



Australian Government

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

Gene Technology Technical Advisory Committee

26 August 2024

Communiqué

This Communiqué covers matters considered at the 39th videoconference of the Gene Technology Technical Advisory Committee (26 August 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 CONSULTATION RARMPs – LIMITED AND CONTROLLED RELEASE

DIR-205 – Limited and controlled release of canola genetically modified for abiotic stress tolerance

Licence application DIR-205 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO) is for a field trial of genetically modified (GM) canola modified for abiotic stress tolerance to environmental stress. The trial would be conducted at up to 3 sites per year, with a maximum planting area of 1.5 ha per site in the first year and 2 ha per site in the subsequent years, for 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 following key topics:

- the presence of a hemagglutinin peptide tag in some GM canola and possible impacts if the GMO is consumed – although this trial does not involve the use of the GM canola in human food or livestock feed, and the likelihood of harm would be negligible
- considerations around the evidence related to allergenicity – noting that the purpose of the trial would be to gather more data, including on allergenicity
- considerations around weediness – the proposed controls would be appropriate for containing the GMO at the scale of this trial, and the trial is expected to provide further data on weediness.

Resolutions

- The committee agrees that the risk assessment identified all plausible risk scenarios by which the proposed release could potentially give rise to risks relating to the health and safety of people or the environment.
- The committee agrees that the measures to limit and control the release would be appropriate for the field trial.
- The Regulator should further consider risks associated with the human influenza hemagglutinin peptide tag.
- 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-698 – A clinical trial of ECUR-506 for treatment of males with genetically confirmed neonatal onset Ornithine Transcarbamylase (OTC) deficiency

The Murdoch Children's Research Institute applied for a licence to conduct a clinical trial of a gene therapy for the treatment of OTC deficiency. The therapy is based on an adeno-associated virus (AAV) and is expected to promote the integration of a functional human ornithine transcarbamylase gene in the trial participants.

GTTAC noted the conclusion of the RARMP that the proposed application poses low to moderate risks to the health and safety of people or the environment. The Committee discussed the following key topics:

- risks to clinical staff, carers or family members of the patients from inadvertent exposure to the GMOs
- the novelty of the chosen nuclease, risks from its off-target effects, including the potential for oncogenicity from off-target effects on a specific epigenetic regulator
- considerations around restricting trial participants from donating blood, tissue or organs
- protection for carers and family members interacting with a trial participant in the early days following gene therapy administration
- requirement for a person who may have been exposed to the GMO to seek medical advice from the licence holder

- potential that a person exposed to the GMO may be immunised against the AAV serotype used in the clinical trial, making them ineligible for future gene therapy treatments involving the same AAV serotype.

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 that the risk associated with the exposure of personnel conducting the dealings, carers or family members to the GMOs resulting in harm is negligible to moderate.
- The Regulator should consider increasing restrictions around trial participant blood, tissue and organ donation to other people.
- The Regulator should further consider an additional control for people to cover any cuts when interacting with a trial participant and their secretions in the early days following administration.
- The Regulator should require people exposed to GMO to seek medical advice from the licence holder.
- The committee agrees that the other measures and controls included in the draft licence are appropriate to minimise the risks posed by this clinical trial to the health and safety of people or the environment.
- 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.