Australian Government

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

Gene Technology Technical Advisory Committee
4 March 2024
Communiqué

This Communiqué covers matters considered at the 59th meeting of the Gene Technology Technical Advisory Committee (4 March 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 which 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 201 – Limited and controlled release of wheat and barley genetically modified for yield enhancement.

Licence application DIR 201 from the University of Adelaide is for a field trial of genetically modified (GM) wheat and barley, modified for enhanced yield. The trial is proposed to take place between May 2024 and January 2029, on one site with a maximum area of two hectares per year.

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

- the presence of antibiotic resistance genes in these GM crops and that they did not pose a substantive risk in the context of this trial.
- the cleaning of equipment used to thrash GM crops and risk mitigation imposed to address potential spread of GMOs.

- the potential for confusion with two trials (DIR 201 and DIR 186) being conducted at the same site, noting that consistent conditions are imposed on both licences.

Resolutions

- The Committee agreed 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 agreed that the measures to limit the release, particularly to restrict exposure of humans and animals to the GMO, are appropriate for the trial.
- The Committee did not identify additional information that should be considered.
- The Committee agreed with the overall conclusion of the RARMP.

DIR 203 – Limited and controlled release of cotton genetically modified for herbicide tolerance and insect resistance.

Licence application DIR 203 from Monsanto Australia Pty Ltd is for a field trial of GM cotton, modified for herbicide tolerance and insect resistance. The trial would be conducted at up to 25 sites, with a maximum planting area of 100 hectares each year, from September 2024 to September 2029.

GTTAC noted the conclusion of the RARMP 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 intended use of the resulting products, given the large trial size.
- whether licence conditions would apply to GM cottons taken to processing/ginning facilities after harvest, noting that conditions require physical separation of GM and non-GM cotton.
- the potential impacts of stacked traits on insects, soil microorganisms and ecosystems, noting that further information would be required from the applicant if approval was sought for a larger scale or commercial release.

Resolutions

- The Committee agreed 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 agreed that the measures to limit and control the release, particularly to restrict persistence and gene flow of the GM cotton, are appropriate for the trial.
- The Committee did not identify additional information that should be considered.
- The Committee agreed 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 688 – Clinical trial of a treatment for refractory/relapsing B-cell malignancies

Premier Research (Australia) Pty Ltd has applied for a licence to assess the safety and effect of a lentiviral vector containing a transgene for chimeric antigen receptor (CAR) specific to CD20.

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

- licence conditions that require the use of contraceptives for patients receiving treatment.
- the potential for exposure to the GMO by needlestick injury.
- the potential oncogenicity of the therapy.
- aspects of the RARMP that address specificity of the CD7-binding molecule to target cells and transformation of germ cells.

Resolutions

- The Committee recommended the Office evaluate the risk of oncogenicity, address the potential impact on germ cells, separate the risk characterisation of intravenous versus non-intravenous exposure of personnel, and clarify licence conditions around the use of contraceptives by subjects.
- The Committee concluded that the risk associated with the non-intravenous exposure of personnel (including lab staff) conducting the dealings, carers or family members to the GMO resulting in harm is low. However, the Committee recommended that the office revisit the consequence assessment for non-subjects in relation to intravenous or needlestick exposure to the GMO and the potential negative impact on heathy B-cells. The committee proposed that the consequence of this highly unlikely scenario is more likely to be major, which would result in a moderate risk.
- The Committee identified additional relevant information on the potential oncogenicity of the therapy.
- The Committee did not agree with the overall conclusion of the RARMP and recommended the Office:
    - Revisit the risk characterisation of personnel inadvertently exposed to the GMO via needle stick injuries.
    - Strengthen consideration of the specificity of the CAR T-cells in the risk assessment.
    - Address the risk of germ line transformation.
    - Evaluate the risk of oncogenicity taking into consideration new literature in this area.

ENQUIRIES

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