

# National Framework for the Development of Ethical Principles in Gene Technology

Gene Technology Ethics Committee

## **National Framework for the Development of Ethical Principles in Gene Technology**

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## **Gene Technology Ethics Committee**

# **National Framework for the Development of Ethical Principles in Gene Technology**

June 2006

The Gene Technology Ethics Committee (GTEC) is a statutory advisory committee established under Section 111 of the *Gene Technology Act 2000* (Cwth) to advise the Gene Technology Regulator and the Gene Technology Ministerial Council. The opinions expressed in this discussion paper represent the views of the GTEC and do not necessarily reflect those held by the Office of the Gene Technology Regulator that provides the Secretariat to the Committee.



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# 1 Introduction

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The *National Framework for the Development of Ethical Principles in Gene Technology* (National Framework) has been developed by the Gene Technology Ethics Committee (GTEC) to raise awareness of ethical issues relating to gene technology under the *Gene Technology Act 2000* (see section 112) (the Act).

In the following sections, the purpose and intended audience of the National Framework are explained. Section 2 provides background information on how and why the National Framework was developed, while Sections 3 and 4 discuss the main values relating to gene technology, and list the nine ethical principles derived from the values.

## 1.1 Purpose of the National Framework

The purpose of this National Framework is to provide the Australian community, particularly scientists working in gene technology, with a national reference point for ethical considerations that may be taken into account when developing values and ethical principles relevant to environmental and health issues in gene technology, genetically modified organisms (GMOs) and genetically modified (GM) products.

**This National Framework:**

- identifies values and ethical principles relevant to work involving gene technology
- aims to promote discussion on the ethical development of gene technology for the good of the community by protecting its health and safety, and to recognise obligations to protect the environment and other living things
- provides nine principles relating to gene technology and to GMOs in particular, which are intended to be useful to scientists and the community.

The National Framework was developed with the understanding that a transparent decision-making process clearly showing the reasoning used is most likely to result in well-informed ethical decisions. Therefore, GTEC hopes that all those involved in gene technology will integrate the values and ethical principles of the National Framework into their decision making, to make ethical decisions with confidence, transparency and good judgement. This is consistent with the *Australian Biotechnology: A National Strategy (2000)* (the National Strategy) (see Appendix 2), which aims to foster public trust in gene technology.

## 1.2 Audience

The National Framework is intended to guide all those working in gene technology by listing the issues that those working in gene technology should reflect in their work and decision making.

By providing this information, the National Framework is also of general interest to the Australian community, who may be affected – either directly or indirectly – by gene technology.

The National Framework is of particular relevance to scientists working in the field of gene technology, and highlights the values and principles relevant to their work that extend beyond the specific provisions of the Act. The values and principles cover research involving gene technology, and the scientific issues and consultative processes that are involved in preparing risk-assessment and risk-management plans that form the basis of licence decisions by the Gene Technology Regulator (the Regulator).

Consequently, the values and principles are also relevant to members of Institutional Biosafety Committees that are recognised under the Act, and that carry out essential risk-assessment functions on behalf of their organisations. Institutional Biosafety Committees form an important connection with the Office of the Gene Technology Regulator (OGTR), and GTEC hopes that the National Framework will be useful for such committees.

The National Framework is also relevant to members of Animal Ethics Committees (AECs are specific to each jurisdiction or institution) when they consider applications that involve the genetic modification of animals. The National Framework therefore also supplements the *Australian Animal Welfare Strategy* (National Consultative Committee on Animal Welfare 2004), the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* and the *Guidelines on the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes* (National Health and Medical Research Council 2004 and 2006 respectively).

### 1.3 National Framework: Guidance not Guidelines

The National Framework is intended to provide a national reference point to promote an ongoing dialogue on values and ethical principles relevant to gene technology. The National Framework may also provide guidance for the development of values and ethical principles for those working with gene technology, scientists, research institutions, regulatory and ethics committees, as well as the general community.

The National Framework does not provide enforceable directions. These values and ethical principles are a guide but are not mandatory. The National Framework is a foundation document, which may be used to shape future guidelines and codes of practice.

GTEC will review the National Framework after three years, and will consider whether these values and ethical principles should be continued, amended, or possibly recommended to the Ministerial Council for introduction as mandatory Policy Principles under the *Gene Technology Act 2000* (see Sections 21-24, 112).

During this three year period, GTEC will promote the National Framework, both nationally and internationally, and maintain an ongoing dialogue with the research community, such as through presentations at conferences and to Institutional Biosafety Committees.



