Gene Technology Technical Advisory Committee

COMMUNIQUE
No. 25

This is the 25th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 35th meeting of GTTAC, held on 22 April 2009.

GTTAC is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide scientific and technical advice 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.

The Regulator receives advice from GTTAC on Risk Assessment and Risk Management Plans (RARMPs) prepared in respect of applications for licences to conduct dealings with genetically modified organisms (GMOs).

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any resolutions the Committee has provided to the Regulator with regard to those applications and RARMPs.

The Communiqué also provides an overview of any other major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Dealings Involving the Intentional Release of GMOs (DIRs) involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

The RARMP for every DIR licence application is released for public comment as part of the consultation process. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

GTTAC Advice

The Regulator must seek GTTAC advice on RARMPs prepared in respect of all DIR applications. The Regulator must also seek GTTAC advice during the preparation of the RARMP for all DIR applications which are **not** assessed as 'limited and controlled' under Section 50A of the Act.

Advice on Consultation RARMP – Commercial Release
GTTAC considered the consultation RARMP prepared in response to the following commercial release application:

DIR 090 – Commercial release of rose genetically modified for altered flower colour

The application, from Florigene Pty Ltd, involves the commercial release of a Hybrid Tea Rose genetically modified to alter flower colour from pink to purple/blue. When GTTAC's advice was sought during the preparation of the RARMP they advised that the risk assessment should be done on the assumption that, if released commercially, the GM rose would be widely grown in home gardens. The committee also advised that there is potential for exposure of humans and animals to products derived from the GM flowers, but that no issues were identified which might give rise to adverse outcomes. The committee noted that these points had been included in the consultation RARMP.

> *RESOLUTION: GTTAC advised the Regulator that the RARMP for DIR 090 adequately identifies and addresses risks to people and to the environment and that they had nothing to add to the advice given at their previous meeting (Meeting 34, 15 October 2008)*

Advice on Consultation RARMPs – Limited and Controlled Release

GTTAC considered the Consultation RARMPs prepared in response to the following applications for limited and controlled releases:

DIR 092 – Limited and controlled release of wheat genetically modified for altered grain composition

The application, from CSIRO, involves the release of 16 lines of wheat which have been genetically modified for altered grain composition, on a limited scale and under controlled conditions. The trial is proposed to take place at one site in the Australian Capital Territory. GTTAC agreed that the RARMP for DIR 092 adequately identifies and addresses risks to people and the environment.

> *RESOLUTION: GTTAC advised the Regulator that the following items should be considered when finalising the Risk Assessment and Risk Management Plan:*
> - *Consider how best to ensure conditions that would adequately stimulate the germination of volunteers in the last six months of the monitoring period; and*
> - *Consider defining the amount of soil moisture necessary to promote germination of volunteers post-harvest.*

DIR 093 – Limited and Controlled Release of wheat and barley genetically modified for altered grain starch composition

This application, also from CSIRO, involves the release of three lines of wheat and one line of barley, genetically modified for altered grain starch composition, on a limited scale and under controlled conditions. The trial is proposed to take place at one site in the Australian Capital Territory. GTTAC noted that the application includes proposed human nutritional trials, which would require approval from a Human Research Ethics Committee (HREC). GTTAC agreed that the RARMP for DIR 093 adequately identifies and addresses risks to human health and safety and risks to the environment from the proposed release.

RESOLUTION: GTTAC advised the Regulator that the following items should be considered when finalising the Risk Assessment and Risk Management Plan:

- *Consider how to ensure conditions that would adequately stimulate the germination of volunteers in the last six months of the monitoring period;*
- *Consider requiring that proposed human nutritional trials be endorsed by an independent HREC; and*
- *Consider defining the amount of soil moisture necessary to promote germination of volunteers post-harvest.*

OTHER ADVICE:

DEALINGS NOT INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Dealings not involving the intentional release of GMOs (DNIRs) are dealings that are usually undertaken within a facility where the organism is physically contained.

DNIR 461 – Phase 3 clinical trial with Oncovex^{GM-CSF} compared to subcutaneously administered GM-CSF.

GTTAC considered the RARMP prepared by the Regulator in response to an application from PPD Australia Pty Ltd. The application concerns a randomised phase 3 clinical trial to evaluate the efficacy and safety of treatment of melanoma with a genetically modified *human herpesvirus 1* JS1 strain (Oncovex^{GM-CSF}). Treatment with the GM virus will be compared with subcutaneously administered Granulocyte Macrophage Colony Stimulating Factor (GM-CSF). The trial will involve previously treated melanoma patients with unresectable Stage IIIb, IIIc and IV disease. GTTAC discussed possible risks to health and safety of clinical staff administering the GMO and noted that the GM virus would be severely weakened and would be unlikely to cause infection in healthy people

RESOLUTION: In relation to the RARMP for DNIR 461 GTTAC advised that the Regulator:

- *Should seek further information from the applicant regarding the capacity of the GM virus for replication; and*
- *Should consider the risk to health and safety of clinical staff administering the GMO as low rather than negligible*

GTTAC also advised that consideration be given to recommending:

- *double gloving for persons administering the GM virus;*
- *a training log to be kept for approved personnel;*
- *prophylactic treatment (acyclovir) to be immediately available to clinical staff in the event of exposure to the GM virus; and*
- *treated trial subjects to be advised to avoid contact with the aged and newborns*

NB: Safety issues related to participants form part of the ethical and scientific review of clinical trials conducted by Human Research Ethics Committees prior to endorsement. In addition, the TGA may seek additional information and clarification about safety or other aspects of clinical trials that are notified as part of the CTN/CTX process.

REVIEW OF THE *GENE TECHNOLOGY REGULATIONS 2001*

GTTAC received a report on progress in the review of the *Gene Technology Regulations 2001,* including an analysis of submissions from the regulated community on potential areas of amendment. GTTAC noted that an Out of Session package seeking advice on proposals for amendments being considered would be sent to members before the next meeting. The committee also noted that, following feedback from GTTAC and policy approval by the Gene Technology Ministerial Council (GTMC), detailed drafting instructions will be provided to the Office of Legislative

Publishing and Drafting in the Attorney-General's Department. GTTAC will be consulted on the draft amendment regulations when ready.

RESOLUTION: GTTAC advised the Regulator that they strongly supported the proposed clarification of language describing pathogenicity and pathogenic characteristics of hosts and vectors in Schedules 2 and 3 of the Regulations.

ENQUIRIES AND RISK ASSESSMENT AND RISK MANAGEMENT PLANS

For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please phone the OGTR on 1800 181 030. The RARMPs are also available electronically from our website at http://www.ogtr.gov.au