Australian Government

Department of Health, Disability and Ageing

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
16 December 2024
Communiqué

This Communiqué covers matters considered at the 41st videoconference of the Gene Technology Technical Advisory Committee (16 December 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-208 – RARMP – Clinical trial of GM vaccinia virus for the treatment of solid tumours

Licence application DIR-208 from Novotech (Australia) Pty Ltd is for a clinical trial in subjects with solid tumours. The trial would involve up to 40 participants at clinical trial sites and hospitals within Australia over a period of 5 years.

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

- the description of enriched replication of the GMO in tumour cells.
- clarifying language around the use of barrier contraception in the context of potential inadvertent exposure.

- considerations around potential inadvertent exposure to lab staff handling and analysing biological specimens from the trial.

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 clinical trial.
- The Regulator should consider rewording text around selective replication in tumours.
- The Regulator should further consider broadening controls associated with exposure to seminal and vaginal fluids.
- The Regulator should further consider risks to lab staff handling biospecimens from the participants.
- The committee agrees with the overall conclusion of the RARMP.

DIR-209 – RARMP – Limited and controlled release of *Sorghum* genetically modified for altered reproduction from sexual to asexual

Licence application DIR-209 from the University of Queensland is for a field trial of sorghum lines genetically modified to produce clonal seed. The trial would be conducted over 3 years at the University of Queensland, covering a maximum planting area of 1 hectare per year. The purpose of the trial is to assess agronomic and genetic characteristics of the GM sorghum plants under field conditions.

GTTAC noted the conclusion of the RARMP is that the proposed field trial poses negligible risks to people and that the identified low risks to the environment can be managed. The committee further noted that:

- pollen bags are designed to facilitate controlled pollination rather than prevent pollen dispersal.
- the licence proposes a monitoring zone to reduce the likelihood of outcrossing to sexually compatible plants outside the trial.
- the specified distance between the trial site and waterways is intended to reduce the likelihood of seed dispersal in the event of flooding.
- the licence conditions specify other limits and control measures to restrict potential spread and persistence of GM sorghum outside the trial site, as well as adverse event notifications.

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 proposed risk treatment measures to restrict pollen flow are appropriate to manage the identified risk.
- The committee agrees that the other limits and controls are appropriate for the field trial.
- The committee agrees with the overall conclusion of the RARMP.

DIR-210 – RARMP – Clinical trials of controlled infection with seasonal Influenza viruses

Licence application DIR-210 from Doherty Clinical Trials Ltd is a clinical trial to better understand influenza infections and to test the efficacy of potential vaccines and therapeutic drugs. The trial will be conducted over a period of five years at a Doherty Clinical Trials clinical facility, involving up to 150 healthy trial participants.

GTTAC noted that in assessing potential risks to human health and the environment, the conclusion of the RARMP is that the proposed clinical trial poses negligible to moderate risks to the health and safety of individuals as a result of gene technology. The Committee discussed the following key topics:

- the low pathogenicity of the wild-type strain upon which the GMO is based and its high sensitivity to antivirals.
- isolation requirements for trial participants following administration of the GMO.
- consistency in the RARMP and licence conditions with respect to transportation and disposal requirements.
- clarification around donning and doffing procedures for personal protective equipment.
- the access, layout and ventilation system of the isolation room.

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 clinical trial.
- The Regulator should further clarify entry and exit procedures as well as the layout and ventilation of the isolation room.
- 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.