## 2 Context for developing the National Framework

The National Framework was developed by GTEC in the context of its responsibilities under the Act. The national regulatory system for gene technology is a key component of the National Strategy. Box 1 summarises the development of the Strategy, Act and National Framework.

### Box 1 A nationally consistent approach to gene technology regulation

In 1999, the Interim Office of the Gene Technology Regulator developed draft legislation for gene technology regulation, following an extensive consultation process involving a wide range of key stakeholders, including the public.

In 2000, the Gene Technology Bill 2000 was passed to become the *Gene Technology Act 2000* (the Act), and *Australian Biotechnology: A National Strategy (2000)* (the National Strategy), developed by Biotechnology Australia, was released.

The Gene Technology Ethics Committee's *National Framework for the Development of Ethical Principles in Gene Technology* was developed in the context of its responsibilities under the Act. The national regulatory system for gene technology is a key component of the National Strategy.

The National Strategy is aligned with international standards and acknowledges the emergence and development of environmental ethics that underpin gene technology, such as the care and protection of the environment and natural ecosystems, respect for biodiversity, the precautionary approach, and encouraging sustainability.

The National Strategy, which is committed to the development of biotechnology and safeguarding human health, and ensuring the protection of the environment, states:

Consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment.

Public trust is an important factor in the success of the National Strategy. Compliance with the legislation, as well as the maintenance of high ethical standards in the private or public sector, are essential for public trust.

The National Framework has been developed with reference to the work of earlier Australian committees, including the Genetic Manipulation Advisory Committee (1987–2001), the Recombinant DNA Monitoring Committee (1981–87), and the Academy of Science Committee on Recombinant DNA Molecules (1975–81).

The Academy of Science Committee on Recombinant DNA Molecules was created in 1975 to oversee the development and use of gene technology in Australia. The Recombinant DNA

Monitoring Committee took over this function in 1981, but was succeeded in 1987 by the Genetic Manipulation Advisory Committee (GMAC) following the development of new techniques for modifying the genetic make-up of cells. GMAC was a non-statutory body, which assessed risks to human health and the environment posed by novel techniques of genetic manipulation.

## 2.1 The *Gene Technology Act 2000*

The development of the Gene Technology Bill (the Bill) took place over a two-year period and was a collaborative effort between the Australian Government, and state and territory governments. It involved an extensive public consultation process that included circulation of a consultation paper (titled *Proposed national regulatory system for genetically modified organisms – How should it work?*). Calls for submissions and invitations to public forums were published in newspapers in all jurisdictions, on the Interim Office of the Gene Technology Regulator's website, and mailed directly to more than 2500 interested individuals and organisations.

This comprehensive process generated broad agreement that the object of the Act would be to protect the health and safety of people and the environment from risks posed by, or as a result of, gene technology by identifying those risks and managing them through the regulation of certain dealings with GMOs. Many submissions stressed the importance of ethics in the development of gene technology, as well as a rigorous scientific assessment of risks. These submissions influenced the introduction of a specialist ethics committee in the draft legislation.

The Bill was referred to a Senate Committee Inquiry and also subjected to extensive parliamentary debate over a six-month period. This resulted in a number of amendments before the Act passed into law in December 2000, and commenced operation on 21 June 2001.

The Act, supported by the *Gene Technology Regulations 2001* (an intergovernmental agreement signed by all jurisdictions), and corresponding legislation that is being enacted in each state and territory, constitutes Australia's nationally consistent system for regulating dealings with GMOs (including experimentation, production, breeding, importation, or use of GMOs in manufacture) to protect human health and safety and the environment.

The Act sets down a comprehensive and rigorous process for the scientific identification, assessment and management of risks posed by gene technology. The Act also includes comprehensive consultation processes as part of risk-assessment procedures for intentional releases of GMOs into the environment, and allows associated ethical issues to be considered.

Further information is available on the OGTR website (<http://www.ogtr.gov.au/about/index.htm>).

## 2.2 The Gene Technology Ethics Committee

Under the Act, three committees were established to provide advice to the Regulator. These committees are the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Community Consultative Committee (GTCCC), and the Gene Technology Ethics Committee (GTEC). Part 8 of the Act sets out the range of skills or experiences that committee members must have.

GTEC provides advice to the Regulator on ethical issues relating to gene technology, the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons, and codes of practice in relation to ethics.

Policy principles are documents issued by the Gene Technology Ministerial Council. The Regulator must not act inconsistently with policy principles issued by the Ministerial Council.

At this stage, it is not intended that this National Framework be recommended as a policy principle.

