Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator
Gene Technology Ethics &
Community Consultative Committee

# National Framework of Ethical Principles in Gene Technology 2012

## Gene Technology Ethics and Community Consultative Committee



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The Gene Technology Ethics and Community Consultative Committee (GTECCC) is a statutory advisory committee established under section 106 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 GTECCC and do not necessarily reflect those held by the Office of the Gene Technology Regulator (OGTR) that provides the Secretariat to the Committee.

National Framework of Ethical Principles in Gene Technology 2012

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# Contents

# Summary

Decisions about gene technology require researchers and all others involved in gene technology to assess the ethical consequences of their actions. As well as considering whether an action is scientifically or technically achievable, they must also consider whether it is ethically acceptable. The *National Framework of Ethical Principles in Gene Technology 2012* (the National Framework 2012) is a set of principles which Australian scientists and researchers are expected to abide by when dealing with gene technology and genetically modified organisms (GMOs) at all times. It is a means to encourage ethical conduct in gene technology – in particular where it relates to human health, the environment, genetically modified organisms and products.

The National Framework 2012 builds on the principles laid down in the *National Framework for the Development of Ethical Principles in Gene Technology* 2006 and draws on international and Australian ethical frameworks and community input.

The National Framework 2012 is an outcome of a review of the 2006 Framework conducted by the Gene Technology Ethics and Community Consultative Committee (GTECCC). This is a statutory advisory committee established under Section 106 of the *Gene Technology Act 2000* (Cwth) to advise the Gene Technology Regulator and the Gene Technology Ministerial Council[1].

The National Framework 2012 presents ten key ethical principles relating to gene technology, and to genetically modified organisms (GMOs) in particular, to guide scientists and to inform the community. These principles have been prepared to shape policies and actions that arise when dealing with gene technology.

## Principle 1 – Acting with integrity

Act with integrity in the search for and application of knowledge and benefits in gene technology research, both in the design of the research and having appropriate scientific qualifications to undertake the work and follow relevant codes of best scientific practice.

## Principle 2 – Avoiding conflicts of interest

Declare and properly manage any conflicts of interest under the terms of the Australian Code for the Responsible Conduct of Research or other relevant requirements.

## Principle 3 – Maintaining records of scientific data

According to best scientific practices, maintain accurate and comprehensive records of all relevant facts and data in dealings with gene technology to the standards required by regulatory authorities, including records of all negative as well as positive results.

[1] In 2011 the Gene Technology Ministerial Council became the Legislative and Governance Forum on Gene Technology.

## Principle 4 – Caring for the environment and sustainability

Conduct dealings with gene technology so as to protect the environment, including genetic diversity, organisms, species and natural ecosystems, and to promote improvements in human health and sustainable agriculture and industry.

## Principle 5 – Avoiding harm to humans and animals

Minimise risks of harm or discomfort to humans and animals likely to be adversely affected by gene technology research by ensuring compliance with the gene technology legislation.

## Principle 6 – Assessing long-term impacts

Conduct dealings with gene technology with regard to the impact on present and future generations, including assessment of the long-term side effects of applications of gene technology.

## Principle 7 – Sharing knowledge and benefits

Respect intellectual property rights, endeavour to promote access to scientific developments and share knowledge, and ensure that the Australian community benefits from gene technology.

## Principle 8 – Promoting benevolent purposes

Conduct dealings with gene technology that promote their benevolent application and discontinue dealings that involve risk outside the relevant authorisation requirements.

## Principle 9 – Ensuring transparency

Conduct dealings with gene technology in a manner that ensures transparency and public scrutiny of the processes and that allows community consultation with those with a direct or potential interest.

## Principle 10 – Considering responsibility beyond national borders

Ensure that dealings with gene technology do not cause damage to the environment in Australian or beyond the limits of the national jurisdiction.

# 1. Aims and objectives

*The National Framework of Ethical Principles in Gene Technology 2012* (the National Framework 2012) is intended to encourage ethical conduct in gene technology – in particular where it relates to human health, the environment, genetically modified organisms and products. Decisions about gene technology require researchers and all others involved in gene technology to assess the ethical consequences of their actions. As well as considering whether an action is scientifically or technically achievable, they must also consider whether it is ethically acceptable.

