Australian Government

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

Gene Technology Technical Advisory Committee
14 November 2023
Communiqué

This Communiqué covers matters considered at the 36th videoconference of the Gene Technology Technical Advisory Committee (14 November 2023)

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 – COMMERCIAL RELEASE

DIR 199 – Commercial release of banana genetically modified for resistance to Fusarium wilt tropical race 4

Licence application DIR 199 from The Queensland University of Technology is for the commercial cultivation of GM bananas modified for resistance to the fungal disease Fusarium wilt tropical race 4 (TR4) or Panama disease.

GTTAC considered the potential for novel protein expression and discussed methods used by the applicant to detect expression, noting that bioinformatic analysis had not identified additional allergens or toxins.

Resolutions

- The Committee agreed that 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 had been identified.
- The Committee did not identify additional information that the Office should consider.
- The Committee agreed with the overall conclusion of the RARMP.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 200 – Fermentation and processing of recombinant proteins using genetically modified *Pichia pastoris*

Licence application DIR 200 from Cauldron Molecules Pty Ltd is for the growth, transport, storage, and disposal of a GM *Pichia pastoris* (yeast) to produce bovine milk, chicken egg and spider silk fibre proteins.

GTTAC discussed the applicant's proposal for decontamination and inactivation methods of material produced. The committee considered information provided by the applicant and recommended that further clarification be sought from the applicant regarding methods for decontamination and inactivation, noting that verified methods would be provided to the Regulator following small and large scale testing runs.

GTTAC discussed the potential for accidental release of viable GM yeast carrying antibiotic resistance genes into the environment by way of use as animal feed or soil conditioner and recommended that further information be sought from the applicant regarding processing pathways of inactivated yeast. The Committee further recommended that consideration should be given to limiting the end-use of material from GM yeast containing antibiotic resistance genes.

Resolutions

- The Committee agreed that all plausible risk scenarios by which the proposed dealings could give rise to risks relating to the health and safety of people or the environment had been identified.
- The Committee noted the relatively large volume of antibiotic resistance marker genes and proteins potentially generated. The Committee suggested that the Office seek further clarification from the applicant on the fate of DNA and DNA products and the efficacy of the decontamination and inactivation pathways and methods for these. In the absence of such data, the Office should consider segregating GM yeast containing antibiotic resistance genes from use for soil conditioning or in animal feed.
- The Committee recommended that the Office clarify the definition of 'inactivation' in the licence.
- The Committee agreed that the limits and controls proposed in the licence are appropriate to manage risks to human health and the environment.
- The Committee did not identify additional information that the office should consider.
- 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 680 – Vaccinia vectored vaccines against SARS-CoV-2 and Influenza A virus

The University of Melbourne has applied for a licence to conduct laboratory-contained research to assess Modified Vaccinia Ankara vectored vaccine for SARS-CoV-2 and Influenza A virus in mice.

GTTAC discussed the work practices proposed for vaccinating mice and the potential for needlestick injuries. Following clarification from the OGTR that other licences allow for mice to be restrained by hand, the Committee suggested that the Regulator should consider amending licence condition 34(h) to exclude or limit restraint of mice by hand.

Resolutions

- The Committee agreed that all plausible risk scenarios by which the proposed dealings could give rise to risks relating to the health and safety of people or the environment had been identified.
- The Committee agreed that the containment measures proposed in the licence are appropriate to manage risks to human health and the environment.
- The Committee recommended that the Office consider amending licence condition 34(h) to preferably exclude or limit restraint of mice by hand to reduce the risk of needle stick injury.
- The Committee did not identify additional information that the Office should consider.
- The Committee agreed with the overall conclusion of the RARMP.

REPORTS

An officer from FSANZ provided an overview of the assessment process for GM food, in relation to GM bananas produced under DIR 199. FSANZ's assessment of the GM bananas concluded that they are not toxic or allergenic.

ENQUIRIES

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