## 2.3 Influences in the development of the National Framework

To develop the National Framework of values and principles, GTEC took the following documents and discussions into account (see Appendix 1 for selected references):

- provisions of the Act
- provisions of the National Strategy
- provisions of international conventions
- relevant philosophical and academic literature
- surveys of, and literature on, community concerns and uncertainty about GM technology
- established codes of ethics governing research integrity, and medical and animal research ethics
- other ethical frameworks dealing with environmental ethics and gene technology.

GTEC circulated two draft versions of the National Framework and received submissions covering a wide range of issues from a diversity of sources. Comments included suggestions for aligning the National Framework with existing guidelines, concern about how the principles would be implemented and regulated, and recommendations that sections on environmental ethics be strengthened.

Overall, submissions were supportive of the need for, and intent of, the National Framework to provide a foundation for future discussions and guidelines relating to ethics in gene technology, as well as to establish a consistent approach to assessing the ethics of such technology in Australia.

## 2.4 Existing ethics frameworks and codes

GTEC notes and supports the complementary ethics codes and statements developed by state and territory governments, as well as the ethics framework prepared by the New Zealand Environmental Risk Management Authority.

The current review of the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (1997) by the National Health and Medical Research Council, the Australian Vice-Chancellors' Committee and the Australian Research Council, is an opportunity to integrate gene technology principles with a broader set of guidelines.

The Queensland Government has revised and renamed its code of ethical practice for biotechnology, the *Code of Ethical Practice for Biotechnology in Queensland*. This code was released in 2001 and addresses a broad range of matters relating to the use of biotechnology such as GMOs, consumer and patient information, and medical research and health care. The principles identified in this code are integrity, beneficence and non-maleficence, respect for people, care and protection of animals, justice, and respect for the law and system of government.

The Victorian Biotechnology Ethics Advisory Committee has published the *Victorian Statement of Ethical Principles for Biotechnology* (2006). The ethical principles identified in the Victorian Statement are respect for persons, respect for animals, respect for the natural environment, respect for the public good, benefit and harm, justice and equity, probity and accountability.

Similarly, the principles identified in the New Zealand Environmental Risk Management Authority *Ethics Framework* (2005) are complementary to those identified by GTEC. Their Ethics Framework contains two general principles (respect for the environment and respect for people, including past, present and future generations), which are manifested in nine specific principles of concern for animal welfare, autonomy, cooperation, cultural identity and pluralism, human rights, human dignity, justice and equality, sustainability, and wellbeing or nonharm.

These general and specific principles are achieved through procedural standards of honesty and integrity, transparency and openness, sound methodology, community and expert consultation, and a fair decision-making process.

## 3 Ethics for gene technology

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### 3.1 Background

Ethical issues are based on individual, group and societal answers to questions about what they value as good, or what they believe to be the right thing to do. Acceptable — and unacceptable — practices are defined in legislation; therefore, a society's ethical values, and the ethical consequences of any decisions, must be considered when drafting new legislation or regulation.

In addition, a society's cultural and spiritual values are reflected in its ethical considerations. Ethical decision making, for example about environmental issues such as GMOs, should take into account these values, including different views on the relationships between human beings, animals and the environment.

Decisions about gene technology require those involved to assess the ethical consequences of their actions. This requires them to not only consider whether an action is scientifically or technically achievable, but also whether it is ethically acceptable. Therefore, strict scientific analysis of risk is not sufficient for ethical decision making about gene technology (for more information, see Robins and Fleming 2004, and Environmental Risk Management Authority New Zealand 2005, in Appendix 1).

In the area of research involving humans, the basic regulatory framework depends on well-established codes of ethical practice, such as the key international reference point of the *Declaration of Helsinki*. In Australia, the reference point is the *National Statement of Ethical Conduct in Research Involving Humans* (National Health and Medical Research Council 1999). In the case of research involving animals, there is a statutory framework within state and territory animal welfare acts. The statutory framework has been supplemented gradually by codes of practice and ethical principles developed by the National Health and Medical Research Council, in particular the seventh edition of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (2004) (the Code of Practice). Section 1 of the Code of Practice sets out the general principles for the care and use of animals for scientific purposes, including the responsibilities of investigators and institutions, and the use of replacement, reduction and refinement techniques wherever possible.

Where genetic modification involves animals, the Code of Practice specifies principles of conduct relating to the welfare of laboratory animals used to develop genetically modified animals, and the genetic modification of production animals.

In developing the National Framework, GTEC recognises that ethical thinking in areas of medical and animal research is well developed. Environmental ethics or the ethics of gene technology are at earlier stages of development. There are no gene technology or environmental equivalents of human research ethics committees or animal care and welfare committees. Existing codes

of medical research ethics contain statements of broadly agreed and consistent principles, but there are no equivalent international codes in relation to generally agreed principles for environmental ethics. However, there are a number of international declarations and statements dealing with the environment.

