

Gene Technology Ethics Committee Meeting
9-10 April 2003, Canberra

COMMUNIQUE

The Gene Technology Ethics Committee (GTEC) held its fourth meeting in Canberra on the 9th and 10th of April 2003. GTEC was established by the *Gene Technology Act 2000* (the Act) as a statutory advisory committee to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministerial Council. All committee members and expert advisers hold office on a part-time basis. (A reference to ‘members’ in the communique includes ‘expert advisers’).

At its fourth meeting the current GTEC working groups reported on their activities since the previous meeting and agreed on new work for a number of the groups. In addition to the existing work plan priorities, a new working group was established at the April meeting to build upon foundation research undertaken in the previous eighteen months by the Committee. Members were kept informed of relevant work from other national committees via cross-member reports and the Committee received a Chair’s activity report and a report from the Regulator on activities undertaken by the Office of the Gene Technology Regulator (OGTR) since the third meeting held in October 2002. Key outcomes from the meeting are reported below.

GTEC’s Work Plan

GTEC’s first communique from its inaugural meeting in December 2001 detailed a number of priority areas that would form the basis of the Committee’s future work plan and result in the provision of advice to the Regulator. Since that time the working groups have been developing and refining their ideas out-of-session and at each subsequent meeting of the Committee. Details of the status of a number of the current working groups are provided below for information.

Ethical Guidelines in Relation to Genetically Modified Organisms

At the April meeting the Committee resolved to develop a set of specific ethical guidelines in relation to genetically modified organisms. The development of practical ethical values and principles specifically relevant to gene technology will be based upon preliminary work undertaken by one of the working groups and the contributions of a number of individual members. The Regulator has also requested that the Committee provide advice on the proposed implementation of the new guidelines.

A new working group has been established to draft an initial paper for the Committee’s consideration later in 2003. The new guidelines are to be completed before the end of the inaugural GTEC term of appointment in October 2004.

Qualitative Survey of Institutional Biosafety Committees

The Committee has been examining the need for an ethical review process for all types of applications for genetic modification work in relation to plants and animals. Earlier this year the GTEC and the Victorian Biotechnology Ethics Advisory Committee (VBEAC) have discussed the possibility of a joint survey of Institutional Biosafety Committees (IBCs) in

Victoria. The VBEAC is an advisory committee that has been established to provide independent advice to the Victorian Government on the social and ethical issues of biotechnology.

At the April GTEC meeting it was resolved that a member of the VBEAC would formally join the GTEC survey working group to work collaboratively on a broad fact-finding exercise to be conducted with selected IBCs. GTEC is very aware of the current IBC workload nationally leading up to the 21 June 2003 expiration of deemed instruments¹. Therefore, the proposed consultations with IBCs will proceed after June 2003 and the working group will report on its findings to the GTEC later in 2003.

*Ethical Issues Associated with Transkingdom Gene Transfer*²

A working group was established to consider the ethical issues associated with transkingdom gene transfer. The working group reported at the April meeting and presented a revised paper for consideration. GTEC resolved to seek the Regulator's support to refer the paper to the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Community Consultative Committee (GTCCC) for comment.

When the paper has been finalised by the GTEC it will be published on the Committee's page on the OGTR website later in 2003.

Managing Risk Ethically

One of the proposed outcomes for the paper being developed by the 'Managing Risk Ethically' working group is that it will inform a planned review of the *Risk Analysis*

¹ The *Gene Technology Act 2000* (the Act) and the Gene Technology Regulations 2001 contain transitional provisions related to approvals granted under the previous voluntary scheme. Section 190 of the Act sets out the arrangements that have the effect of 'deeming' certain dealings to be licensed if a Genetic Manipulation Advisory Committee Advice to Proceed covering that dealing was in force on 21 June 2001 when the Act came into effect.

All of these deemed instruments lapse in June 2003 and the Regulator has no powers to extend that date. The OGTR has been communicating with organisations that currently hold these instruments to try to ensure that they can continue their work uninterrupted. Most of these organisations have now submitted appropriate applications to ensure that this work can continue and these applications form part of the overall figures reported here.

Over 3000 deemed instruments were transferred from the former voluntary system into the new regulatory scheme including:

- 49 dealings involving the intentional release of a GMO into the environment;
- 504 dealings not involving the intentional release of a GMO into the environment; and
- 1057 notifiable low risk dealings (which must take place in contained facilities).

In addition, the transitional arrangements involved:

- deeming the certification of 1550 contained facilities at various levels of security; and
- the accreditation of 119 organisations.

² Transkingdom gene transfer involves the transfer of DNA into the cells of an organism from a different 'kingdom'. Organisms are grouped on the basis of fundamental similarities and common ancestry into a taxonomic system. One widely accepted taxonomic system designates five such kingdoms: animals; plants; fungi; prokaryotes (bacteria); and protista (algae and molds).

Framework for Licence Applications to the OGTR in 2003. The working group will also seek the Regulator's assistance to refer the paper to the GTTAC and GTCCC for comment.

GTEC Attendance at Australian Health Ethics Conference

The GTEC/Australian Health Ethics Committee (AHEC) cross-member and a local GTEC member attended a recent AHEC conference, 'Ethics in Human Research Conference', held from 2-4 April 2003 in Canberra.

It was reported that the national conference was well attended as was an associated research ethics training day held prior to the conference. The two GTEC delegates reported on their attendance and expressed the view that the conference was informative and that their attendance had been valuable.

GTEC and Relationships with Other Committees

As a standing item at every GTEC meeting, the Committee receives verbal reports on activities from the cross-members with the GTTAC and the GTCCC. Communiqués from meetings of these committees are also published on the OGTR website. At this meeting, the GTTAC cross-member report included advice regarding the Committee's workload and recent membership changes and the GTCCC cross-member report included updates on the progress of the working groups established by that Committee.

The verbal cross-member report from the AHEC contained advice in relation to a number of projects being completed by that committee including finalisation of draft ethical guidelines on the use of reproductive technology in clinical practice and research. GTEC resolved to make a submission to the AHEC in response to the recent public invitation to comment on the draft guidelines.

GTEC also considered advice from one of its members in relation to the National Health and Medical Research Council's (NHMRC) invitation for public consultation on a *Draft Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. GTEC resolved to prepare a submission by the due date of 4 June 2003.

The NHMRC has announced that it will hold a second round of public consultation on xenotransplantation in 2003. GTEC intends to prepare a second submission building on their first submission on this topic in 2002. A copy of the first GTEC xenotransplantation submission is available on the Committee's page on the OGTR website.

Next Meeting

The next GTEC meeting will be held in late 2003.

**For all inquiries, please contact the Office of the Gene Technology Regulator on
1800 181 030 (free-call)**