Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
13 December 2021
Communiqué

This Communiqué covers matters considered at the 28th videoconference of the Gene Technology Technical Advisory Committee (13 December 2021)

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 INVOLVING THE INTENTIONAL RELEASE OF A GMO

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

For commercial releases, the Regulator must seek GTTAC advice twice. The first consultation is on matters to consider when preparing the RARMP and the second is on the RARMP itself. For limited and controlled releases, the Regulator must seek GTTAC advice only once on the RARMP.

The RARMP for every DIR licence application is issued 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 186 – Limited and controlled release of wheat and barley genetically modified for yield enhancement and improved abiotic stress tolerance

Licence application DIR 186 from the University of Adelaide is for a field trial of genetically modified (GM) wheat and barley containing genes for yield enhancement and abiotic stress tolerance (water-use efficiency). The trial is proposed to take place between 2022 and 2027, at one site in South Australia and one site in Western Australia. The proposal is to plant on a maximum of two sites per year, with a combined total of 2 ha across both sites in any year.

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

- the possibility that the genetic modification may alter uptake of heavy metals, noting this has been identified as an area of uncertainty in the RARMP, and that the licence conditions would prohibit the GMO from being used in food and feed
- whether light emitted from the Red Fluorescent Protein (RFP) marker gene could affect insect and other animal behaviours during the trial

Resolutions

- The Committee agreed with the overall conclusions of the RARMP
- The Regulator should further consider possible risks associated with RFP expression and whether there may be changes in insect and other animal behaviours during the trial

DIR 187 – Clinical trial of a genetically modified alphavirus for treatment of cancer

Licence application DIR 187 from VRT Pharmaceuticals Pty Ltd is for a clinical trial using GM *Getah virus* (GETV) as a treatment for cancer. Up to 20 adults with cancer would receive treatment in a hospital setting in Australia.

GTTAC considered many topics in relation to the safety of the proposal noting several uncertainties associated with the application, including the duration of passive viremia following treatment and the risks to animals susceptible to GETV.

The Committee discussed key topics in relation to the GMO, including:

- whether the GMO is attenuated by the genetic modifications
- the relatively low dose of the GMO needed to lead to an immune response
- the biosecurity status of the parent organism
- the potential for various modes of transmission
- the length of treatment period and uncertainty about shedding
- whether the proposed risk management measures are sufficient.

Resolutions

- The Regulator should further consider risks associated with transmission to other people and animals.
- The Regulator should consider whether additional information and risk management measures are required.

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 (DIR) of GMOs into the environment, please call the OGTR on 1800 181 030 or email ogtr@health.gov.au. DIR RARMPs are also available on the OGTR website.