The New Zealand *Ethics Framework* (Environmental Risk Management Authority New Zealand 2005) identifies the following practical problems in environmental decision making and management that raise ethical questions:

- sparse or poor-quality data
- uncertainty or lack of understanding of cause–effect relationships
- long lead times between cause and effect and realisation of harm or benefit (thus involving the balancing of short-term gain against possible long-term loss)
- the need for complex interactions between the social, cultural, ecological, economic and technical aspects to be considered
- methods of selecting reference points for measuring changes in ecosystems
- the need to consider the acceptability or tolerability of particular environmental risks
- the perspectives and needs of multiple decision makers and stakeholders
- complications arising from multiple objectives.

This National Framework seeks to redress the deficiency in relation to gene technology and the environment in the Australian context.

### 3.2 Values relating to gene technology

In developing the National Framework, and in particular the nine principles, GTEC identified the following values as the most relevant for ethics of gene technology. The values are derived from general philosophical writings and debate, environmental discussions, and international documents (for examples, see Appendix 1). Although this list may not be exhaustive, these values are important because they are part of a common currency in discussions about the ethics of gene technology.

#### Respect for human life

Gene technology is grounded in the life sciences. Accordingly, the value of respect for human life is of central importance. All humans intrinsically deserve respect — irrespective of age, ethnic background, cultural group, gender, economic status, religious beliefs, or any other factor. Respect for human beings is expressed as regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage, both individual and collective, of people likely to be affected by gene technology. No person should ever be used merely as a means to some other end; however, fair conduct is not reducible to the idea that all people should be treated ‘equally’ in all circumstances. In some cases, it may be equitable to treat differently those individuals or groups who have relevant differences such as needs and entitlements. Where relevant differences are cited as a reason for discriminatory treatment (whether favourable or not), the arguments and criteria should be transparent and well justified. For example, in making ethical decisions

involving GMOs, people should ensure the fair and just treatment of all whose interests are, or are likely to be, affected.

### Respect for animals

There is widespread recognition of the value of respect for animals, though different views exist on how such respect should be defined and what the resulting human obligations are toward animals. Some philosophers have argued that animals have significant intrinsic moral status. More commonly, many people believe that the value of respect for animals arises from recognition that some types of animals are sentient (able to feel pain and endure suffering). This approach is reflected in animal welfare legislation in most countries, including Australia, that is designed to prevent cruelty to animals. In addition, there are guidelines to regulate animal research which require researchers to strive to replace animals with other types of experimental models or systems, to reduce the number of animals involved in individual experiments, and to refine experimental research projects to minimise harm to animals. Respecting animals used or generated for research involving genetic modification also requires consideration of the possible consequences associated with the welfare of modified animals, as well as the possible effects on human and animal health and the environment.

### Respect for the environment

The environment is of great objective value, and humans have legal and ethical duties to protect, conserve and preserve organisms, species, natural ecosystems, natural and physical resources, and the qualities and characteristics of locations, places and areas, both on local and global levels.

Respect for the environment is often associated with sustainable development and management, as well as protecting biodiversity and ecosystem integrity and showing respect for individual species. Humans should ensure that the built environment and human activities cause the least possible harm to the environment as a whole, to animal and plant populations, and to sites of historic or cultural significance. Decision making should consider the impact on these components of the environment, how they function as a whole, and how the environment evolves over time in response to external stimuli.

Humans also have duties to achieve sustainable development for present and future generations, while recognising that environmental protection is an integral part of development and cannot be considered in isolation from it.

### Freedom of choice

Freedom of choice is closely related to the value of respect for human life. The capacity to make autonomous choices underpins the possibility of attributing responsibility to humans, and allows them to be responsible for their actions and their influence on the world, rather than being mere spectators to unfolding events. Therefore, freedom of choice is central to the recognition of the autonomy of humans and the respect that they enjoy as people. The possible effects of gene technology on human life and freedom should be major considerations in any debates about the value of knowledge to be gained from this type of research.

## Acquiring and applying knowledge

Knowledge is a cornerstone of human civilisation and has diverse origins. As the highest achievement of the human mind, it is of intrinsic value and allows humans to reach a deeper understanding of themselves and the world in which they live. The application of knowledge can also increase human, animal and environmental wellbeing. This is recognised in the National Strategy, which encourages the development and application of research and scientific knowledge associated with gene technology for the benefit and wellbeing of the community. In addition, sharing and reflecting on existing knowledge held by stakeholders outside of the scientific community, may also contribute to the wellbeing of humans and animals and the environment.