The National Framework 2012 will continue to provide a national reference point for promoting the ethical conduct of dealings with gene technology consistent with the national regulatory system that the Gene Technology Regulator (the Regulator) administers under the *Gene Technology Act 2000* (Cwth) (the GT Act). The object of the Act is "to protect the health and safety of people and 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".

This National Framework 2012:

- identifies ethical principles and values relevant to work involving gene technology, as set out in Section 5 of this document
- provides ten principles (Section 5.1) relating to gene technology and to GMOs in particular, which are intended to be useful to scientists and the community
- aims to promote well-informed ethical decision making within a transparent decision-making process.

The National Framework 2012 is intended to provide assurance to the Australian community that not only are the risks involved in the technology being properly managed but that ethical issues are also being properly considered.

# 2. Audience

The National Framework 2012 provides guidance on values and ethical principles for the 'regulated community'. This term covers anyone, organisation or individuals, regulated under the *Gene Technology Act 2000* (Cwth) (GT Act) and includes:

- researchers, scientists and other practitioners working with gene technology, including those who deal with genetically modified organisms (GMOs)
- organisations accredited under the GT Act and their associated Institutional Biosafety Committees (IBCs)

It also provides guidance for other regulatory and ethics committees, including Human Research Ethics Committees (HRECs) and Animal Ethics Committees (AECs).

Importantly, it has also been written as a reference point for the general public in the interests of transparency and maintaining public trust.

# 3. How the Framework will be applied

The National Framework 2012 provides a national reference point to promote the ethical conduct of dealings with gene technology consistent with the national regulatory system.

Organisations accredited under the Act, researchers and IBCs are encouraged to take account of the principles presented here although they are not a requirement under the legislation (See Section 6).

Australian scientists and researchers are encouraged to abide by these principles when dealing with gene technology and genetically modified organisms (GMOs) at all times. Researchers should provide evidence that they have considered these principles when seeking approval for their research projects.

The National Framework 2012 provides guidance to IBCs. These review committees should include the ethical aspects of any dealings with gene technology in their review work.

The National Framework 2012 also provides guidance to HRECs. Research on humans requires ethical approval from HRECs before the research can be undertaken (*National Statement on Ethical Conduct in Research Involving Humans*, NHMRC 2007). Where this work involves genetic modification, approval under the GT Act is also required.

Similarly, the National Framework 2012 will guide research involving animals. This research requires AEC approval in each jurisdiction under 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* (NHMRC 2004 and 2006, respectively). Where the work involves genetic modification, additional approval under the Act is required (as well as any other required approvals).

The National Framework 2012 will fill the current gap where gene modification research does not involve humans and animals – not only will approval be required and risk assessment carried out by the OGTR, but also the ethical aspects of the work should be considered by the institution's IBC and researchers.

# 4. The National Framework 2012: Context

## 4.1 Regulatory scheme and the role of the Gene Technology Regulator

All dealings with GMOs require authorisation under the *Gene Technology Act 2000* (the GT Act). (See Appendix 1.) The objective of the GT Act is "to protect the health and safety of people and 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". The Gene Technology Regulator (the Regulator) administers the national regulatory system established by the Act.

The Office of the Gene Technology Regulator (OGTR) provides administrative support to the Regulator in the performance of his functions. The Regulator, supported by the OGTR, is responsible for assessing and issuing licences for dealings with GMOs, accrediting organisations undertaking gene technology, and certifying facilities. Requirements for ensuring risk management and monitoring all dealings with GMOs and, where licensed, any intentional release are variously provided through the GT Act, the Regulations, Guidelines issued by the Regulator, and conditions imposed through licences, certification of facilities and accreditation of organisations.

The Regulator's approach to undertaking risk assessments of dealings with GMOs is set out in the Risk Analysis Framework (the RAF) (OGTR 2009). The RAF deals with how long-term and short-term impacts of dealings with GMOs should be assessed and the way that dealings should be managed according to identified best scientific practices.

