



Australian Government

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

Gene Technology Technical Advisory Committee

5 November 2024

Communiqué

This Communiqué covers matters considered at the 40th videoconference of the Gene Technology Technical Advisory Committee (5 November 2024)

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 that 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.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR-207 – Commercial release of a genetically modified (GM) mosquito strain to help prevent dengue outbreaks

Licence application DIR-207 from Oxitec Ltd (Australia) is for commercial release of a GM mosquito strain to reduce the population of *Aedes aegypti* mosquitoes to help prevent dengue outbreaks in Queensland. GTTAC's advice was sought on matters the Regulator should consider in preparing the RARMP.

GTTAC noted that the GMO is not a gene drive, and the technology is commercially approved in Brazil, with field trials conducted in Brazil and USA.

The committee discussed the potential for impacts on animals that feed on the GM mosquitoes and on the environment as a result of reduced mosquito populations.

GTTAC considered the potential for persistence of the GMO in the environment. GTTAC considered this was unlikely to come about through reversion but that the Regulator should

consider possibilities that could lead to persistence of the GMO in the environment. GTTAC also discussed the potential for the GM mosquitoes to crossbreed with other closely related species.

Resolutions

- The committee agrees that the following should be included in the RARMP:
 - Potential for harm due to accidental exposure of humans and animals to the GMO, including the impact of the expression of foreign protein on animals feeding on mosquitoes.
 - Potential for persistence of the GMO in the environment.
 - Potential for the GMO to be harmful to the environment, including the potential harm to other mosquito species in the environment and the impact on animals or plants relying on these mosquitoes for their survival.
- The Regulator should consider potential for crossbreeding with other mosquitoes.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR-206 –Clinical trial for the treatment of mycobacterial infections using bacteriophages

Licence application DIR-206 from the Western Sydney Local Health District is for a clinical trial of a bacteriophage treatment for mycobacterial infections. The trial would be conducted on at least 3 participants, under the Therapeutic Goods Administration's Special Access Scheme, over a period of 5 years.

GTTAC noted the conclusion of the RARMP is that risks to the health and safety of people or the environment from the proposed release are negligible. The committee discussed:

- the range of proposed trial sites including non-clinical administration sites
- the various modes of administration proposed
- the high specificity of the GMO for targeting its host mycobacterium
- decontamination requirements following administration of the GMO
- available information on shedding of the GMO after administration, noting the trial is intended to gather data on this.

Resolutions

- The committee agrees that the risk assessment identifies all plausible risk scenarios by which the proposed dealings could potentially give rise to risks relating to the health and safety of people or the environment.
- The committee agrees that the risk associated with the exposure of personnel conducting the dealings, carers, family members and other people to the GMO resulting in harm is negligible.
- The Regulator should consider an additional requirement for decontaminating surfaces following administration of the GMO.
- The Regulator should consider clarifying administration protocols and consistency in the RARMP.
- The committee agrees with the overall conclusion of the RARMP.

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-703 – A clinical trial of UB-VV111 in combination with rapamycin for the treatment of relapsed/refractory CD19+ hematologic malignancies

Medpace Australia Pty Ltd applied for a licence for a trial therapy to treat adult patients with B cell lymphoma. The location of the trial is St Vincent's Hospital Melbourne and it would run over a period of 5 years.

GTTAC noted the conclusion of the RARMP that the proposed GMO dealings pose negligible to moderate risk to the health and safety of people or the environment. The committee discussed key topics including:

- potential off-target effects including insertional mutagenesis in non-target cells of the patient
- the timeframe for prohibiting organ donation following treatment.

Resolutions

- The committee agrees that the risk assessment identifies all plausible risk scenarios by which the proposed dealings could potentially give rise to risks relating to the health and safety of people or the environment.
- The committee agrees that the risks associated with the exposure of personnel conducting the dealings, carers or family members to the GMO resulting in harm are negligible to moderate.
- The Regulator should reconsider the classification of highly unlikely in Risk Scenario 1 following a needlestick.
- The Regulator should reconsider the classification of highly unlikely in Risk Scenario 2 and seek further information about insertion sites.
- The Regulator should further consider whether to allow organ donation.
- 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.