Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
3 June 2025
Communiqué

This Communiqué covers matters considered at the 45th videoconference of the Gene Technology Technical Advisory Committee (3 June 2025)

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 CONSULTATION RARMPS – COMMERCIAL RELEASE

DIR-207 RARMP – 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 discussed whether tetracycline present in the environment may influence the survival of female GM mosquitoes but was satisfied that this wouldn't be expected to be the case.

GTTAC discussed the ability of the GM mosquitoes to interbreed with the *Aedes aegypti* found in Queensland (including those carrying *Wolbachia*). The committee considered that the RARMP comprehensively addressed this issue.

Resolutions

- The committee agrees that the risk assessment identifies all plausible risk scenarios by which the proposed release could give rise to risks relating to the health and safety of people or the environment.
- The committee agrees that the licence conditions in the draft licence are appropriate for the commercial release of the GMO.
- The committee agrees with the overall conclusion of the RARMP.
- The committee recommends that the fold concentration of tetracycline required in the environment to reverse the mortality of the GM female mosquitos be noted in 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-729 RARMP – Clinical trial of a genetically modified *Plasmodium falciparum* in healthy adult participants

The Walter and Eliza Hall Institute of Medical Research (WEHI) applied for a licence to generate human blood infected with GM *Plasmodium falciparum* which can be used to study and develop future treatment against malaria. The trial would be conducted at the Doherty Clinical Trials Limited and WEHI, involving 6 patients, and would run over a period of 5 years.

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

- clarify in the exclusion criteria of the RARMP that female participants should prevent pregnancy through contraception
- clarify in the RARMP and licence the locations where trial participants are not allowed to travel
- considerations around the sensitivity of blood tests for residual parasites to better inform the management of risk
- a Human Research Ethics Committee would separately consider the benefits and risks of the trial
- GTTAC noted that while trimethoprim exposure is to be avoided to prevent triggering a high level of gametocyte production, it recognised that this antibiotic is generally available in the community and is used to treat cuts and eye infections.
- greater consideration of the wide variety of forms and preparations of trimethoprim.

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 licence conditions in the draft licence are generally appropriate for the clinical use of the GMO.
- The committee agrees with the overall conclusions of the RARMP.
- The committee advises that the pregnancy exclusion criteria for trial participants should be better expressed in the RARMP and the licence.
- The committee recommends that clear instructions are provided in the RARMP and the licence when and where the participants can travel.
- The committee recommends further clarity of the extent and confidence with the efficacy of the pharmacological elimination of the *Plasmodium falciparum* in the trial participants.
- The committee recommends further clarity be sought about the sensitivity of the test assay for *Plasmodium falciparum* in blood samples from the trial participants.
- The committee recommends further clarity be provided about the transport, processing and storage of the blood samples from the trial participants that are used in the Master Cell Bank.
- The committee recommends further clarity be sought about the widespread use of the trimethoprim and similar drugs in the community.
- The committee advises the Regulator that advice should be provided to a HREC regarding: travel, re-emergence of the GMO, trimethoprim and the large blood volume extracted from trial participants.

ENQUIRIES

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