The RAF acknowledges the importance of considering ethical dimensions of risk assessment and notes that OGTR's risk analysis process should be consistent with the principles outlined by GTECCC. When the RAF was revised and updated in 2007, specific reference was made to the ethical issues of safeguards where data is lacking, scientific uncertainty, environmental impacts and the "precautionary principle" as defined in the GT Act, namely that "where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

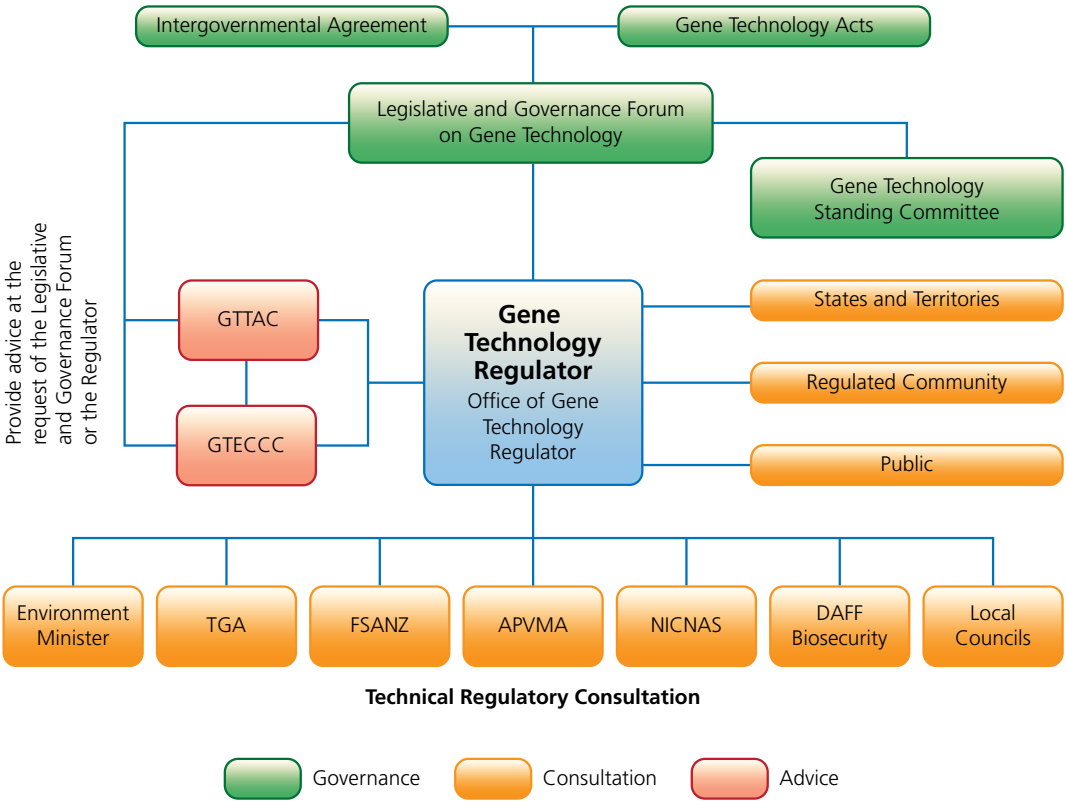
## 4.2 The Gene Technology Ethics and Community Consultative Committee

The GTECCC is a statutory advisory committee established under section 106 of the GT Act to advise both the Gene Technology Regulator and Legislative and Governance Forum on Gene Technology. The GTECCC continues to provide 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.

In this role, GTECCC developed the National Framework 2012 to provide a national reference point to promote the ethical conduct of dealings with gene technology consistent with the objectives of the GT Act.

The opinions expressed in this discussion paper represent the views of the GTECCC and do not necessarily reflect those held by the Office of the Gene Technology Regulator (OGTR) that provides the Secretariat to the Committee.

