the definition of “environment” not be amended to expand the scope of the GT Act.

Definition of “health”

GTEC notes that “health” is currently not defined within the GT Act. If it is to be defined in the Act then it should be defined narrowly. The World Health Organization (WHO) defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (1948 - not amended). While this is an appropriately broad definition of health for many public health purposes GTEC considers that it is too broad for the GT Act if the Act is to remain consistent with its current risk analysis function.

The GT Act and the OGTR currently includes in an assessment of dealings with GMOs physical health aspects such as: allergenicity, and toxicity in the scientific risk assessment as evidenced in the RARMPs prepared pursuant to the GT Act. Consideration of mental and social health and well-being from, for example, fear and anxiety due to a real perception of risk from genetically modified organisms (regardless of whether those perceptions are

grounded in facts supported by natural science) are beyond the scope of the current GT Act. GTEC does not discount the importance of the mental and social well-being of individuals in the community but does consider that this should not form part of the risk analysis of genetically modified organisms pursuant to the GT Act. However, all aspects of mental and social well-being relating to genetically modified organisms might be assessed and responded to within the broader national health and regulatory framework. GTEC also notes that some aspects of fear and anxiety can be potentially mitigated through appropriate risk management and risk communication and, especially, through attention to ethical communication of information within a scientific risk analysis process, such as that pursuant to the GT Act. GTEC considers that these issues are appropriate for general consideration by expert advisory committees such as GTEC and GTCCC and, particularly, through the use by OGTR of regulatory expertise on risk perception, risk management and risk communication in the RARMPs.

GTEC also notes the WHO draft definition of “environmental health” which “comprises those aspects of human health, including quality of life, that are determined by physical, chemical, biological, social, and psychosocial factors in the environment.” The definition also refers to the theory and practice of assessing, correcting, controlling, and preventing those factors in the environment that can potentially affect adversely the health of present and future generations. Many other definitions of “environmental health” exist from a diverse array of sources and GTEC considers that a modified or adapted definition of environmental health has the potential to be consistent with the current objects of the GT Act.

Recommendation 6: Definition of “health” or “environmental health”

GTEC recommends that consistent with the narrow scope of the GT Act, “health” also should be defined narrowly and in terms of physical health, or indeed, environmental health.

Definition of “risk” and related terminology

The term “risk” is not defined in the GT Act. GTEC has previously considered that a broad definition of “risk” is appropriate to risk assessment, risk management and risk communication pursuant to the GT Act. In *Managing Risk Ethically* GTEC proposes a broad approach to “risk”. This paper has informed the development of the revised Risk Analysis Framework currently applied by the OGTR in the preparation of RARMPs (OGTR, RAF 2nd edition, 2005).

The RAF, in its glossary, defines key terminology underpinning risk analysis pursuant to the GT Act but that terminology is not currently defined in the GT Act. GTEC suggests that, as part of the review, the definition of key terminology relevant to risk, within the GT Act, ought to be considered. However, GTEC notes that defining risk is not straightforward as such definitions vary depending upon the context. For instance, the United States Society of Risk Analysts set up a definitions committee in 1985 and after two years of deliberating published thirteen definitions (Beer and Ziolkowski, *Environmental Risk Assessment: An Australian Perspective*, Commonwealth of Australia, 1995, p.21). One commonly used definition comes from toxicology: risk = hazard x likelihood of occurrence, where hazard = exposure x

effects. In the OGTR's RAF, risk is defined as "the chance of something happening that will have an undesired impact" (OGTR, 2nd edition, 2005 p.2) and risk assessment is defined as hazard identification x likelihood and severity of the consequences. This definition also incorporates uncertainty (OGTR, 2nd edition, 2005 p.18). GTEC notes that, in terms of regulatory design, the definition and explanation of risk terminology and the risk analysis processes in a document such as the RAF has considerable advantage. The accessible form and relative ease with which it may be reviewed, updated and amended by the OGTR permits the risk analysis process to remain appropriately adaptive and responsive to a complex and rapidly evolving risk discourse, as has occurred during the first five years of operation of the GT Act.

If key risk terminology is to be defined within the GT Act, GTEC recommends the adoption of a broad definition of risk and related terminology consistent with the approach taken in the RAF. In this way sections of the Act dealing with risk assessment and risk management (and any additional sections dealing with risk communication) could be universally broadened and re-framed to acknowledge the limits of technical risk analysis in a new field such as gene technology and levels of uncertainty or indeterminacy and how these are managed or taken into account in the decision to issue a licence.

Recommendation 7: Definition of "risk"

GTEC recommends that the wider context of risk analysis ought to be recognised and integrated into the risk assessment, risk management and risk communication provisions of the GT Act (Recommendation 3). Consistent with Recommendation 3, GTEC also recommends that if "risk" is to be defined within the GT Act it should be given a broad definition.

Act achieving objects

2. Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is appropriate.

