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

Gene Technology Technical Advisory Committee
25 August 2025
Communiqué

This Communiqué covers matters considered at the 46th videoconference of the Gene Technology Technical Advisory Committee (25 August 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 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 RARMP – COMMERCIAL RELEASE

DIR-216 RARMP – Commercial release of *Gossypium hirsutum* genetically modified for insect resistance and herbicide tolerance

Licence application DIR-216 from Bayer CropScience Pty Ltd is for the commercial release of genetically modified (GM) cotton produced by conventional breeding of five previously approved GM parent cottons genetically modified for insect resistance and herbicide tolerance. The GM cotton would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has assessed and approved food made from each of the five parent GM cottons.

GTTAC discussed several matters, including the antibacterial resistance promoter Tn7. GTTAC requested clarification in the RARMP in relation to the Tn7 promoter.

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 with the licence conditions in the draft licence are appropriate for the commercial release of the GMO.
- The committee agrees with the overall conclusion of the RARMP.
- The committee recommends that the Tn7 promoter should be further clarified.

DIR-217 RARMP – Commercial supply of Nadofaragene firadenovec for bladder cancer treatment

Licence application DIR-217 from Ferring Pharmaceuticals Pty Ltd is seeking approval to supply a GMO therapeutic for bladder cancer treatment. A licence is sought for import, transport, storage and disposal of the GMO. The GMO would be administered inside urology and oncology facilities in hospitals.

GTTAC discussed the following topics:

- decontamination process of the GMO following urination
- potential for replication competence leading to recombination with the wildtype
- potential for inadvertent exposure of infants and immunocompromised people to replication competent adenovirus during the period following treatment.

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 recommends that the information on the prevalence and serotyping of HAdV in Australia be clarified.
- The committee recommends that clarity be sought about the testing method from the applicant.
- The committee recommends that the Regulator consider providing advice to the TGA on the matter of potential risks to personnel involved with the commercial supply of this GMO, including the low potential for integration by adenovirus.
- 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.