**Figure 1.** Australian system for regulation of gene technology



NOTES:

**APVMA:** Australian Pesticides and Veterinary Medicines Authority

**DAFF Biosecurity:** Department of Agriculture, Fisheries and Forestry Biosecurity (formerly Australian Quarantine & Inspection Service)

**FSANZ:** Food Standards Australia New Zealand

**GTTAC:** Gene Technology Technical Advisory Committee

**GTECCC:** Gene Technology Community Consultative Committee

**NICNAS:** National Industrial Chemicals Notification and Assessment Scheme

**Regulated Community:** accredited organisations and Institutional Biosafety Committees (IBCs)

**TGA:** Therapeutic Goods Administration

## 4.3 National Framework 2006

The National Framework 2012 builds on the principles laid down in the *National Framework for the Development of Ethical Principles in Gene Technology* 2006 (National Framework 2006). The National Framework 2006 was developed by the former Gene Technology Ethics Committee (GTEC) – now the Gene Technology Ethics and Community Consultative Committee (GTECCC) – to provide guidance on the ethical issues relating to gene technology under the GT Act (see section 107). The National Framework 2006 was consistent with international standards at the time and acknowledged the emergence and development of environmental ethics that underpin gene technology. This includes the care and protection of the environment and natural ecosystems, respect for biodiversity, the precautionary approach, and encouraging sustainability.

GTECCC reviewed the National Framework 2006 in 2009–10 through an independent national survey[2]. Survey responses identified a need to strengthen the application of the principles in the National Framework 2006 and provide better promotion of its use. The survey gave support to the National Framework as a means to encourage ethical conduct in gene technology — in particular where it related to human health, the environment, genetically modified organisms and products. Based on these results, GTECCC decided to publish this new National Framework 2012, reflecting feedback from the survey as well as international instruments and developments, changes to the regulatory context and community attitudes. The National Framework 2012 provides ethical guidance which can be used by regulated entities, and which they can be encouraged to refer.

[2] An online survey of regulated and non-regulated stakeholders was conducted by ORIMA Research Pty Ltd in March–April 2010: *Survey of Regulated and Non-Regulated Clients to Inform the Review of the National Framework for the Development of Ethical Principles in Gene Technology*.

# 5. The National Framework 2012: Principles

## 5.1 Ethical principles in gene technology

### Background

GTECCC has developed the following ten principles to guide decisions on ethical matters relating to research on gene technology and genetically modified organisms (GMOs) in particular, and to inform the community. These principles help to ensure that the values identified in Section 5.2, shape policies and actions that arise when dealing with gene technology. Researchers, scientists and others are encouraged to apply the principles during the course of their work. They should attempt to apply individual principles without substantially compromising other principles. Researchers should provide evidence that they have considered these principles when seeking approval for their research projects.

Public trust is a critical component of the regulatory system. The maintenance of high ethical standards in the private or public sector is essential for public trust.

### Principles

#### Principle 1 – Acting with integrity

Act with integrity in the search for and application of knowledge and benefits in gene technology research, both in the design of the research and having appropriate scientific qualifications to undertake the work and follow relevant codes of best scientific practice.

#### Principle 2 – Avoiding conflicts of interest

Declare and properly manage any conflicts of interest under the terms of the Australian Code for the Responsible Conduct of Research or other relevant requirements.

#### Principle 3 – Maintaining records of scientific data

According to best scientific practices, maintain accurate and comprehensive records of all relevant facts and data in dealings with gene technology to the standards required by regulatory authorities, including records of all negative as well as positive results.

#### Principle 4 – Caring for the environment and sustainability

Conduct dealings with gene technology so as to protect the environment, including genetic diversity, organisms, species and natural ecosystems, and to promote improvements in human health and sustainable agriculture and industry.

## Principle 5 – Avoiding harm to humans and animals

Minimise risks of harm or discomfort to humans and animals likely to be adversely affected by gene technology research by ensuring compliance with the gene technology legislation.

## Principle 6 – Assessing long-term impacts

Conduct dealings with gene technology with regard to the impact on present and future generations, including assessment of the long-term side effects of applications of gene technology.

## Principle 7 – Sharing knowledge and benefits[3]

Respect intellectual property rights, endeavour to promote access to scientific developments and share knowledge, and ensure that the Australian community benefits from gene technology.

## Principle 8 – Promoting benevolent purposes

Conduct dealings with gene technology that promote their benevolent application and **discontinue dealings that involve risk outside the relevant authorisation requirements**.

## Principle 9 – Ensuring transparency

Conduct dealings with gene technology in a manner that ensures transparency and public scrutiny of the processes and that allows community consultation with those with a direct or potential interest.