Section 4 (aa) Inclusion of Precaution in the Regulatory Framework to Achieve Object

GTEC considers that the issue of scientific uncertainty relating to the potential effects of genetically modified organisms on health and safety of people and the environment is a key concern of the regulatory regime. However, GTEC considers that the discussion of precaution in relation to scientific uncertainty, in section 4(aa) of the GT Act, does not address or specify sufficiently issues of scientific uncertainty in decision-making within the regulatory regime.

In this submission GTEC will consider this issue in two parts, dealing first with precaution (or the precautionary principle), and secondly, with the treatment of scientific uncertainty.

(i) Precaution, a Precautionary Approach or the Precautionary Principle

GTEC notes that there are multiple sources of contradiction and ambiguity about the status, meaning and operational effect of precaution within the current GT Act.

- Firstly, the GT Act does not refer to the Precautionary Principle by name, although it does incorporate part of the text of the precautionary approach from Principle 15 of the *Rio Declaration of the Environment 1992*. Within the RAF (OGTR, 2nd edition,

2005) the OGTR has adopted the terminology of precaution (rather than the precautionary principle) and has referred to precaution as one of the 'pillars' of the regulatory system.

- Secondly, the GT Act is in sharp contrast to the EPBC Act (s 391), which lists the decisions for which it is mandatory for the Minister for the Environment to apply the "precautionary principle". In the GT Act there is no equivalent direct obligation placed on the decision-maker to apply the precautionary principle in decision-making.
- Thirdly, there is limited legal elaboration or further definition of the principles of precaution in Federal statutes. Australian legal precedent, such that it is, originates from the lower specialist State and Territory courts and tribunals, thus precedent on the precautionary principle could only ever be persuasive and not binding on Federal courts. Further ambiguity arises because there is also considerable uncertainty and contradiction within that body of lower court case law (Fisher, E. (2003) "Law, Precaution and Administration: The Precautionary Principle and Australian Courts 1993 – 2003", paper presented at *The Precautionary Principle and Environmental Regulation: 10 Years since Leach*, 20-21 November 2003, The Australian National University, Canberra).
- Fourthly, the interpretation of precaution or precautionary principles in Australian statutes is, arguably, dependent upon the statutory regime into which it has been inserted, making it difficult to draw any generalisable legal conclusions about the meaning and interpretation of precaution or the precautionary principle in Australia. Thus, the precise operation of precaution will inevitably depend upon its statutory context.

The legal uncertainty about the interpretation and meaning of precaution in Australia resonates with continued debates in international law and the international academic discourse on precaution and the precautionary principle. These debates have a number of strands that include consideration of: the correct formulation or wording of the principle and its interpretation; the strength or weakness of the principle; the appropriate thresholds of scientific uncertainty for application of the principle; and the extent to which the principle is intended to operate as a scientific principle or as a non-scientific guide for decision-makers. The distinction between precaution, a precautionary approach and the precautionary principle is unclear from the international literature with no definitive terminology (see for example: the terminology of the Wingspread Statement 1998 (Raffensberger, C. Tickner, J (eds) *Protecting Public Health and the Environment*. Washington DC: Island Press 1999); the glossary in Sterling *et al.* (1999) *On Science and Precaution In the Management of Technological Risk*, an ESTO Project Report prepared for the European Commission ; and, more recent EC terminology in Renn *et al* (2003) *The Application of the Precautionary Principle in the European Union: Regulatory Strategies and Research Needs to Compose and Specify a European Policy on the Application of the Precautionary Principle (PrecauPri)*, European Commission). Furthermore, there is also no clear distinction between the precautionary principle, a precautionary approach and precaution in Australian domestic case law.

All of these factors currently contribute to a high level of uncertainty about the legal meaning and interpretation of precaution in Australia and in the GT Act. Nonetheless, the current inclusion of precaution in section 4(aa) of the regulatory regime reasonably creates a public expectation that some notion of 'precaution' - or even, given that the Rio wording is used, the precautionary principle - will be adhered to in decision-making relating to gene modification of organisms. Some interest groups regard the Rio Declaration, or even the wording of section

4(aa) of the GT Act as a ‘strong version’ of the precautionary principle - without appreciating that many academics regard this form of *precaution* as problematic (For a critique of ‘strong’ precaution see Sunstein, C (2003), “Beyond the precautionary principle”, *Pennsylvania Law Review* 151, pp 1003 – 1058; and for a review of both ‘strong’ and ‘weak’ forms see Dorman, P (2005) “Evolving knowledge and the precautionary principle” *Ecological Economics* 53, pp 169 - 176).

GTEC also notes the inclusion of “cost-effective” within section 4 (aa), where it mimics the Rio Declaration but is inconsistent with the broader scope of the GT Act, which excludes social and economic considerations. At least one other Federal legislative formulation of precaution (eg, EPBC, s 391) excludes the words “cost-effective”. In reviewing the GT Act, GTEC recommends that section 4(aa) should be amended to improve consistency with the remainder of the statute. If social and economic considerations are to remain excluded from the GT Act then the term “cost-effective” could be removed.

