Australian Government

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

Gene Technology Technical Advisory Committee
15 May 2023
Communiqué

This Communiqué covers matters considered at the 33rd videoconference of the Gene Technology Technical Advisory Committee (15 May 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. Information on how to obtain copies of DIR applications and RARMPs is provided at the end of this document.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR 196 – Commercial supply of Qdenga, a live attenuated genetically modified (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, as part of its commercial supply in Australia as a human vaccine against dengue virus. This GM vaccine would be used for immunisation against dengue disease in Australians travelling to endemic areas.

The Office of the Gene Technology Regulator (OGTR) is preparing a RARMP for the application which is expected to be released for public consultation in late August 2023, and had identified the following as key issues to be considered in preparing the RARMP:

- Potential for accidental exposure of humans and animals to the GMOs leading to harm

- Potential for recombination, reversion, or mutation events which change the viral characteristics and lead to a pathogenic phenotype
- Potential for the GMOs to be harmful to the environment.

Members noted that the Therapeutic Goods Administration has regulatory responsibility for evaluating the efficacy of the vaccine and patient safety. The Committee discussed the number of doses of Qdenga administered under international approvals.

GTTAC agreed that inadvertent exposure of humans or animals leading to harm is very unlikely. The Committee considered that recombination and reversion events are also unlikely. Members observed that dengue outbreaks in Australia have become less frequent since the release of mosquitoes carrying *Wolbachia*.

Resolutions

- The Committee agreed that the matters identified by the office should be considered when preparing the RARMP.
- The Committee did not identify additional relevant information that should be considered.

DIR 199 – Commercial release of banana genetically modified for resistance to Fusarium wilt tropical race 4 (TR4)

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. The OGTR is preparing a RARMP for the application which is expected to be released for public consultation in August 2023, and had identified the following issues to be considered in preparing the RARMP:

- the potential for the GM banana to be harmful to people through toxicity or allergenicity
- the potential for the GM banana to be harmful to other organisms through toxicity
- the potential for the introduced traits to increase the weediness of the GM banana, leading to harm to the environment
- the potential for harm to result from gene flow to related species
- the potential for commercial release to result in changes to agricultural practices that may have an adverse environmental impact.

GTTAC noted that Food Standards Australia New Zealand will assess the use of the GM banana and its products as food for human consumption.

GTTAC noted that the applicant has indicated that the GM banana plants are not intended to be grown in Australia unless there is a disease outbreak. The Committee agreed that the scope of the RARMP should be for commercial scale production of the GMO and not assume any limitations on the release.

Resolutions

- The Committee agreed that the matters identified by the office should be considered when preparing the RARMP.
- The Committee did not identify additional relevant information that should be considered.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 195 – Trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils

The University of Tasmania is seeking approval for a trial with a GM vaccine for the prevention and/or treatment of devil facial tumour disease in Tasmanian devils. The proposed trial would be conducted within contained trial sites in Tasmania. Up to 22 Tasmanian devils would receive the GM vaccine in the trial.

GTTAC noted the conclusion of the RARMP that the proposed trial poses negligible risks to the health and safety of people and the environment as a result of gene technology.

Members discussed the possibility of transmission to wildlife and agreed that the design of the enclosures and proposed control measures would minimise the exposure of other animals. The Committee agreed that the risk from shedding to the environment is negligible, given the nature of the attenuated virus and the very small chance of shedding.

Other topics discussed by the Committee included:

- the testing regime required prior to release of the trial animals
- the use of safety needles or other measures to reduce the risk of needle stick injuries in personnel
- the use of personal protective equipment to reduce the risk of personnel being bitten or scratched by the trial animals.

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 agrees that the limits and controls proposed in the draft licence to prevent the spread of the GM vaccine are appropriate for the trial.
- The Regulator should reconsider the necessity of 12 negative tests over 6 months before releasing the devils into the wild.
- The Regulator should further consider the risks to personnel from needle stick injuries, and devil bites and scratches.
- 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) and clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 665 - Generating mouse models with altered inheritance

South Australian Health and Medical Research Institute has applied for a licence to conduct dealings with GM gene drive mice in containment. No GM mice are intended or permitted to be released into the environment.

GTTAC noted the conclusion of the RARMP 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 additional data that would be required before any potential release of a GM gene drive mouse could be considered. GTTAC considered the potential for unintended crossing with GM mice from other authorised dealings located in the same facility and agreed that this scenario was unlikely in the context of the measures in place to keep mice separate.

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 agrees the proposed conditions, including to restrict dealings with live mice to the PC2 animal facility, are appropriate for dealings.
- The Regulator should consider clarifying how the dealings under DNIR 627 would be separated from the dealings proposed under DNIR 665.
- 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.