



**OGTR Response to the *National Framework for the Development of Ethical Principles in Gene Technology* developed by the Gene Technology Ethics Committee**

The *National Framework for the Development of Ethical Principles in Gene Technology* (the Framework) was developed by the Gene Technology Ethics Committee (GTEC) 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”. It lists nine principles which are based on the values of respect for human life, animals and the environment; freedom of choice; acquiring and applying knowledge; reasoned argument and decision making; trust; and integrity.

This document discusses how current practices of the Office of the Gene Technology Regulator (OGTR) align with the principles and values articulated in the Framework. It also outlines activities undertaken or proposed in response to the Framework.

**Current Practices of the OGTR**

A number of the nine principles are given effect in the OGTR by way of legislation, including the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, the *Public Service Act 1999*, the APS Code of Conduct and APS Values, the *Freedom of Information Act 1982* and the *Privacy Act 1988*.

A number of other documents support the operation of the principles and values within the OGTR, including the OGTR’s Service Charter and Risk Communication Charter. The Service Charter outlines the standards of service that the public and users of Australia’s scheme for gene technology regulation can expect, and the avenues available should these standards not be met. The Risk Communication Charter (set out in the *Risk Analysis Framework*) presents the principles of risk communication which the OGTR aims to uphold and demonstrates the Regulator’s commitment to active risk communication.

**Integrity**

**Principle 1:** *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*

The OGTR adheres to the APS Code of Conduct and APS values, which require that all APS employees behave honestly and with integrity, and treat everyone with respect and courtesy.

Procedures are in place to ensure that information which has been declared Commercial Confidential Information is protected.

As part of the accreditation and application processes under the legislation, the OGTR checks for any relevant convictions and cancellations of licences or permits relating to human health and safety or the environment which may render an applicant unsuitable to hold a licence.

The OGTR also displays integrity and credibility in its dealings with other national and international agencies and often provides expert or technical advice on the regulation of gene technology.

### **Respect for the Environment**

**Principle 2:** *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 4:** *Assess and respect the environmental and health needs of present and future generations*

The object of the *Gene Technology Act 2000* (the Act), which underpins the regulatory system, is:

“to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.”

Hence the Gene Technology Regulator (the Regulator), supported by the OGTR, is charged with protecting both people and the environment and OGTR activities align with Principles 2 and 4.

The OGTR conducts a thorough, scientifically rigorous risk assessment for each application to release a GMO into the Australian environment. The Regulator must not issue a licence unless satisfied that risks to human health and safety and the environment can be managed.

While ‘long-term’ is not defined in the Act, in accordance sub-regulation 10(2) of the Gene Technology Regulations 2001, the Regulator considers both the short-term and the long-term in considering risks that may be posed by gene technology. Potential long-term effects have been addressed through the introduction of a Post Release Review component into the *Risk Analysis Framework* that guides the evaluation process for licence applications. This will provide for ongoing oversight of commercial, or general, releases of GMOs, enable verification of the findings of risk assessments, and enhance quality control and review mechanisms in the regulation of GMOs.

**Principle 5:** *Conduct research in a manner that protects the environment, including protection of genetic diversity, organisms, species, natural ecosystems, and natural and physical resources*

The OGTR does not undertake experimental research itself, its role is to assess the applications which are submitted and endeavours to ensure (see Principles 2 and 4) that gene technology research and development is conducted in a manner which protects both humans and the environment. Any research commissioned by the OGTR must meet the same requirements.

## **Respect for Human and Animal Life**

**Principle 3:** *Minimise risks of harm or discomfort to humans and animals likely to be adversely affected by gene technology*

**Principle 6:** *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*

While the OGTR does not specifically evaluate the ethical implications of proposed research, licences authorising research involving humans require that relevant ethical approvals be obtained from a human research ethics committee (HREC). For proposed research involving gene therapy in humans, HRECs can seek advice from the NHMRC's Cellular Therapies Advisory Committee (which replaces the former Gene and related Therapies Research Advisory Council). In some cases, specific approval may also be needed from the Therapeutic Goods Administration, in accordance with its requirements.

It is also a condition of all licences authorising research involving animals that animal ethics committee approval be obtained prior to commencement.

The Regulator can consult the Gene Technology Ethics Committee<sup>1</sup> if an application raises ethical issues which warrant additional consideration. The OGTR also cooperates with other bodies with a specific role in ensuring that matters such as justice and proper consent are addressed, such as the NHMRC's Animal Welfare Committee (AWC) and the Australian Health Ethics Committee (AHEC).

