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

Gene Technology Technical Advisory Committee
5 May 2025
Communiqué

This Communiqué covers matters considered at the 44th videoconference of the Gene Technology Technical Advisory Committee (5 May 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-218 Application – 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 provided advice on the preparation of the consultation RARMP, where the following have been identified as key issues:

- the potential for the GM tomato to be harmful to the environment
- the potential for the GM tomato to be harmful to people through toxicity or allergenicity
- the potential for the GM tomato to be harmful to other organisms through toxicity
- the potential for harm to result from gene flow to other tomatoes

- whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact.

The Regulator is seeking advice on:

- whether the committee agrees that these issues should be considered when preparing the RARMP and
- any other issues that should be considered in the preparation of the RARMP for this application.

GTTAC considered potential horizontal gene transfer (HGT) of antibiotic resistance genes from the GMO to human gut microbiome or the environment, noting that the genes and expressed proteins would likely be degraded in the human digestive system. The committee discussed the potential scope and use of the GMO commercially. GTTAC considered that any information on HGT of antibiotic resistance genes from overseas trials and approvals of the GMO may be informative for assessment of this application.

GTTAC discussed potential for off-target gene expression in the GMO, leading to increased toxicity or allergenicity (e.g. toxic alkaloids). The committee considered that it may be useful to obtain more information on any upregulated genes/proteins in the GMO which may lead to increased levels of antinutritional compounds.

Resolutions

- The committee agrees that the following should be included in the RARMP:
  - the potential for the GM tomato to be harmful to the environment
  - the potential for the GM tomato to be harmful to people through toxicity or allergenicity
  - the potential for the GM tomato to be harmful to other organisms through toxicity
  - the potential for harm to result from gene flow to other tomatoes
  - whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact.
- The committee advised that the Regulator should further consider the potential risks associated with horizontal gene transfer to the human gut microbiome from widespread consumption.
- The committee advised that the Regulator should further consider the potential risks to consumers from the off-target production of other compounds including toxic alkaloids.
- The committee advised that the Regulator should seek more information related to tomato allergens in the GMO.
- The committee advised that the Regulator should seek more information related to the up-regulation of other genes in the GMO.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR-212 RARMP – Limited and controlled release of canola genetically modified for increased photosynthesis and photorespiration (The University of Adelaide)

Licence application DIR-212 from the University of Adelaide is a field trial of canola lines genetically modified for increased photosynthesis and photorespiration. The proposed field trial would take place between April 2025 and January 2030, on one site with a maximum area of 2 hectares per year, located in Light Regional Council in South Australia. The purpose of the trial is to evaluate the performance of the GM canola under field conditions.

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.

GTTAC discussed the possibility of overexpression of the Pip1;3 protein affecting pollen hydration in the female parent. The committee suggested to clarify the evidence that Pip1;3 overexpression is only relevant in the female parent.

GTTAC suggested clarifying terminology to separate discussion of seed dispersal characteristics and effects on the number and size of seeds.

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 limits and controls proposed in the draft licence are appropriate for the field trial.
- The committee agrees with the overall conclusion of the RARMP.
- The committee advises that the Regulator should consider clarifying the degree of hydration with Pip1;3 overexpression in pollen.

DIR-213 RARMP – Clinical trial of a genetically modified human adenovirus for the treatment of melanoma (Novotech (Australia) Pty Ltd)

Licence application DIR-213 from Novotech (Australia) is a clinical trial of a genetically modified human adenovirus for the treatment of melanoma.

The proposed trial would assess the safety and efficacy of the GMO in trial participants diagnosed with metastatic melanoma. The applicant proposes to conduct the trial at clinical trial sites and hospitals within Australia. Up to 30 participants would participate in the trial.

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:

- the proposed maximum dose of the GMO and how it compares to similar clinical trials
- the proposed technique for administering the GMO
- the specificity of the GMO for tumour cells
- consideration around overexpression of CD40 ligand and association with autoimmune diseases and other conditions
- appropriate precautions and training for clinical staff to reduce the risk of inadvertent exposure to the GMO
- clarifying the wording in the licence conditions related to safe-sex practices, to reduce the risk of inadvertent exposure to the GMO
- clarification regarding decontamination procedures
- the difference in consequence of inadvertent exposure for immunocompromised and non-immunocompromised individuals.

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 GMO are appropriate for the trial.
- The committee agrees with the overall conclusions of the RARMP.
- The committee advises that the Regulator should consider clarifying the dose, sites of intervention and risks associated with delivery including the fanning technique during application in the RARMP.
- The committee advises that the Regulator should consider clarifying the evidence provided by the applicant regarding the specificity of this adenovirus.
- The committee advises that the Regulator should consider clarifying the risk potential of autoimmune diseases from the overexpression of CD40L.
- The committee advises that the Regulator should clarify the interpretation related to the exclusion of 'immunocompromised' individuals involved in dealing with this GMO.
- The committee advises that the Regulator should consider the risks of processing blood and other biological samples under the licence.
- The committee advises that the Regulator should clarify the language in the RARMP related to safe-sex practices.
- The committee advises that the Regulator should clarify the management of spills associated with this GMO.
- The committee advises that the Regulator should refine the risk level in the RARMP as a result of systemic exposure to the GMO for different populations.

ENQUIRIES

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