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

Gene Technology Technical Advisory Committee
1 December 2025
Communiqué

This Communiqué covers matters considered at the 47th videoconference of the Gene Technology Technical Advisory Committee (1 December 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-218 RARMP – Commercial release of tomato genetically modified for purple fruit colour

Licence application DIR-218 from All Aussie Avocados Pty Ltd is for the commercial release of a tomato genetically modified for purple fruit colour.

GTTAC discussed various matters, including the use of antibiotic resistance genes in GM crops and potential for horizontal gene transfer (HGT), to be highly relevant to the risk assessment. The committee considered that potential risks associated with HGT have been identified and adequately addressed in the RARMP.

GTTAC agreed with conclusions in the risk scenarios, which identified that the risks associated with the GMO are considered negligible.

Resolutions

- The committee agrees that the risk assessment identified 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 with the overall conclusions of the RARMP.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR-220 Application – Commercial supply of multivalent cat vaccines containing a genetically modified component for the prevention of feline leukemia virus infection

Licence application DIR-220 from Intervet Australia Pty Ltd is for the commercial supply of multivalent cat vaccines containing a GM component for the prevention of feline leukemia virus infection.

GTTAC provided advice on the preparation of the consultation RARMP, where the following have been identified as key issues:

- Potential for accidental exposure of humans and animals to the GMO leading to harm;
- Potential for complementation and recombination of the GMO with other alphaviruses; and
- Potential for the GMO to be harmful to the environment.

The Regulator is seeking advice on:

- Whether the committee agrees that these issues should be considered when preparing the RARMP; and
- Other issues that should be considered in the preparation of the RARMP for this application.

GTTAC considered that the application contained sufficient detail required for a thorough assessment of the identified key issues.

The Committee discussed various matters, including the potential risk of a needlestick injury resulting in inadvertent exposure to the GMO. GTTAC suggested that in addition to seeing a general practitioner, the risk assessment may also require seeking ‘expert advice’.

Resolutions

- The committee agrees that the issues raised in this paper should be considered when preparing the RARMP

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR-221 RARMP – Clinical trial of GM *E. coli* for treatment of ulcerative colitis (Melius Microbiomics Pty Ltd)

Licence application DIR-221 from Melius Microbiomics Pty Ltd is a clinical trial of genetically modified (GM) *Escherichia coli* for the treatment of ulcerative colitis.

The proposed trial is to assess the efficacy and safety of the GMO. The trial would be conducted at a hospital and clinical trial sites in Brisbane, Australia. Up to 36 trial participants would be enrolled over a five-year period.

GTTAC noted the conclusion of the RARMP, that the proposed clinical trial poses negligible risks to the health and safety of individuals and the environment as a result of gene technology. The Committee suggested clarification in the RARMP in relation to:

- the bacteriophage attachment site of the GMO
- disinfectant concentrations
- minimisation of inadvertent faecal/oral exposure of the GMO
- potential for sexual transmission of the GMO – including to consider referring to a public health resource for advice.

GTTAC discussed the following matters, including:

- whether the parent organism should be considered as 'highly likely' to be present in the Australian environment
- uncertainty in relation to survival of the GMO inside a healthy gut compared to an ulcerated gut, which may possibly increase the risk of transmission of the tetrathionate reductase (ttr) operon to other organisms, including pathogenic bacteria
- GTTAC suggested to specify the food containing natural probiotics in the exclusion criterion for participants who have taken probiotics.

Resolutions

- The committee does not agree 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, specifically related to risk scenario 2.
- The committee does not agree that the limits and controls proposed in the draft licence to prevent the spread of the GMO are appropriate for the trial, specifically related to risk scenario 3.
- The committee does not agree with the overall conclusion of the RARMP.
- The Regulator should consider clarifying licence condition wording aiming to reduce faecal-oral contact/transmission.
- The Regulator should consider whether the uncertainty in the pre-clinical data is sufficient to support that the likelihood of transmission of the ttr operon to pathogenic bacteria is negligible or low.
- The Regulator should further consider clarifying the exclusion criterion relating to taking probiotics and whether probiotics should be defined.

ENQUIRIES

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