The most significant issue about *precaution* within the GT Act probably is that it has been inserted into a statutory framework that adheres to a scientific risk assessment and risk management process. Since the Rio Declaration in 1992, the international interdisciplinary academic discourse, especially in Europe, has progressed significantly beyond the ‘strong’ versions of the principle first enunciated. Furthermore, leading European academics now consider that the relationship between precaution and a scientific approach can be “consistent and even mutually reinforcing” (Stirling, A and Gee, D. (2002) “Science, Precaution and Practice” *Public Health Reports* 117, pp 521 - 533). Considerable interdisciplinary research effort and expertise, such as the *PrecauPri* project (referred to above) has been directed towards the development and advancement of sophisticated regulatory strategies for the application of the precautionary principle. Academic consideration of the precautionary principle in terms of the role of science and risk analysis within the context of principles of ‘good’ public administration is clearly continuing (see Fisher, E (2005) “The Precautionary Principle, Administrative Constitutionalism, and European Integration”, accepted for publication in Vos, E (ed)). Furthermore, numerous re-statements of the text of the precautionary principle (for example Wingspread Statement 1998 (referred to above) and the Lowell Statement on Science and The Precautionary Principle 2001, available from: URL: <http://www.uml.edu/centers/lcsp/precaution/> (Accessed 11 July 2005)) have evolved with the current discourse on precaution. GTEC recommends that, in the course of reviewing section 4(aa) of the GT Act, consideration be given to amending either the text of section 4(aa), or some other part of the statute, to make it clear that the inevitably ‘strong’ form of precaution, sometimes historically and popularly associated with the text of Principle 15 of the Rio Declaration, is not regarded as the sole and only legitimate reference point for interpretation and application of precaution within the GT Act.

GTEC supports the science-based risk analysis process, inclusive of precaution, within the current GT Act and notes that the insertion of precaution into a broad regulatory framework, without further statutory prescription, creates potentially significant regulatory discretion as to its use and application within the GT Act. GTEC considers that since the international discourse and experience with precautionary administration is evolving, this high level of regulatory discretion is appropriate at present. GTEC also notes that the Regulator has taken steps, in the first five years of the GT Act, to increase the transparency of the application of precaution within the regulatory framework by further elaborating the OGTR’s approach to precaution within the RAF. GTEC notes that the OGTR, in its most recent RAF (OGTR, 2005, 2nd edition) has engaged with international expertise on broader forms of precaution and

risk analysis as evidenced by reference to the *PrecauPri* project (Renn et al, 2002 (see above)) and the current academic literature (OGTR, 2005, 2nd edition, p 8 – 9. and 103 – 104).

GTEC considers that broad discretion regarding the interpretation and application of precaution is appropriate and allows the Regulator and OGTR, within its scientific risk analysis framework, to respond to international developments in interdisciplinary research on precaution and its application in science-based risk assessment especially as it might relate to regulatory design for the regulation of genetically modified organisms. GTEC has considerable capacity and expertise to advise the Regulator on matters relating to risk assessment and precaution and could develop this further. GTEC considers that the GT Act could be amended to state expressly that the function of the GTEC (s 112) and its membership (s 111 (5)), on the request of the Regulator, is to provide advice on ethical and interdisciplinary issues relating to the review and implementation of a precautionary approach to risk analysis.

Recommendation 8: Precaution within Risk Analysis

GTEC specifically recommends *against*

- (i) adopting the Rio Formulation of the precautionary principle as a mandatory consideration in issuing a licence pursuant to the GT Act.

GTEC recommends

- (ii) retaining ‘precautionary’ or ‘a precautionary approach’ within a risk analysis framework;
- (iii) revising the text of section 4(aa) to reflect current conceptions of precaution within a risk analysis framework and defining relevant terms consistent with current conceptions of precaution within a risk analysis framework;
- (iv) retaining the Regulator’s broad discretion to apply precaution as a part of the risk analysis framework within the GT Act; and
- (v) amending the Functions of GTEC (s 112) to expressly include an advisory role for GTEC relating to the review and implementation of a precautionary approach to risk analysis.

(ii) Issues of scientific uncertainty in risk assessment

GTEC notes the evidence-based approach to risk analysis within the statute and regulations. GTEC also notes the comprehensive treatment of scientific uncertainty in the RAF. GTEC emphasizes the importance of open, transparent statements of scientific uncertainty in order to build public trust and confidence in risk regulation. GTEC considers that transparent exposition and acknowledgement of the limitations to objectivity of science and subjective factors in expert and risk determinations is consistent with a broader approach to risk and an appreciation of the wider context of risk analysis.

Recommendation 9: Scientific Uncertainty

GTEC recommends that separate to consideration of precaution, careful consideration be given to whether or not issues of scientific uncertainty might be referred to in the GT Act, consistent with a broad approach to risk and an appreciation of the wider context of risk analysis.