In line with the APS Values and Code of Conduct, OGTR staff demonstrate professionalism by displaying:

- fairness and impartiality without fear, favour, affection and without undue influence or ill will;
- respect for the dignity of all people including their need for confidentiality, discretion and preservation of their privacy; and
- the application of skill, care and diligence in all undertakings.

The OGTR undertakes monitoring and compliance activities to identify and respond to possible contraventions of the legislation. In conducting compliance activities OGTR inspectors act fairly by complying with all formal requirements of the Commonwealth generally, and the Act in particular. They do so equitably, without malice, prejudice or personal bias, and including obtaining proper consent. The framework and protocols which describe how the OGTR undertakes monitoring and compliance activities, including the level of response, are provided to regulated organisations and published on the OGTR website.

## **Access to Knowledge**

**Principle 7:** *Promote equitable access to scientific developments and sharing knowledge, and recognise the value of benefit sharing*

A number of the principles go beyond the scope of the Act, particularly Principle 7 which is more relevant to developers of gene technology. The regulatory system was established to identify and manage risks to people and the environment that may be posed by the development and use of GMOs. The Act does not include the consideration of benefits, therefore it is outside the scope of the office to promote benefit sharing.

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<sup>1</sup> From January 2008 the Gene Technology Ethics Committee will be replaced by the Gene Technology Ethics and Community Consultative Committee as a result of amendments to the legislation.

## **Benevolent and Malevolent Uses of Gene Technology**

**Principle 8:** *Conduct research in a manner that promotes the benevolent and avoids the malevolent uses of gene technology*

The Regulator assesses applications on the basis of the dealings proposed to be undertaken. However, if during the assessment process a concern arose regarding a potential malevolent use of gene technology, advice could be sought from the Gene Technology Technical Advisory Committee (GTTAC) and GTEC.

The OGTR maintains a watching brief on developments in gene technology and its applications. The OGTR contributes its technical expertise to Australian Government activities to identify and prevent malevolent uses of biological research, including gene technology. At a national level this includes cooperation with the Office of Health Protection in the Department of Health and Ageing (which has responsibility for implementing the *National Health Security Act 2007*). In relation to international initiatives, such as the Biological Weapons Convention and the Australia Group, the OGTR participates with other agencies, particularly the Department of Foreign Affairs and Trade.

If a significant issue with regard to a potential malevolent use of a GMO was identified, the Regulator would liaise with the appropriate Australian Government authorities in relation to determining how to respond.

As previously noted, the Act does not include the consideration of benefits, and the OGTR does not have a role in the promotion of the benevolent uses of gene technology.

## **Consultation and Transparency**

**Principle 9:** *Conduct gene technology research after appropriate consultation and ensuring transparency and public scrutiny of the processes*

The OGTR exceeds the extensive consultation requirements of the Act with key stakeholders (eg State and Territory Governments, local councils, other government agencies and regulatory authorities, applicants and the public). Information on how advice received has been considered is included in the decision documents and provided in responses to submissions.

The OGTR makes publicly available a broad range of information which is relevant to each decision. This information uses non-technical language, as much as possible, to ensure that it is accessible to everyone regardless of their level of scientific knowledge.

The OGTR's approach to assessing GMOs, such as communication strategies and processes including the Risk Communication Charter, are outlined in the *Risk Analysis Framework* (RAF).

Considerable additional information on other aspects of the regulatory system is provided on the OGTR website and via a mailing list of self-registered, interested individuals and organisations. Those regulated are consulted and updated on operational changes via correspondence with accredited organisations and their Institutional Biosafety Committees. Together these processes maintain the transparency of the regulatory system.

The OGTR also organises and participates in relevant public forums to ensure that the public understands the regulatory system and to encourage public scrutiny of the regulatory system.

## **Changes Undertaken/Proposed in Response to the Ethics Framework**

1. When the OGTR is developing operational policies, relevant Principles of the Ethics Framework are taken into consideration and used as a basis for the consideration of any ethical issues relating to the policy. The Ethics Framework will also be provided to the Gene Technology Ethics and Community Consultative Committee for use as a foundation document.
2. The Ethics Framework will be made suggested reading for any organisations applying for accreditation. The accreditation form will be modified to include a brief statement on the purpose of the Ethics Framework and a recommendation that relevant members of the organisation/IBC read the document.
3. In future revisions of application forms the OGTR will consider opportunities to draw the attention of applicants to the Ethics Framework.
4. The next revision of the RAF will take into account the values and principles outlined in the Ethics Framework. (2008)
5. The OGTR will promote the Ethics Framework as a learning instrument in Australian universities by sending copies to staff responsible for research training, including Deputy Vice-Chancellors Research.