Gene Technology Technical Advisory Committee
Videoconferences 25 June and 13 August 2012
Canberra
Communiqué

This communiqué covers matters considered at the meetings of the Gene Technology Technical Advisory Committee (GTTAC) held by videoconference on 25 June and 13 August 2012.

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 Legislative and Governance Forum on Gene Technology (formerly the Gene Technology Ministerial Council). All Committee members and expert advisers hold office on a part-time basis.

The Regulator seeks 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 GTTAC's consideration of applications and RARMPs and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any Committee resolutions provided to the Regulator regarding those applications and RARMPs.

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. The Regulator may seek GTTAC advice on RARMPs prepared in respect of all DIR applications.

1. ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

1.1 Videoconference 25 June 2012

GTTAC considered the consultation RARMP prepared in response to the following application for a limited controlled release:

DIR 115 - Limited and controlled release of cotton genetically modified for enhanced fibre yield.

GTTAC noted that the application from the Commonwealth Scientific and Industrial Research Organisation (CSIRO) was for a limited and controlled release of cotton lines, genetically modified (GM) for enhanced fibre yield. The trial is proposed to take place at one site in Narrabri, New South Wales.

The purpose of the trial is to evaluate the potential for increasing cotton fibre yield under field conditions. The trial will also generate information on genetic regulation of fibre development. The GM cotton would not be permitted to enter the human food or animal feed supply chains.

GTTAC noted the proposed licence conditions, which are similar to those used for other recent cotton licences.

RESOLUTION:

GTTAC advised the Regulator that:

- Members agreed with the overall conclusions of the RARMP for DIR 115 and agreed with the OGTR's suggestions for clarification of some text in the RARMP in response to pre-meeting comments.

1.2 Videoconference 13 August 2012

GTTAC considered the consultation RARMP prepared in response to the following application for a limited controlled release:

DIR 116 - Limited and controlled release of genetically modified live viral vaccines against prostate cancer.

GTTAC noted that the application from PPD Australia Pty Ltd was for a limited and controlled release of two GM live viral vaccines against prostate cancer. The two GM vaccines are based on a *Vaccinia virus* and a *Fowlpox virus* that have been modified to contain the same four human genes. Expression of these genes is expected to induce immune responses against the *prostate-specific antigen* (PSA) and to stimulate the immune system to attack and destroy prostate cancer cells expressing PSA.

The purpose of the proposed clinical trial is to evaluate the efficacy of the GM vaccines, and their safety and tolerability. The proposed trial would form part of an international clinical trial involving up to 1200 patients in approximately 22 countries. A proportion of these trial participants will be in Australia, and trial activities will take place in the ACT, NSW, QLD, SA, VIC and WA. If approved, the trial is expected to be completed within five years.

GTTAC noted that the following are also required for the trial :

- authorisation under the Therapeutic Goods Administration's (TGA's) Clinical Trial Notification scheme, and
- approval by a Human Research Ethics Committee.

RESOLUTION:

GTTAC advised the Regulator that:

- The Regulator should further consider risks to birds as a result of exposure to the GM Fowlpox vaccine; and
- The Regulator should further consider the likelihood of pock formation (from the GM Vaccinia vaccination).

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 Office of the Gene Technology Regulator (OGTR) on 1800 181 030. RARMPs are also available electronically from our website at <http://www.ogtr.gov.au>.