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

Gene Technology Technical Advisory Committee
28 March 2025
Communiqué

This Communiqué covers matters considered at the 43rd videoconference of the Gene Technology Technical Advisory Committee (28 March 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 APPLICATIONS – COMMERCIAL RELEASE

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

Licence application DIR-207 from Oxitec Australia Pty Ltd is for the commercial release of a GM mosquito strain to reduce the population of *Aedes aegypti* mosquitoes to help prevent dengue outbreaks in Queensland.

GTTAC provided advice on the preparation of the RARMP at the 40th videoconference on 5 November 2024. At the 43rd videoconference further advice was sought on the preparation of the consultation RARMP, where the following have been identified as key issues:

- Potential for harm due to accidental exposure of humans and animals to the GMO.
- Potential for persistence of the GMO in the environment.
- Potential for the introduction of the GMO to increase mosquitoes that can transmit arboviruses.

- Potential for the GMO to have a negative impact on the environment.
- Potential for the GMO to interbreed with other species of mosquitoes.

The Regulator sought advice on any additional issues or key literature that should be considered in the preparation of the RARMP for this application.

GTTAC discussed possible impacts on animals that consume mosquitoes and concluded the risk to the environment in general was minimal or non-existent, which was supported by no deleterious effects being observed in overseas releases of the GMO.

GTTAC considered there could be indirect harm to humans if the GMO was to impact Wolbachia carrying mosquitoes in Queensland. GTTAC affirmed the RARMP should consider the effect of the GM mosquitoes on Wolbachia carrying mosquitoes.

GTTAC recommended the RARMP provide more clarity on the presence of arboviruses and incidence of disease in Australia.

GTTAC recommended the RARMP use consistent wording to describe loss of the transgene in the mosquito population after a certain time and non-detection of the transgene. GTTAC suggested clarifying the reported incidence of dengue in Queensland and across Australia.

Resolutions

- The committee advises that the Regulator should consider the impact of the GM mosquito release on the population of Wolbachia mosquitoes and any subsequent health risks to people from dengue.
- The committee advises that the Regulator should consider the incidence of arboviruses in the environment.
- The committee advises that the Regulator should consider consistency of wording around how long the GM mosquitoes will persist in the environment.
- The committee advises that the Regulator should resolve the number of dengue cases in the different jurisdictions.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR-214 RARMP – Trial of a GM vaccine for the prevention of respiratory disease in horses

Licence application DIR-214 from the University of Queensland is a GM vaccine trial for the prevention of *Rhodococcus equi*-induced respiratory disease in foals (rattles). The proposed trial would be conducted at an animal facility at the University of Queensland, treating up to 10 foals to assess the safety and efficacy of the GM vaccine.

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

- potential inadvertent exposure of clinical staff administering the GMO
- considerations around the use of antiviral drugs given the GMO is replication-incompetent
- clarification of chemical decontamination requirements.

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 limits and controls proposed in the draft licence to prevent the spread of the GM vaccine are appropriate for the trial.
- The committee advises that the Regulator should clarify the disinfectants used for decontamination.
- The committee agrees with the overall conclusion of the RARMP.

DIR-211 RARMP – Limited and controlled release of safflower genetically modified for dairy protein production and altered fat composition

Miruku Australia Pty Ltd applied for a licence to conduct a field trial of safflower lines genetically modified for dairy protein production and altered fat composition. The purpose of the trial is to assess production of dairy protein and altered fat composition under field conditions. The proposed field trial would be conducted over 4 years and 8 months, at up to 52 trial sites with a total maximum area of 981 ha.

GTTAC noted the conclusion of the RARMP that the proposed field trial poses negligible risks to the health and safety of individuals and the environment as a result of gene technology. The Committee discussed the following key topics:

- requirements for cleaning of harvesting machinery, given the difficulty in harvesting safflower
- possible effects of the genetic modification on dormancy and weediness
- the potential for ingestion during sensory testing, noting that sensory testing would also require approval by a human research ethics committee
- distance requirements between the field trial and watercourses and the meaning of ‘flood prone’.

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 advises that the Regulator should further consider risks associated with the potential for increased dormancy and increased weediness as a result of the fusion protein and changed fat profile.
- The committee advises that the Regulator should further consider controls in regard to cleaning of equipment and verification of the cleaning process.
- The committee advises that the Regulator should seek more detail about the sensory testing, and whether further controls around the testing are required.
- The committee advises that the Regulator should reconsider the distance of the trial sites from waterways.
- The committee advises that the Regulator should consider clarifying what is considered flood prone.
- The committee agrees with the overall conclusion of the RARMP.

DIR-215 RARMP – Limited and controlled release of canola genetically modified for dairy protein production

Miruku Australia Pty Ltd applied for a licence to conduct a field trial of canola lines genetically modified for dairy protein production. The purpose of the trial is to assess production of dairy protein in GM canola under field conditions. The proposed field trial would be conducted over 4 years and 8 months, at up to 52 trial sites with a total maximum area of 436 ha.

GTTAC noted the conclusion of the RARMP that the proposed field trial poses negligible risks to the health and safety of individuals and the environment as a result of gene technology. The Committee discussed the following key topics:

- requirements for cleaning of harvesting machinery, given that canola seeds are small
- possible effects of the genetic modification on development
- the potential for ingestion during sensory testing, noting that sensory testing would also require approval by a human research ethics committee
- clarification of distance requirements between the field trial and watercourses in relation to topography, and the meaning of 'flood prone'.

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 advises that the Regulator should further consider risks associated with the potential for increased dormancy and increased weediness as a result of the fusion protein.
- The committee advises that the Regulator should further consider controls in regard to cleaning of equipment and verification of the cleaning process.
- The committee advises that the Regulator should seek more detail about the sensory testing, and whether further controls around the testing are required.
- The committee advises that the Regulator should reconsider the distance of the trial sites from waterways.
- The committee advises that the Regulator should consider clarifying what is considered flood prone.
- 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.