## Principle 10 – Considering responsibility beyond national borders

Ensure that dealings with gene technology do not cause damage to the Australian environment or to the environment beyond the limits of the national jurisdiction.

[3] UNESCO *Universal Declaration on Bioethics and Human Rights* 2005 provides some guidance on benefit sharing. Examples of benefit sharing may include:

- Art 15(a) special and sustainable assistance and acknowledgment of the persons or groups that have taken part in the research
- Art 15(e) access to scientific and technological knowledge
- Art 15(f) capacity-building facilities for research purposes – see Appendix 3.

## 5.2 Values underlying the ethical principles for gene technology

### Background

The value of public trust is implicit and recognised in *Australian Biotechnology: A National Strategy (Biotechnology Australia 2000*, the National Strategy, see Appendix 1), the gene technology regulatory framework established in the GT Act, and the corresponding state and territory legislation. The National Strategy encourages the development and application of research and scientific knowledge associated with gene technology for the benefit and wellbeing of the community.

The National Statement on Ethical Conduct in Research Involving Humans (NHMRC 2007) and the Australian Code for the Responsible Conduct of Research (NHMRC/ARC/UA 2007) require researchers to conduct research with integrity.

In developing the principles in this National Framework, GTECCC identified the values set out below as the most relevant for the ethics of gene technology. The values are derived from international documents, in particular the UNESCO *Universal Declaration of Bioethics and Human Rights* (2005) which includes a number of principles relevant with respect to the environment (see relevant sections in Appendix 3). Other relevant national and international documents are set out in Appendix 2. In addition, GTECCC took account of the general values of the Australian community and values that were expressed during public consultations and in parliamentary debates that informed the development of the *Gene Technology Act 2000* (the GT Act). GTECCC notes that concerns for the environment are at the forefront of government agendas internationally in continuing debates about climate change and sustainability. 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. Ethical decision-making about environmental issues should take these values into account.

### Values

#### Value 1 — Integrity

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 corporations.

### Value 2 — Trust

Public trust in institutions, public officials and the professions are critical to a democratic society. The accountability of corporations, institutions and scientists working in the development and use of gene technology is an important value for the success of these technologies.

### Value 3 — Respect for the environment

The environment is of great value, and humans have 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 associated with sustainable development and management, as well as protecting biodiversity and ecosystem integrity and showing respect for individual species. Decision making should consider the short- and long-term impact of genetically modified organisms (GMOs) on the environment for present and future generations.

### Value 4 — Respect for persons

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.

### Value 5 — Respect for animals

Respect for animals, is reflected in animal welfare legislation that is designed to prevent cruelty to animals. This legislation is in place in most countries, including Australia. Respecting animals used or generated for research involving genetic modification also requires consideration of the possible consequences associated with the welfare of genetically modified animals, as well as the possible effects on human and animal health and the environment.

### Value 6 — Research and the application of knowledge

The freedom to pursue ethical research to acquire new knowledge is an important value. The application and sharing of knowledge can also benefit human, animal and environmental wellbeing.

# 6. Future review of the National Framework

The original National Framework 2006 provided guidance on ethical aspects of gene technology. The National Framework 2006 was not enforceable and was an aspirational set of principles aimed to raise awareness of ethical issues relating to gene technology. The former GTEC did not recommend that the Ministerial Council introduce the National Framework 2006 as mandatory Policy Principles[4] under the GT Act (see sections 21–24, 112).

Similarly, GTECCC does not recommend that the National Framework principles set out in Section 5 be introduced by the Ministerial Council as mandatory Policy Principles under the GT Act (see sections 21–24, 112) at this stage[5]. However, GTECCC recommends to the Regulator that OGTR promote the National Framework 2012 more widely to identified audiences to maximise awareness and application of the principles in the framework. GTECCC will again review this revised version of the National Framework within five years of the date of the current publication (2012). GTECCC will consider whether the Ethical Principles in Section 5.1 should be proposed to be Policy Principles under the GT Act. If this is legislated, the Principles would become enforceable.

Further information is available on the GTECCC website: www.ogtr.gov.au

[4] Policy principles are issued by the Ministerial Council. The Regulator must not issue a licence if that would be inconsistent with a policy principle (s57(1) of the GT Act).

