Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

29 October 2019

Communiqué

This Communiqué covers matters considered at the 56th meeting of the Gene Technology Technical Advisory Committee (29 October 2019, Canberra)

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 Legislative and Governance Forum on Gene Technology.

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 (the Regulations), to publish Committee resolutions given to the Regulator. The Communiqué also provides an overview of any other major issues discussed by the Committee.

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.

The Regulator must seek GTTAC advice during the preparation of a RARMP for DIR applications that do not qualify as limited and controlled under Section 50A of the Act. The Regulator must also seek advice from GTTAC on RARMPs that have been prepared for all DIR applications.

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 169 – Limited and controlled release of microalgae genetically modified (GM) for increased production of fatty acids

Licence application DIR 169 from The University of Queensland (UQ) is for a licence to grow GM microalgae modified for increased production of medium chain fatty acids. The trial would be conducted at a single pilot plant at a UQ's Pinjarra Hills campus. GM microalgae would be grown in several batches in closed outdoor culture vessels, with a combined cultivation period of up to 12 months. The trial would be finished at the end of 2022

The Committee noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to people or the environment. The main topic discussed by members was the setup of the facilities and the proposed measures to limit and control the release. GTTAC

noted that the OGTR intended to visit the facilities before finalising the RARMP to ensure the draft licence conditions are appropriate.

The Committee also discussed the genetic modifications and their possible effect on the phenotype of the GM microalgae, including growth rate and fatty acid profile.

GTTAC agreed to the following resolutions.

Resolutions

- The Committee agrees with the overall conclusions of the RARMP.
- The Regulator should further consider the requirements for containing the GMOs to the trial site.
- The Regulator should further consider additional phenotypic information for the GMO and whether there is potential for adverse human health and environmental effects.

DIR 170 – Trial of genetically modified vaccines against Ross River virus infection in horses

Licence application DIR 170 from UQ is for a trial of three live GM vaccines for protection of horses against *Ross River virus* infection. The proposed trial would be conducted at the UQ Gatton campus in the Lockyer Valley over a period of four years. Up to 40 horses would be vaccinated in the trial.

The Committee noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to people or the environment. GTTAC discussed the potential for recombination and noted that screening the horses for the presence of *Ross River virus* or other viruses would take place up to seven days before the trial commenced, leaving a window where infection with another virus could occur undetected. Nevertheless, members agreed that co-infection of the same cell with another virus capable of recombining with the GMO is very unlikely.

GTTAC discussed the potential for accidental exposure to the GMO and suggested considering the risk to people with conditions such as dermatitis. Other topics briefly considered by the Committee included cleaning measures and the low likelihood of shedding the GMO or lesion formation.

GTTAC agreed to the following resolutions.

Resolutions

- The Committee agrees with the overall conclusions of the RARMP
- The Regulator should consider whether people with wounds or active dermatitis should be excluded from administering the vaccine
- The Regulator should further consider whether additional control measures are required to minimise potential recombination, especially where ross river virus infection may occur after the screening process.

OTHER ADVICE

Post-release review

The Committee was informed of a post-release review of Roundup Ready® canola recently conducted by the OGTR. GTTAC advice was sought on the following issues.

- Is there additional relevant information that should be considered?
- Does the Committee agree with the overall conclusion of the risk analysis review?

GTTAC commended the OGTR on undertaking this project and noted the assessment concluded that there is no new information to suggest that the risk assessment for Roundup Ready® canola is not valid and that changes to the risk management plan are required.

GTTAC agreed to the following resolution.

Resolution

- The Committee agrees with the overall conclusion of the risk analysis review.

INFORMATION ITEMS AND REPORTS

The Committee received an update from the Department of Health on the Third Review of the National Gene Technology Scheme and progress towards implementation to date.

The Committee received routine reports on relevant activities undertaken since the previous face-to-face GTTAC meeting in April 2018 from the cross-member with the Gene Technology Ethics and Community Consultative Committee, the Chair and the Regulator.

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 of GMOs into the environment, please call the OGTR on 1800 181 030 or email ogtr@health.gov.au. RARMPs are also available on the GMO Record page of the OGTR website.