Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

27 July 2018

Communiqué

This Communiqué covers matters considered at the 15th video conference of the Gene Technology Technical Advisory Committee (27 July 2018)[1]

The Gene Technology Technical Advisory Committee (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.

The Regulator seeks advice from GTTAC on licence applications to work with genetically modified organisms (GMOs) and on Risk Assessment and Risk Management Plans (RARMPs) prepared for applications. The purpose of this Communiqué is to provide a brief overview of GTTAC's consideration of applications and RARMPs and, in accordance with the Gene Technology Regulations 2001, to publish committee resolutions given to the Regulator. The Communiqué also provides an overview of any other deliberations of the committee.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO

Dealings involving the Intentional Release (DIR) of a GMO can involve a limited and controlled release (clinical trial or field trial) or a commercial (general) release.

The Regulator must seek GTTAC advice during the preparation of a RARMP for DIR applications which do not qualify as limited and controlled under Section 50A of the Act. The Regulator must also seek advice from GTTAC on RARMPs that have been prepared for all DIR applications.

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

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 163 – Limited and controlled release of canola genetically modified for altered oil content and herbicide tolerance

Nuseed Pty Ltd applied for a licence to conduct field trials of canola plants that have been genetically modified (GM) for altered oil content and herbicide tolerance.

GTTAC noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to the health and safety of people and the environment. GTTAC discussed proposed licence conditions including the field trial layout, requirements for post-cleaning inspections, and what constitutes a significant disturbance at burial sites.

[1] The video conference was held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Perth and Melbourne.

Resolutions

- The Committee agrees with the overall conclusions of the RARMP and no additional relevant information is required.

DEALINGS NOT INVOLVING THE INTENTIONAL RELEASE OF A GMO

The Regulator may seek GTTAC advice on RARMPs prepared for an application for Dealings Not involving an Intentional Release (DNIR) into the environment. DNIR licences include research work with GMOs undertaken in physical containment facilities (e.g. certified by the Regulator) or clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 585 – Clinical trial of an oncolytic vaccine for the treatment of cancers caused by the human papilloma virus (HPV)

Clinical Network Services Pty Ltd has applied for a licence to conduct clinical trials to assess the efficacy and safety of an oncolytic vaccine for treatment of cancers caused by *human papilloma virus* infection.

GTTAC noted the key points in the draft consultation RARMP including the assessment of the risks as negligible. In addition to topics addressed in resolutions below, GTTAC discussed a range of topics, including:

- the mode of operation of the E6E7 construct, and subsequent stimulation of an immune response against E6E7-derived peptides
- the biology of the *Maraba virus*, noting that recent literature and clinical trial data may address some data gaps
- the possibility for viable virus to remain in the body in the context of the relatively high administration dose and the ability of the virus to replicate in tumour cells

Resolutions

- The Regulator should consider clarifying:
  - whether immunocompromised people will be excluded from the trial
  - whether viable *Maraba virus* is shed or is present in other body fluids
  - protocols for handling dressings by patients
  - whether further relevant information is available from previous clinical trials
- The Regulator should note that ethanol is not effective against Adenovirus.
- The Regulator should consider any additional information provided by the committee.
- The Regulator should further consider:
  - risks associated with transmission by Australian sand flies
  - work practices relevant for preparation and administration of the GMOs

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 call the OGTR on 1800 181 030 or email ogtr@health.gov.au. RARMPs are also available on the OGTR website.