Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
12 September 2022
Communiqué

This Communiqué covers matters considered at the 32nd videoconference of the Gene Technology Technical Advisory Committee (12 September 2022)

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 Gene Technology Ministers' Meeting.

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. It does not include information which is treated as Confidential Commercial Information in accordance with the Act.

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) and clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 654 – Understanding Coronavirus infection and disease

The University of Melbourne has applied for a licence to study virus host-range, virulence, replicative fitness, transmissibility and susceptibility to antiviral drugs and vaccines, with the aim of developing better vaccines, antiviral drugs, and other treatment regimens for COVID-19. The applicant has proposed to conduct *in vitro* and *in vivo* experiments in mammalian cells and laboratory mice in Physical Containment level 2 (PC2) and PC3 laboratories.

GTTAC noted the conclusion of the RARMP that the proposed application poses negligible to low risks to the health and safety of people or the environment. The Committee discussed the following key topics:

- testing for SARS-CoV-2 infections in staff working in PC3 facilities
- personal protective equipment proposed for use in the laboratories
- proposed requirements for transporting the GMOs, including packaging and labelling
- proposed methods to inactivate samples, agreeing that these are appropriate.

Resolutions

- The Committee agrees that all plausible risk scenarios have been identified
- The Regulator should further consider the testing of staff for the GMOs
- The Regulator should consider whether additional controls to restrict exposure to the GMOs are required
- The Committee agrees with the overall conclusion of the RARMP

ENQUIRIES

For all enquiries, please call the OGTR on 1800 181 030 or email ogtr@health.gov.au.