Operation of the Act

4. Review the consultation provisions of the Act including:

- a) their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide.**

Consultation provisions in the Act include consultation with the public, consultation with stakeholders relevant to licence applications and consultation with expert advisory committees.

Consultation with the public occurs primarily as part of the process for considering licence applications for DIRs. The Regulator may call for public submissions following her initial consideration of a proposed dealing. She is required under Section 52 of the Act to notify the public and invite written submissions on RARMPs. The public input called for, here, relates specifically to the risks to human health and safety or to the environment posed by particular dealings and addressed by RARMPs. This is in keeping with the object of the Act. However, concerns expressed by the public about gene technology frequently extend beyond risk to human health and safety and risk to the environment to encompass related concerns about economic, market, benefit, social or political impacts. The applications for a licence that have received most public submissions have been those proposing to commercially release a GMO. In particular, the applications for commercial release of GM canola by Monsanto and Bayer (DIR 20 and DIR 21) attracted a large number of public submissions, many of which raised matters of concern that were beyond the statutory competence of the Regulator in her decision to issue a licence. We have already emphasised the fact that GTEC supports the science-based risk analysis within the current GT Act and considers that the institutional separation of scientific risk analysis from consideration of other impacts of GMOs, such as economic, marketing and trade or social factors, is a positive feature of the current regulatory system. However, it is important to note that public submissions to the OGTR indicate that the

institutional separation of risk from other types of impact assessments is not well understood by the public.

The inclusion in public submissions of concerns about the economic, market, benefit, social, ethical or political impacts of GMOs may reflect the reasonable assumption that such matters are considered by the Regulator through the work of GTEC and GTCCC. Few members of the public would be aware that these committees do not see submissions made in relation to licence applications or take part in the process of assessment and decision making leading up to the issuing of a licence by the Regulator. It is imperative that if the OGTR has a public consultation process it needs to function effectively. Public submissions are not valuable to the Regulator unless they address matters that have a bearing upon the risks to human health and safety and to the environment posed by the proposed dealing. And, public consultation is valuable to the public only if it has a reasonable chance of being considered by the Regulator. If the public feel that they are listened to, the probability is that the presentation of concerns and advice in public submissions will be carefully considered and that the transparency and accountability dividends from the public consultation process will be enhanced. This raises two questions: Is there a need to respond to those public concerns that lie beyond a strictly scientific appraisal of risk to human health and safety and risk to the environment? If so, how might this be achieved if the object of the Act is not amended?

GTEC thinks that public consultation should continue in relation to licence applications for dealings involving intentional release of a GMO into the environment and that the Regulator should continue to take such public submissions into account, in so far as they raise issues relevant to the decision whether or not to issue a licence. GTEC also supports the provision in the Act currently (s 53(1)) that enables the Regulator to hold a public hearing for the purpose of deciding on an application. However, as noted above under 1(a), GTEC and the GTCCC do not currently consider licence applications for any type of dealing and that the inclusion of these two statutory committees within the regime and the exclusion of ethics and community concerns from what the Regulator can consider when preparing a RARMP or when issuing a licence, arguably creates an anomaly or at least a tension within the Act. GTEC proposes that some of this tension might be addressed by an expansion and re-definition of the roles and functions of the GTEC and the GTCCC.

Recommendation 10: Public Consultation

GTEC recommends that public consultation should continue in relation to licence applications for dealings involving intentional release of a GMO into the environment and the Regulator should take public submissions into account in so far as they raise issues relevant to the decision whether or not to issue a licence.

4(b) the functions and roles of the statutory advisory committees

The current Act provides for three committees of advice to the Regulator on;

1. scientific and technical matters related to gene technology, GMOs and GM products (the Gene Technology Technical Advisory Committee (GTTAC);
2. ethical issues relating to gene technology (the Gene Technology Ethics Committee (GTEC); and

3. matters of general concern in relation to GMOs (the Gene Technology Community Consultative Committee (GTCCC)).

Each of the three committees has the potential to offer advice guided by well-ordered intellectual frameworks. For example, GTTAC has provided expert scientific and technical advice in relation to applications for licences and RARMPs; GTEC has undertaken considerable work on the synthesis of different perspectives in ethics (see B Summary of Activities and Role of GTEC: 2001-2004), and GTCCC has considered ways of improving the communication efforts of the OGTR (such as the website and in RARMPs).

As mentioned previously, GTEC thinks that social, economic, market and trade issues should not be considered by the Regulator when making decisions in relation to licence applications. Nevertheless, such matters form the broader context in which the regulatory system functions. For instance, the regulatory system is viewed by Government as a key component of the overall NBS for the promotion of biotechnology in Australia. Managing risk ethically requires an acknowledgement of this wider context of risk analysis.

The fact that there is a GTEC and GTCCC in the statute suggests that ethical and community issues will be addressed. Under the operation of the Act currently GTEC and GTCCC can raise matters of general ethical or community concern but they do not contribute in any direct way to the consideration of licence applications made under the Act. These two committees may appear, from the outside, to sit apart from the main work of the OGTR and it may be very difficult for an outsider to understand how the deliberations of the ethics and community consultative committees might have an input into a regulatory system that deals exclusively with scientific and technical risk.

