

**OFFICE OF THE GENE TECHNOLOGY REGULATOR**

**GENE TECHNOLOGY ETHICS AND COMMUNITY  
CONSULTATIVE COMMITTEE**

**ISSUES PAPER**

**PUBLIC CONSULTATION:  
COMMUNITY AND STAKEHOLDERS**

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## **Glossary**

Act	The Gene Technology Act 2000
ANZFA	Australia New Zealand Food Authority
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
DIR	Dealing involving Intentional Release (of a GMO)
FSANZ	Food Standards Australia New Zealand
GMO	Genetically Modified Organism
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTR	Gene Technology Regulator
IBC	Institutional Biosafety Committee
LGA	Local Government Authority
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
OGTR	Office of the Gene Technology Regulator
RARMP	Risk Assessment and Risk Management Plan
Regulator	Gene Technology Regulator
TGA	Therapeutic Goods Administration

## **1 Introduction**

One of the Government's objectives in establishing the OGTR in 2001 was to provide greater transparency and accountability in the regulation of gene technology (*Explanatory Memorandum to the Gene Technology Bill 2000*). The *Gene Technology Act 2000* (the Act) requires the Regulator to undertake consultation at various stages of the decision-making process, particularly when evaluating a licence application for a DIR.

This paper outlines the extensive consultation which the Regulator is required to undertake by law and the additional measures which are routinely implemented as part of the Regulator's decision-making processes.

## **2 Key Consultative Aspects of the Gene Technology Regulatory System**

The release of GMOs into the Australian environment is of significant interest to a wide spectrum of the community, including state, territory and local governments, NGOs, community groups, businesses, companies and individuals. The Act stipulates specific organisations with which the Regulator must consult in preparing a RARMP for a DIR. Under the Act the Regulator is obliged to consult with State governments, local councils, a number of prescribed Australian government agencies (FSANZ, AQIS, NHMRC, NICNAS, APVMA, TGA), the Environment Minister and the public. In addition, the OGTR maintains a client register of people and organisations (approximately 1200) that have registered to receive information from the OGTR on issues relating to the regulation of gene technology.

The *Explanatory Guide to the Gene Technology Act 2000* states that:

“Given the high level of community interest in gene technology, it is important that both the GTR and the Ministerial Council remain “in touch” with community views on issues surrounding the regulation of gene technology. Both the GTR and Ministers will benefit from the community's input into the development of the policy guidelines and codes of practice which will underpin the regulatory scheme.”

The GTCCC was established under the Act to fulfil this role. A separate GTEC was established to provide advice on the request of the Regulator or the Gene Technology Ministerial Council on ethical issues relating to gene technology, and the need for and content of, policy principles and codes of practice which will cover dealings with GMOs.

In March 2007 a combined meeting of GTEC and GTCCC agreed that the OGTR currently has good systems in place for community consultation. The Committees noted that, while the legislation details the community consultation which the Regulator is required to carry out, the OGTR routinely exceeds the requirements of the Act in its consultation processes. For

example, the OGTR maintains a Client Register of people who have expressed an interest in issues relating to the regulation of gene technology. People on the Register receive Early Bird Notification of new DIR applications with an invitation to request a copy of the application and to provide comment(s) for consideration in the preparation of the RARMP. The OGTR also publishes notices in regional and rural newspapers and promotes awareness by participating in conferences, workshops and other public forums. In considering DIR applications, sections 50 and 52 of the Act state that the Regulator must seek advice from any local council considered appropriate, but when considering applications for commercial release of a GMO, all local government authorities in Australia are given the opportunity to comment.

Current public consultation practices undertaken by the OGTR are described in more detail in Chapter 5 of the Risk Analysis Framework.

### **3 The consultative role of the GTECCC**

From 1 January 2008 GTEC and GTCCC were replaced by the GTECCC, which was established as a result of the *Gene Technology Amendment Act 2007*.

Following the statutory review of the Act in 2005, it was found that there had been considerable overlap between the roles of GTEC and GTCCC. The Review recommended the two committees be combined into one advisory committee - GTECCC - with the combined functions of GTEC and GTCCC. The new committee also has additional functions in advising the Regulator and the Ministerial Council on community consultation in respect of the process for DIR licence applications and on risk communication matters in relation to DIR's.