[5] The GTECCC considered that the ethical principles might potentially be operationalised (if issued as Policy Principles) in the following ways:

- The Regulator could require researchers to show consideration of the National Framework 2012 when making licence applications.
- The Regulator could require accredited institutions /IBCs to check that National Framework 2012 was considered under the terms of the Act for accreditation, annual reports or licence applications.
- The National Framework 2012 and OGTR could be listed in the *Australian Code for the Responsible Conduct of Research (NHMRC)*, providing an opportunity to integrate gene technology principles within these broader set of research integrity standards.

# Appendix 1: Background to the National Framework 2006

The National Framework 2006 was developed by GTEC in the context of its responsibilities under the GT Act. In 2000, the Commonwealth of Australia, published the *Australian Biotechnology: A National Strategy* (Biotechnology Australia 2000) which expressed commitment to the development of biotechnology and safeguarding human health, and ensuring the protection of the environment. The establishment of the national regulatory system for gene technology was considered a key component of the *Australian Biotechnology: A National Strategy*. The National Strategy stated "Consistent with safeguarding human health and ensuring environmental protection, that Australia captures the benefits of biotechnology for the Australian community, industry and environment" (at page 7).

The National Framework was developed with reference to the work of earlier Australian committees, including the Genetic Manipulation Advisory Committee (GMAC 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 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.

GTEC circulated draft versions of the National Framework 2006 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 supported the need for, and intent of, the National Framework 2006 to provide a foundation for future discussions and guidelines relating to ethics in gene technology, as well as establishing a consistent approach to assessing the ethics of such technology in Australia.

## The *Gene Technology Act 2000*

The development of the Gene Technology Bill 2000 (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.

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.

This comprehensive process generated broad agreement that the object of the GT 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 GT Act passed into law in December 2000, and commenced operation on 21 June 2001.

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

The GT Act, supported by the Gene Technology Regulations 2001, an Intergovernmental Agreement signed by all jurisdictions, and corresponding legislation enacted in each state and territory, constitutes Australia's nationally consistent scheme 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 GT Act and corresponding state and territory legislation is administered by an independent statutory office holder, the Gene Technology Regulator (the Regulator). The scheme operates in conjunction with other regulatory systems (Figure 1).

The GT Act sets down a comprehensive and rigorous process for the scientific identification, assessment and management of risks posed by gene technology. The GT 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.

The GT Act also set down a range of requirements for the *nationally consistent scheme* supported by penalties for non-compliance. In particular:

- licences from the Regulator are required to undertake contained research, field trials, or commercial releases of GMOs
- dealings with GMOs are prohibited unless they are: Licensed; a notifiable low risk dealing (NLRD); Exempt or on the GMO Register
- organisations conducting research or dealing with GMOs must be accredited

- accreditation of an organisation requires Institutional Biosafety Committees (IBCs) to be established to provide oversight of and monitor research
- research on GMOs cannot be undertaken without certification of the accredited organisations' laboratories (to specified containment levels).

The GT Act provides for the Ministerial Council to issue policy principles; policy guidelines; and codes of practice.

The GT Act 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)
- the issue of policy principles or codes of practice (sections 22, 24).

The workings of the office and licences issued by the Regulator are publicly available on the OGTR website.

Under the GT Act, three committees were originally 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 GT Act sets out the range of skills or experiences that committee members must have.

After the 2006 review of the legislation, the GTEC and GTCCC were combined to form the Gene Technology Ethics and Community Consultative Committee (GTECCC) in 2008.

# Appendix 2:
# Review of other codes of ethics

In developing the original National Framework, GTEC (now GTECCC) recognised that ethical thinking in areas of medical and animal research is well developed. Environmental ethics or the ethics of gene technology were at earlier stages of development. However, IBCs are now well established within the regulatory system and in a better position to effectively consider ethical aspects of gene technology. In addition, HRECs or AECs may consider ethical aspects of gene technology. Existing codes of medical research ethics contain statements of broadly agreed and consistent principles; there are no equivalent international codes in relation to generally agreed principles for environmental ethics.