There is a need for greater transparency in the role and function of GTEC and GTCCC, as part of the overall operations of the OGTR under the Act. Currently the consultative role of these two committees is limited and it is unclear how “matters of general concern in relation to GMOs”, for instance, (GTCCC function) would ever find their way into the deliberations of the Regulator unless the object of the Act were broadened to include such matters – a change GTEC does not endorse.

The dilemma is more readily stated than resolved but one possibility is for risk analysis to be construed as a more comprehensive problem solving exercise that has its own set of ethical and social impacts. GTEC is aware that a strong tradition in bioethics after 1950 concentrated on individualist perspectives in ethics but notes that, since about 1990, the discussion of political or, more accurately, civic ethics has re-appeared. From that perspective, GTEC (and GTCCC) could legitimately consider both immediate environmental and wider ecological and social implications of dealings with GMOs and consider the mechanisms for sounding, articulating and informing public discussion of the science, technology and social impact of gene technology research and application.

One model for a broader approach to risk analysis that would be consistent with the current object of the GT Act is that proposed by the German Scientific Advisory Council for Global Environmental Change (Renn and Klinke, “Systemic risks: a new challenge for risk management”, *EMBO Reports*, Vol. 5, special issue, 2004 p.S42). In addition to scientific and technical considerations the German Council includes consideration of matters that are of a social and ethical nature. For instance, one of the risk assessment criteria is “violation of equity: the discrepancy between those who benefit and those who bear the risks”, and another

is “potential mobilization: potential violation of individual social or cultural interests and values that generate social conflicts and psychological reactions by individuals and groups who feel afflicted by the consequences. These could also result from perceived inequities in the distribution of risks and benefits”.

Potential mobilization has been divided further by the Centre of Technology Assessment, Stuttgart, into four main elements: 1. inequity and injustice associated with the distribution of risks and benefits over time, space and social status; 2. psychological stress and discomfort associated with the risk or the risk source as measured by psychometric scales; 3. potential for social conflict and mobilisation i.e. public and political pressure on regulatory agencies; and 4. spill-over effects that are expected when highly symbolic losses have repercussions on other fields such as on financial markets or loss of credibility of management institutions (*Ibid.*).

Whilst GTEC is not recommending that its function include consideration of such matters specifically, the criteria outlined above are nevertheless an important reminder of the social context in which the regulation of gene technology takes place. Certain recent disasters, such as the BSE / vCJD example, also remind us that such matters should never be ignored and the effectiveness of risk analysis should never be taken for granted. GTEC and GTCCC could be given a crucial role in evaluating these important ethical and social criteria for the success and acceptance of the regulatory system’s risk analysis. This may have important implications for how risk is communicated and how public consultation is conducted. GTEC is not suggesting that social, economic, or political factors be included in the risk analysis process for licence applications but that the statutory committees could play a more active and explicit role in considering the social, political and ethical ramifications of risk analysis.

GTEC submits that the general ambit of advice to the Regulator covered by GTEC and GTCCC currently should be maintained, with an emphasis on
estimating and articulating the constituency in relation to particular techniques for and products of gene technology and their implications
and
on providing continuing advice about the intellectual frameworks for assessing public concerns.

As noted above, GTTAC, GTEC and GTCCC each has different functions and roles described in the current Act. GTTAC is the only one of these committees to consider licence applications. The current Act limits the scope for input from GTEC and GTCCC on matters relevant to licence applications.

GTEC provides advice “on the request of the Regulator or the Ministerial Council” (GT Act s 112) on ethical issues relating to gene technology and on the need for, and content of, codes of practice in respect of conducting dealings with GMOs and policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons. According to the Act, matters that may require a code of practice or a policy principle would need to be identified by the Regulator or Ministerial Council, who would then seek GTEC’s advice. There is no explicit directive for GTEC to make recommendations for codes of practice or policy principles independent of a request from the Regulator or Ministerial Council. The functions of GTEC do not describe it as providing advice on policy guidelines, which appears to be an oversight in the Act. GTEC does not participate in the process of licence applications and decisions to issue licences. Therefore, GTEC is not readily in a position to identify dealings

with GMOs that should not be conducted for ethical reasons (GT Act s112(c)). Furthermore, GTEC does not have any direct involvement with public consultation or public submissions unless requested to do so.

GTCCC provides advice at the request of the Regulator or Ministerial Council on matters of general concern identified by the Regulator in relation to applications made under the Act, matters of general concern in relation to GMOs, the need for policy principles, policy guidelines and codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the content of such principles, guidelines and codes. As with GTEC, GTCCC provides advice at the request of the Regulator or Ministerial Council and is not directed to make recommendations independent of such requests. GTCCC does not participate in the process of licence applications and decisions to issue licences and does not have any direct involvement with public consultation or public submissions undertaken by the OGTR unless requested to do so. Section 107 (aa) suggests that GTCCC could and possibly should provide advice in relation to applications made under the current GT Act, although this would be limited to matters of general concern identified by the Regulator or Ministerial Council.

