Gene Technology Technical Advisory Committee
Meeting 8 November 2011
Canberra
Communiqué

This communiqué covers matters considered at the 40th meeting of Gene Technology Technical Advisory Committee (GTTAC) (8 November 2011)

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).

GTTAC members were appointed by the Hon Catherine King, Parliamentary Secretary for Health and Ageing on 3 February 2011 for a three year term, following consultation with the Regulator, State/Territory Ministers and relevant scientific, consumer, health, environmental and industry organisations. The term for the previous committee expired on 31 January 2011.

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.

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

1. ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

GTTAC considered the Consultation RARMP prepared in response to the following application for limited and controlled releases:

1.1 DIR 108 – Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (InVigor® x Roundup Ready® canola)

GTTAC noted that the application from Bayer Crop Science Pty Ltd was for the commercial release of GM canola, produced by crossing currently approved GM lines; InVigor® canola and Roundup Ready® canola. InVigor® x Roundup Ready® canola was produced by conventional breeding between InVigor® canola and Roundup Ready® canola, which were individually approved by the Regulator in 2003 for commercial release under licences DIR 021/2002 and DIR 020/2002, respectively.

The InVigor® x Roundup Ready® canola proposed for commercial release will contain genes conferring tolerance to the herbicides glufosinate-ammonium and glyphosate, and genes conferring a hybrid breeding system. Bayer is seeking approval from the Regulator to release GM canola derived from conventional breeding between GM Roundup Ready® elite line GT73 and all GM canola lines authorised for release under licence DIR 021/2002.

The applicant proposes the release to occur in all commercial canola growing areas of Australia. GM canola and GM canola-derived products from GM InVigor® x Roundup Ready® canola would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) has approved the use of food derived from GM InVigor® canola and GM Roundup Ready® canola for human consumption. These approvals also cover GM InVigor® x Roundup Ready® canola.

RESOLUTION:

GTTAC advised the Regulator that in preparing the RARMP:

- The Regulator should consider amending the RARMP to outline alternative measures to manage volunteers of the GM canola.

DEALINGS NOT INVOLVING INTENTIONAL RELEASE

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

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

2. ADVICE ON CONSULTATION RARMPS: DEALINGS NOT INVOLVING INTENTIONAL RELEASE

GTTAC considered the Consultation RARMP prepared in response to the following application for dealings not involving intentional release:

2.1 DNIR 509 - The role of host and viral factors in Chikungunya virus disease

GTTAC discussed the RARMP prepared by the Regulator in response to an application from Griffith University and noted that the application involves:

- Modification of glycosylation sites on two envelope proteins of the Chikungunya virus (CHIKV - E1 and E2, two proteins that form a 'spike' on the virus surface and are involved in cell adhesion and entry);
- Tissue culture – viral propagation; and
- Animal infection – monitoring of disease progression.

GTTAC noted that the dealings will be conducted in PC3 facilities and require specific work practices. GTTAC noted that the risk assessment concluded that risks to the health and safety of the general population are negligible. GTTAC discussed possible risks to people undertaking dealings, from exposure to GM CHIKV, noting that the risk is low, provided that PC3 containment and work practices are used. GTTAC advised on other precautions, noting that a number of reasonable precautions had already been proposed to minimise exposure.

RESOLUTION:

GTTAC advised the Regulator that in preparing the RARMP:

The Regulator should consider:

- whether additional precautions may be required to minimise potential for exposure of people conducting inoculations; and
- whether a contingency plan should be required to manage potential accidental exposure.

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>.