

Gene Technology Technical Advisory Committee

Videoconferences 21 March 2013, Canberra ACT

Communiqué

This communiqué covers matters considered at the meetings of the Gene Technology Technical Advisory Committee (GTTAC) held by videoconference on 21 March 2013.

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. 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 GMOs (DIR)

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

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.

A DIR may involve a limited and controlled release (field trial) or a commercial release (general) of a GMO.

1. Advice on Consultation RARMPs – Limited and Controlled Release

GTTAC considered the consultation RARMP prepared by the Regulator in respect of an application from the University of Western Australia (UWA) for a limited controlled release:

DIR 119 - Limited & controlled release of narrow-leafed lupin GM for herbicide tolerance

GTTAC noted that the application was for a limited and controlled release of narrow-leafed lupin, genetically modified (GM) for tolerance to the herbicide glyphosate. The trial is proposed to take place at the New Genes for New Environments (NGNE) facility, run by the Department of Agriculture and Food Western Australia, at Merredin, WA. The purpose of the trial is to test for glyphosate tolerance under field conditions. The GM narrow-leafed lupin would not be permitted to enter the human food or animal feed supply chains. GTTAC considered the proposed licence conditions, which include a pollen trap and isolation zone to limit the potential for transfer of the GM trait by bee mediated pollination.

RESOLUTION:

GTTAC advised the Regulator that:

- GTTAC agreed with the overall conclusions of the RARMP, and
- the Regulator should further consider bee-mediated pollination in the RARMP

DEALINGS NOT INVOLVING INTENTIONAL RELEASE OF GMOs (DNIR)

The Regulator may seek GTTAC advice on RARMPs prepared in respect of a DNIR application.

DNIRs are dealings that a licence applicant undertakes within a facility where the GMO is physically contained.

2. Advice on Consultation RARMPs: Dealings not Involving Intentional Release

GTTAC considered the RARMP prepared by the Regulator in respect of the application from the Royal Alfred Hospital (RPAH) for a dealing not involving intentional release:

DNIR 523 - A clinical trial to treat Hemophilia B using AAV-based gene therapy

GTTAC noted that the application involves gene therapy using a GM adeno-associated virus (AAV) - based vector to treat patients with severe Hemophilia B. GTTAC considered the safety features of the AAV-based vector, noting that the proposed vector system is replication defective, non-pathogenic, and self-limiting. GTTAC addressed the safety of the AAV-based vector for participants in the clinical trial and other humans. Additional safety considerations under the proposed licence conditions included:

- use of appropriate containment protocols and disposal of clinical waste during the clinical trial
- any information relevant to patient safety obtained in the course of OGTR assessment and/or advice would be provided to the Therapeutic Goods Administration's (TGA), and the Human Research Ethics Committee (HREC)

GTTAC noted that the clinical trial also requires:

- approval by a HREC, and
- authorisation under the TGA's Clinical Trial Notification scheme

RESOLUTION:

GTTAC advised the Regulator that:

GTTAC agreed with the overall conclusions of the RARMP for DNIR 523

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>.