The role given to both GTEC and GTCCC under the current GT Act is, therefore, the largely passive one of the provision of advice on request. As noted previously (p. 4 above), consultation on specific applications is possible at the Regulator's discretion. GTEC considers the current provisions of the GT Act, relating to requests for advice are satisfactory, *provided that* the current practice of the Regulator, to accept the advice of GTEC continues. GTEC does not consider it necessary to make a specific recommendation to the Review Panel other than to note the discretionary nature of the referral of matters for GTEC's consideration.

One significant way in which GTEC's input can be made relevant to licence applications is via policy principles (s 21). In the current GT Act the Ministerial Council may issue policy principles on "ethical issues relating to dealings with GMOs". GTEC is working on a framework of ethical values and principles that we anticipate will become a policy principle issued by the Ministerial Council. GTEC recognises that the scope for input of GTEC via policy principles is evolving. Nevertheless, GTEC is of the view that in the revision of the Act consideration should be given to ways in which the expertise of GTEC might be incorporated more fully into the operations of the OGTR. For instance, the core business of the OGTR and the Regulator is the assessment of licence applications. GTEC is of the view that there may be good reasons, at times, for GTEC to consider licence applications directly. Currently the GTCCC provides advice on "matters of general concern identified by the Regulator in relation to applications made under this Act" (s107 (aa)). However, there is no analogous provision in GTEC's functions. GTEC recommends that its function should include consideration of ethical issues in relation to applications made under the Act. To enable this function, applications might be referred to GTEC where appropriate.

The first triennium of GTEC has provided the committee with the opportunity to develop its role and function pursuant to the GT Act. Based on this experience GTEC believes that:

- i) GTEC's consideration of ethics should embrace wider socioeconomic and environmental issues relevant to risk analysis;
- ii) GTEC should provide advice on ethical and interdisciplinary issues relating to the review and implementation of a precautionary approach to risk analysis;

- iii) GTEC should continue to keep abreast of local and international developments in ethics and provide an active forum for discussion of ethical issues relevant to gene technology and its regulation;
- iv) GTEC should give consideration to, and advice on, the ethics of risk analysis that is informed by wider socio-economic and environmental issues;
- v) There may be times when applications might be referred to GTEC where appropriate; and
- vi) GTEC should continue to provide advice on policy principles and codes of practice.

Recommendation 11: Functions and Roles of Statutory Advisory Committees

GTEC recommends that its role and function include:

- a) keeping abreast of local and international developments in ethics and provide an active forum for discussion of ethical issues relevant to gene technology and its regulation;
- b) giving consideration to, and advice on, the ethics of risk analysis that is informed by wider socio-economic and environmental issues relevant to risk analysis;
- c) provision of advice on ethical and interdisciplinary issues relating to the review and implementation of a precautionary approach to risk analysis;
- d) provision of advice on ethical issues identified in relation to applications made under the Act;
- e) consideration of applications for licences where appropriate
- f) provision of advice on the need for, and content of, codes of practice in relation to ethics in respect of conducting dealings with GMOs; and
- g) provision of advice in the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.

General Comments on the role and function of GTEC and GTCCC

The Gene Technology Bill 2000 proposed a GTTAC and one committee (GTEC) to provide advice on ethical issues. During the first triennium of GTEC's operations, however, it embrace ethics in the broad sense noted above, to include consideration of socio-economic and environmental issues that it construed as relevant to proper ethical analysis.

In the three years of GTEC and GTCCC operations there have been many instances where issues of concern have been raised in one committee that were also relevant to the functions of the other committee. On several occasions the cross-member between GTEC and GTCCC has recommended that the two committees would do well to combine their expertise and efforts to address matters such as the release of information and notification of DIRs, public

attitudes on trans-kingdom gene transfer, and public attitudes to GMOs, as they might be relevant to the ethics of risk analysis or to ethical values and principles in general. Some roles and functions of GTEC and of GTCCC also overlap: both provide advice to the Regulator on matters of community concern (ethical and social issues) in relation to gene technology, both are required to keep abreast of local and international developments relevant to gene technology and both provide a forum for discussion and the provision of information to the community. It could be argued that the overlap between the two committees represents a duplication of operations and that greater efficiency would be achieved if one advisory committee were to provide advice on ethical and social issues.

GTEC notes that the membership provisions of GTEC in the s.111 of the Act currently require persons with skills or experience in areas such as ethics, law, religious practices, population health, agricultural practices, animal health and welfare, issues of concern to consumers in relation to gene technology and environmental systems. Membership of the GTCCC requires persons with skills or experience in environmental issues, consumer issues, the impact of gene technology on the community, issues relevant to the biotechnology industry and to gene technology research, public health issues, issues relevant to primary production and local government. Here too there is overlap. Both committees must have members competent to advise on public health, environmental and consumer issues.