Both GTCCC and GTEC had been involved in activities facilitating community consultation on the Gene Technology regulatory system. GTCCC had provided a forum where members of a local council were able to discuss their concerns about GMOs. GTEC undertook two rounds of public consultation as part of the development process for the *National Framework for the Development of Ethical Principles in Gene Technology*, published in 2006.

Sections 22 and 24 of the Act require that any policy principles or codes of practice issued by the Gene Technology Ministerial Council must be developed in consultation with the Gene Technology Advisory Committees as well as Commonwealth and State agencies and industry, environmental, consumer and other groups. The development of the Gene Technology (Recognition of Designated Areas) Principle 2003 involved consultation with all of the prescribed stakeholders.

#### **4 Consultation Processes under other legislation**

In common with OGTR, many other statutory agencies are required to consult with the general community in their decision-making processes. For example, the *National Health and Medical Research Council Act (1992)* outlines the consultation process which must be carried out before the National Health and Medical Research Council (NHMRC) can make regulatory recommendations or issue guidelines. A requirement for consultation and community involvement is also embedded in the Food Standards Australia New Zealand Act, and the National Industrial Chemicals Notification and Assessment Scheme includes a Community Engagement Charter.

#### **5 Consultation with local government**

A key aspect of the Act is the involvement of local government authorities. At a GTCCC meeting in March 2007, strategies for communication with LGAs were discussed. Based on the experience of a number of members, the Committee noted that the number and diversity of LGAs in Australia makes it difficult to develop a 'one size fits all' approach. There are over 700 Australian LGAs, encompassing a wide variety in size, resources and level of engagement with GM issues. The Act states that the Regulator may consult any local council she considers appropriate. The OGTR currently undertakes a significant amount of communication with local councils and contacts councils in relation to specific licence applications which take place in their local area. The OGTR provides information to LGAs and provides representatives to speak directly to councils if requested. The Committee agreed that continuing to communicate with LGAs on a case-by-case basis is the most appropriate approach.

#### **6. Institutional Biosafety Committees**

The main point of contact between the OGTR and most organisations dealing with GMOs is the IBC. IBC's assist organisations by advising on the identification and management of risks associated with GMO dealings undertaken by the organisation, including the containment of GMOs. IBC's provide the main interface between the OGTR and researchers. The OGTR communicates with IBCs about specific applications and also provides information about the regulatory system in general. The OGTR has hosted two National IBC Forums, which not only provided IBC members with large amounts of information about the OGTR and other matters which impact on their work, but also provided a forum for members of IBCs from different organisations to meet and provided useful feedback to the OGTR.

## 7. Website

The OGTR website (<http://www.ogtr.gov.au>) helps to ensure the transparency of the Regulator's decision-making processes through the online publication of operational policies, the OGTR Handbook, guidelines, fact sheets and maps of field trials. Much of the information provided on the website exceeds the requirements outlined in the legislation.

## 8. Conclusion

The 2006 Statutory Review of the *Gene Technology Act 2000* concluded that the consultative structure and process generally worked well, but that it could be improved by combining GTEC and GTCCC. The independent Review found that there was considerable overlap between the roles of GTEC and GTCCC and recommended that they be merged to form the GTECCC. The new committee will allow relevant skills to be distributed across its membership so that it is able to provide clear, balanced, appropriate and better coordinated advice. The functions of GTECCC will include providing advice, on the request of the Regulator or the GTMC, on community consultation and risk communication matters in relation to applications for licences covering dealings that involve the intentional release of a GMO into the environment. The new Committee will continue to provide advice on ethics and social issues and to work towards facilitating and encouraging community input and public participation in the decision making process in relation to gene technology.

### **Some suggested internet sites for further reading:**

#### **Office of the Gene Technology Regulator (OGTR)**

<http://www.ogtr.gov.au>

#### **National Health and Medical Research Council (NHMRC)**

<http://www.nhmrc.gov.au>

#### **Citizenscape (WA Government)**

<http://www.citizenscape.wa.gov.au>

#### **Bioscience for Society**

Biotechnology and Biological Sciences Research Council (BBSRC)

<http://www.bbsrc.ac.uk/society>