Australian Government

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

Gene Technology Technical Advisory Committee
4 September 2023
Communiqué

This Communiqué covers matters considered at the 35th videoconference of the Gene Technology Technical Advisory Committee (4 September 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 196 – Commercial supply of Qdenga, a live attenuated GM dengue vaccine

Licence application DIR 196 from Takeda Pharmaceuticals Australia Pty Ltd is for the import, storage, transport, and disposal of a GM dengue vaccine (Qdenga).

The Committee noted the conclusion of the RARMP that the proposed commercial supply poses negligible risk to people and the environment as a result of gene technology. GTTAC discussed the potential for an adverse reaction in people that experienced a dengue infection following inadvertent exposure to the Qdenga vaccine and noted that such reactions had not been observed in prior clinical trials.

Resolutions

- The Committee concluded that the risk assessment identified 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 considered that no additional relevant information should be considered.
- The Committee agreed with the overall conclusion of the RARMP.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 198 – Clinical trial of a genetically modified alphavirus (Getah virus) for cancer treatment

Licence application DIR 198 from VRT Pharmaceutics is for a clinical trial using GM *Getah virus* (GETV) as a cancer treatment. Up to 12 adult patients would be administered the GMO over a three-month period, in a hospital setting.

GTTAC considered the additional data provided by the applicant and discussed the applicant's claims that the genetic modifications enhance pre-existing selectivity of the virus for cancer cells.

The Committee noted that the unmodified parent species is not present in the Australian environment. GTTAC discussed containment measures proposed by the applicant and noted that ineffective containment measures could increase the likelihood of exposure to animals. The Committee discussed potential impacts on animals and considered these justify stringent containment measures.

Resolutions

- The Committee concluded 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 risk of harm to animals due to mosquito-vectored transmission of the GMO is moderate.
- The Committee agreed that the additional data provided, and controls proposed by the applicant, compared to the previously submitted application are sufficient to minimise the risks posed by the dealings. The Committee advised that the dealings should be limited to specific, certified PC2 facilities in Adelaide, in order to confidently contain the dealings in order to manage the risks.
- No further information was suggested by the Committee.
- The Committee agreed with the overall conclusions 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 673 – Molecular determinants of Newcastle Disease Virus pathogenicity

CSIRO has applied for a licence to conduct laboratory-contained research to identify molecular determinants that contribute to the pathogenicity of Newcastle Disease Virus.

GTTAC discussed the definitions of immunocompromised and immunosuppressed in the context of potential restrictions on who could undertake the dealings, and suggested that these terms should be elaborated in the RARMP. The committee noted other situations in which it was appropriate to restrict who could undertake work with pathogens.

GTTAC queried the airflow differential in the facilities proposed for dealings and recommended that clarification be sought from the applicant on this point.

Resolutions

- The Committee concluded that the risk assessment describes 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.
- The Committee agreed that risks posed by the dealings to immunocompromised and immunosuppressed staff justify their exclusion from the dealings. The Committee recommended elaborating in the RARMP on the scope of what is understood by immunocompromised including clarifying existing exclusion protocols used by CSIRO for PC3 work involving ill or immunocompromised workers, and also exploring the working definition used by TGA.
- The Committee considered that in addition to the aforementioned resolution, the Office should seek clarification from the applicant on airflow data between the anteroom and animal PC3 rooms.
- The Committee agreed with the overall conclusion of the RARMP.
- The Committee agreed that the proposed risk management measures in the draft licence are appropriate.

ENQUIRIES

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