GTEC notes that the GTCCC was established following a Senate amendment to the Bill. GTEC also understands that there is no analogous committee in any other local or international jurisdiction. GTEC suggests that the roles and functions undertaken across the two committees currently might be more efficiently combined and undertaken by one committee. GTEC suggests that the Review Panel consider the possibility of a regulatory system with two, rather than three, advisory committees: a technical advisory committee (GTTAC) and one committee that provides advice to the Regulator and Ministerial Council on ethics but in the broad sense in which GTEC has been operating over the past three years: embracing ethical, social and community concerns. GTEC suggests that an ethics committee, broadly conceived, would, with appropriate membership, in addition to advising on other ethical and risk matters, also have the expertise and experience to provide sound advice to the Regulator and the Ministerial Council on the provision of information to the community on matters of ethical and social concern in relation to gene technology.

4(d) the stakeholders included in consultations for various applications under the Act

GTEC considers that the most appropriate avenue for the expression of stakeholder views is via the process of public submissions and /or public hearings in relation to applications and via the advisory committee/s. Section 47(4) stipulates entities (authorities, committees, agencies and individuals) the Regulator may consult in relation to applications. GTEC proposes that GTEC be added to this section of the Act.

Recommendation 12: Consultation on Applications

GTEC recommends that GTEC be listed under Section 47(4) as committees the Regulator may consult in relation to applications.

Regulatory Burden

- 6. Examine whether compliance and administrative costs, including information requirements, for organisations working in gene technology are reasonable and justified compared to the benefits achieved and possible alternatives to legislation.**

GTEC has in the past expressed the view that full cost recovery of administrative costs of the regulatory system would be highly undesirable. GTEC stands by this view for the following reasons.

1. Full cost recovery has the potential for inequity since it would favour those applicants who could afford to pay and could have the effect of discouraging smaller research organizations or companies from conducting work using gene technology.
2. Seeking full costs from public research institutions would be unfair and potentially futile since researchers would be likely to add the cost to their grant applications or request it from their institution, which in most cases are sources of public funding.
3. Full cost recovery has the potential to undermine public trust in the Regulator if the public perceives, even erroneously, that the approval of licence applications can be bought.

If there is to be a fee charged for licence applications it would need to be set at a level that most potential applicants could afford and publicly-funded research should be exempt.

Recommendation 13: Regulatory Burden

GTEC has serious reservations about implementing full recovery of administrative costs. GTEC proposes that any fee charged for licence applications should be set at a level that most potential applicants could afford and that publicly funded research should be exempt.

Interface with other systems

- 9. Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies, including regulatory gaps and areas needing consistency and harmonization of provisions.**

Section 21 of the GT Act creates a mechanism that permits the Ministerial Council to designate, under State law, areas of the States and Territories that may be GM or non-GM for marketing purposes. GTEC notes that this mechanism enables the scientific assessment of risks to be conducted separately from consideration of other issues (which, so far, have been marketing issues). While the institutional separation of scientific aspects of risk analysis from other considerations, such as economic, social and cultural factors is a positive feature of the current regulatory system, GTEC considers there is an obvious advantage to having a single national scientific risk analysis. However, if States or Territories, having access to that national analysis of potential harm to human health, safety or the environment, subsequently consider that social or economic risks, or indeed the social or economic benefits, of a new

technology outweigh predicted environmental or health effects, then section 21 provides a potential mechanism for more localized (State or Territory based) policy on genetically modified organisms. The separation of the scientific assessment of risk from social and economic policy choices provides for a more open and transparent regulatory system. [There are many examples of regulatory systems and institutional design that achieve this separation, for instance, the Netherlands EIA system <http://www.eia.nl/eia/sitemap.htm>]

GTEC makes no specific recommendation with respect to Term of Reference 9. Rather, it refers the Review Panel to **Recommendation 2**, which also applies to this section of the GTEC submission.

Changing Circumstances

10. Examine emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances.

GTEC should consider international developments and “advise the Regulator accordingly” - because that knowledge would broaden local understanding of the links between consultation, constituency development and the articulation of policy. For example, in both France and the United Kingdom, carefully conducted public consultations have achieved some success both in forcing people anxious about GMOs to address issues and articulate specific responses to them (rather than objecting in general) and in forcing people with high levels of expert knowledge to recognise the relevant field experience of agricultural producers. [See, for example, Les Levidow & C. Marris: “Science & Governance in Europe: lessons from the case of agricultural biotechnology” *Science & Public Policy* 28:5 (2001) 345-360; Durant, Bauer & Gaskell: *Biotechnology in the Public Sphere* (London Science Museum 1998): 217-227; United Kingdom: Environment Agriculture & Biotechnology Commission (2002)]

Recommendation 14: Emerging Trends and International Developments

GTEC should routinely monitor international developments relevant to the wider context of the risk analysis of gene technology and its regulation and advise the Regulator accordingly.

