Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

28 September 2021

Communiqué

This Communiqué covers matters considered at the 27th videoconference of the Gene Technology Technical Advisory Committee (28 September 2021)

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. Information on how to obtain copies of DIR applications and RARMPs is provided at the end of this document.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 185 – Clinical trial with a genetically modified *Bordetella pertussis* for the prevention of whooping cough

Licence application DIR 185 from Novotech (Australia) Pty Ltd is for a clinical trial using a genetically modified (GM) *Bordetella pertussis* as an inhaled vaccine for whooping cough. Up to 300 healthy participants would receive the GM vaccine at clinical trial sites and hospitals in Australia.

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

- the low likelihood of horizontal gene transfer occurring, noting that if it did occur, it would not be expected to confer an advantage

- the low likelihood of GMO being able to colonise anyone accidentally exposed to it
- the presence of an antibiotic resistance gene, noting this is present in the non-GM parental strain
- the potential for exposure by needle-stick injury or aerosolisation of the GMO in the administration room.

Resolutions

- The committee agrees that the risk of the GMO causing disease from accidental exposure is negligible.
- 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 are appropriate for the clinical trial.
- The Regulator should consider clarifying the potential for horizontal gene transfer.
- 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) or clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 646 – Two types of split gene drive for *Drosophila melanogaster* lab experiments

The University of Melbourne has applied for a licence to investigate two types of split gene drive for *D. melanogaster* in a PC2 invertebrate facility.

GTTAC noted that the RARMP concludes that the proposed dealings pose negligible risks to the health and safety of people and the environment as a result of gene technology. The Committee discussed the potential for off-target effects from Cas9 and agreed that the risk would remain low. GTTAC considered the proposed physical containment practices would reduce the likelihood of GMOs being released.

Resolutions

- 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 containment of the GM Drosophila is appropriate.
- The committee did not identify additional relevant information that should be considered.
- The committee agrees with the overall conclusion of the RARMP.

OTHER ADVICE

Information requirements for environmental release of gene drive GMOs

GTTAC discussed the OGTR's preliminary analysis of data/information that may be required for risk assessment of environmental releases of a gene drive GMO (GD-GMO).

Resolutions

- The types of data/information that may be required for environmental risk assessments of GD-GMOs are consistent with OGTR's current application forms and approach.
- Australian and overseas data from research on GD-GMOs would be relevant for environmental risk assessment of any proposed Australian environmental releases.
- Data from studies in physical containment facilities would be of equivalent relevance whether conducted in Australia or overseas.
- Ecosystem modelling data may inform risk assessment and risk management of proposed releases of GD-GMOs in some instances.
- A case by case approach for risk assessment and risk management of environmental releases of GMOs, including data/information requirements, remains relevant and applicable for GD-GMOs.

ENQUIRIES AND RISK ASSESSMENT AND RISK MANAGEMENT PLANS

For all enquiries and to obtain copies of applications or RARMPs for Dealings involving the Intentional Release (DIR) of GMOs into the environment, please call the OGTR on 1800 181 030 or email ogtr@health.gov.au. DIR RARMPs are also available on the OGTR website.