## Queensland and Victoria

Both the Queensland and Victorian Governments have introduced statements on ethics in gene technology:

- *Code of Ethical Practice in Biotechnology in Queensland (2001)*
- *Statement of Ethical Principles for Biotechnology in Victoria (2006).*

The Queensland Government has revised and renamed its code of ethical practice for biotechnology, the *Queensland Biotechnology Code of Ethics (2006)*. This code 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 in Victoria* (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.

## New Zealand

Similarly, the principles identified in the New Zealand Environmental Risk Management Authority (ERMA), (now New Zealand Environmental Protection Authority), *Ethics Framework* (2011) are complementary to those identified by GTEC. The New Zealand *Ethics Framework* contains two general principles:

- respect for the environment
- respect for people, including past, present and future generations.

These 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 non-harm. 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.

The New Zealand *Ethics Framework* (ERMA 2011) 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 risk
- the perspectives and needs of multiple decision makers and stakeholders
- complications arising from multiple objectives.

## International and national

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* (World Medical Association 2008).

In Australia, the reference point is the *National Statement of Ethical Conduct in Research Involving Humans*, 2007 developed jointly by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and Universities Australia.

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 NHMRC, 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.

The *Australian Code for the Responsible Conduct of Research* (NHMRC 2007) sets explicit standards for researchers and public institutions. These standards are enforceable by institutions. Those conducting gene modification research or dealings with GMOs are covered by this Code and are required to comply with its provisions dealing with notification of breaches, investigation adjudication and penalties for infringements. This Code is produced and supported by the NHMRC, Universities Australia and the ARC.

There are a number of international declarations and statements dealing with the environment (see Appendix 3).

# Appendix 3: UNESCO Universal Declaration on Bioethics and Human Rights (2005)

The extracts of Articles presented below are of particular relevance to the National Framework 2012.

## Article 2

The aims of this Declaration are:

(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;

(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;

(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;

(g) to safeguard and promote the interests of the present and future generations;

(h) to underline the importance of biodiversity and its conservation as a common concern of humankind.

## Article 15 *Sharing of benefits*

Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

(a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;

(e) access to scientific and technological knowledge;

(f) capacity-building facilities for research purposes.

## Article 16 *Protecting future generations*

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

## **Article 17** *Protection of the environment, the biosphere and biodiversity*

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

## **Article 20** *Risk assessment and management*

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

# Appendix 4:
# Relevant publications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# Acronyms and abbreviations

| | |
|---|---|
| **APVMA** | Australian Pesticides and Veterinary Medicines Authority |
| **AEC** | Animal Ethics Committee |
| **FSANZ** | Food Standards Australia New Zealand |
| **GMAC** | Genetic Manipulation Advisory Committee (1987-2001) |
| **GMOs** | Genetically Modified Organisms |
| **GTCCC** | Gene Technology Community Consultative Committee (2001-2007) |
| **GTECCC** | Gene Technology Ethics and Community Consultative Committee |
| **GTEC** | Gene Technology Ethic Committee (2001-2007) |
| **GTTAC** | Gene Technology Technical Advisory Committee |
| **GTMC** | Gene Technology Ministerial Council |
| **GTSC** | Gene Technology Standing Committee |
| **HREC** | Human Research Ethics Committee |
| **IBCs** | Institutional Biosafety Committees |
| **IDC** | Inter-departmental Committee |
| **LGFGT** | Legislative & Governance Forum on Gene Technology (formerly Gene Technology Ministerial Council, GTMC) |
| **National Framework** | National Framework of Ethical Principles in Gene Technology |
| **National Strategy** | Australian Biotechnology: A National Strategy 2000 |
| **NHMRC** | National Health and Medical Research Council |
| **NICNAS** | National Industrial Chemicals Notification and Assessment Scheme |
| **NLRD** | Notifiable Low Risk Dealing |
| **OGTR** | Office of the Gene Technology Regulator |
| **RAF** | Risk Analysis Framework |
| **Regulator** | Gene Technology Regulator |
| **TGA** | Therapeutic Goods Administration |
| **the GT Act** | The Gene Technology Act 2000 |
| **the Bill** | The Gene Technology Bill |
| **UNESCO** | United Nations Educational, Scientific and Cultural Organisation |