Changes to the legislation

11. Recommended amendments to the Act (including consideration of those recommendations made by State or Territory Parliamentary Committees), or alternatives to legislation, which improve the effectiveness, efficiency, fairness, timeliness and accessibility of the regulatory system.

GTEC considers that all non-regulatory mechanisms such as (for example) voluntary agreements, market based instruments, self-audit and other voluntary incentives are unsuitable for the regulation of gene technology at this stage. The enforcement of gene technology regulation is more appropriately regulated by traditional ‘command and control’ regulatory techniques.

Recommendation 15: Changes to Legislation

GTEC recommends that nationally consistent legislation be maintained to regulate gene technology in Australia.

E. List of Recommendations

Recommendation 1: Object of the GT Act (s 3) and Risk Analysis Scope of GT Act (ss 51 and 56)

GTEC recommends that the GT Act should continue to give primacy to considerations of human health and safety and to the environment. Therefore these sections of the Act should remain unchanged.

Recommendation 2: Consideration of economic, marketing, trade, cultural and social impacts

GTEC supports the current exclusion of economic, marketing, trade, cultural and social impacts from the decision-making process in relation to GMO applications.

Recommendation 3: The Wider Context of Risk Analysis

GTEC recommends that the wider ethical and social context of risk should be recognised and considered in risk analysis.

Recommendation 4: A Re-examination of the Functions of GTEC within the context of the Scope of the Act

GTEC recommends that there be consideration of its role, and of sections 111 – 112 of the Act, to ensure that the composition and function of GTEC is consistent with the scope of the GT Act. (See also Recommendation 11)

Recommendation 5: Definition of the “environment”

GTEC recommends that the definition of “environment” not be amended to expand the scope of the GT Act.

Recommendation 6: Definition of “health” or “environmental health”

GTEC recommends that, consistent with the narrow scope of the GT Act, “health” also should be defined narrowly and in terms of physical health, or indeed, environmental health.

Recommendation 7: Definition of “risk”

GTEC recommends that the wider context of risk analysis should be recognised and integrated into the risk assessment, risk management and risk communication provisions of the GT Act (Recommendation 3). Consistent with Recommendation 3, GTEC also recommends that, if “risk” is to be defined within the GT Act, it should be given a broad definition.

Recommendation 8: Precaution within Risk Analysis

GTEC specifically recommends *against*

- i). adopting the Rio Formulation of the precautionary principle as a mandatory consideration in issuing a licence pursuant to the GT Act.

GTEC recommends

- ii). retaining a precautionary approach within a risk analysis framework;
- iii). revising the text of section 4(aa) to reflect current conceptions of precaution within a risk analysis framework and defining relevant terms consistent with current conceptions of precaution within a risk analysis framework;
- iv). retaining the Regulator's broad discretion to apply precaution as a part of the risk analysis framework within the GT Act; and
- v). amending the Functions of GTEC (s 112) to expressly include an advisory role for GTEC relating to the review and implementation of a precautionary approach to risk analysis.

(See also Recommendation 11)

Recommendation 9: Scientific Uncertainty

GTEC recommends that, separate to consideration of precaution, careful consideration should be given to whether or not issues of scientific uncertainty might be referred to in the GT Act, consistent with a broad approach to risk and an appreciation of the wider context of risk analysis.

Recommendation 10: Public Consultation

GTEC recommends that public consultation should continue in relation to licence applications for dealings involving intentional release of a GMO into the environment and the Regulator should take public submissions into account in so far as they raise issues relevant to the decision whether or not to issue a licence.

Recommendation 11: Functions and Roles of Statutory Advisory Committees

GTEC recommends that its role and function should include:

- a) keeping abreast of local and international developments in ethics and provide an active forum for discussion of ethical issues relevant to gene technology and its regulation;
- b) giving consideration to, and advice on, the ethics of risk analysis that is informed by wider socio-economic and environmental issues relevant to risk analysis;
- c) provision of advice on ethical and interdisciplinary issues relating to the review and implementation of a precautionary approach to risk analysis;
- d) provision of advice on ethical issues identified in relation to applications made under the Act;
- e) consideration of applications for licences where appropriate
- f) provision of advice on the need for, and content of, codes of practice in relation to ethics in respect of conducting dealings with GMOs; and
- g) provision of advice in the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.

(See also Recommendations 4 and 8)

Recommendation 12: Consultation on Applications

GTEC recommends that GTEC be listed under Section 47(4) as an entity the Regulator may consult in relation to applications.

Recommendation 13: Regulatory Burden

GTEC has serious reservations about implementing full recovery of administrative costs. GTEC proposes that any fee charged for licence applications should be set at a level that most potential applicants could afford and that publicly funded research should be exempt.

Recommendation 14: Emerging Trends and International Developments

GTEC should routinely monitor international developments relevant to the wider context of risk analysis of gene technology and its regulation and advise the Regulator accordingly.

Recommendation 15: Changes to Legislation

GTEC recommends that nationally consistent legislation be maintained to regulate gene technology in Australia.