## Reasoned argument and decision making

The application of reason recognises the importance of evidence and reasoned argument to resolve complex practical and theoretical questions, and conflicts between alternative views. Reasoned decision making stands in contrast to making choices based on unsubstantiated opinions or the narrow pursuit of self or commercial interest.

## Trust

Trust in institutions, public officials and the professions are critical underpinnings of a democratic society. Public trust in, and accountability of, the corporations, institutions and scientists working in the development and use of gene technology is an important value for the success of these technologies. The value of public trust is implicit and recognised in the National Strategy, the regulatory framework established in the Act, and the corresponding state and territory legislation.

The *Gene Technology Act 2000* acknowledges the value of public trust through the inclusion of procedures, particularly those to ensure transparency and consultation. Transparency and public participation are required at many stages in the regulatory system, such as, during consideration of licensing applications and assessments (section 52), inclusion on the GMO Register (section 81), the operation of the advisory committees (part 8) and the issue of policy principles or codes of practice (sections 22, 24). The workings of the office and licences issued by the Gene Technology Regulator are publicly available on the OGTR website at <http://www.ogtr.gov.au/about/index.htm>

## Integrity

The value of integrity is related closely to the value of trust. The value of integrity recognises that individuals have an ethical responsibility for their own conduct to act rightly, avoid conflicts of interest and deal honestly and truthfully with others. The value of integrity applies also to the dealings of corporations. Commitment by individuals, scientists, corporations and institutions to behave with integrity helps to build public trust. In the area of human research, the *National Statement of Ethical Conduct in Research Involving Humans* states that research conducted with integrity is carried out by researchers who are committed to the search for knowledge and the honest and ethical conduct of research (Chapter 1.2).



## 4 Ethical Principles in gene technology

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There is a commitment in the National Strategy to ‘ensuring environmental protection’. In general, this will be achieved through strict compliance with the risk assessment and licensing provisions of the Act. In addition, those working with GMOs should not only adhere to the Act but also aspire to right conduct.

GTEC has developed the following nine principles that should guide researchers and all others involved with gene technology, GMOs and GM products. These principles help to ensure that the values identified in Section 3.2 shape policies and actions that arise when dealing with gene technology, GMOs and GM products.

The principles are not ranked or listed in any particular order, but instead are intended to cover the most important ethical issues that should be taken into account. These principles should be considered in a balanced way, without compromising one principle while attempting to realise another.

**Researchers and all others involved in gene technology should:**

- treat integrity as the guiding value in the search for and application of knowledge and benefits and in regard to the obligations of, and intentions underlying, the national regulatory system and other relevant guidelines and regulations (Principle 1)
- take responsibility for ensuring that activities within their control do not cause damage to the Australian environment or to areas beyond the limits of the national jurisdiction; to achieve this, there must be a thorough assessment of the long-term side effects of applications of gene technology (Principle 2)
- minimise risks of harm or discomfort to humans and animals likely to be adversely affected by gene technology (Principle 3)
- assess and respect the environmental and health needs of present and future generations (Principle 4)
- conduct research in a manner that protects the environment, including protection of genetic diversity, organisms, species, natural ecosystems, and natural and physical resources (Principle 5)
- act justly towards others, and demonstrate respect for human beings (as individuals and group members) in all activities associated with gene technology, including obtaining proper consent (Principle 6)
- promote equitable access to scientific developments and sharing knowledge, and recognise the value of benefit sharing (Principle 7)
- conduct research in a manner that promotes the benevolent and avoids the malevolent uses of gene technology (Principle 8)

- conduct gene technology research after appropriate consultation and ensuring transparency and public scrutiny of the processes (Principle 9)

The principles are provided for *guidance* and are not intended to be prescriptive at this stage. They may form the basis upon which Codes of Practice or policy principles (under the relevant provisions of the Act and the corresponding state and territory acts) may be developed at a later stage.

## 5 Summary and review of the National Framework

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GTEC has developed this National Framework to raise awareness of, and encourage good conduct regarding, ethical issues in gene technology – particularly those relating to human health, the environment, and genetically modified organisms and products.

GTEC is responsible for reviewing the National Framework within three years, and will consider whether the document should be continued or amended. GTEC welcomes advice and comments on the National Framework from its intended audience.

Further information can be found on the GTEC website:  
<http://www.ogtr.gov.au/committee/gtec.htm>



## Appendix 1 Relevant publications

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# Appendix 2 Australia's National Biotechnology Strategy and the regulation of gene technology









