Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
28 February 2022
Communiqué

This Communiqué covers matters considered at the 29th videoconference of the Gene Technology Technical Advisory Committee (28 February 2022)

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 190 – Commercial release of Indian mustard genetically modified for herbicide tolerance

Licence application DIR 190 from BASF Australia Ltd is for commercial cultivation of genetically modified (GM) Indian mustard containing genes for herbicide tolerance. BASF is seeking approval to commercially grow the GM Indian mustard Australia-wide, in all Indian mustard growing areas. The GM Indian mustard and its products would enter general commerce, including use in human food and animal feed. The OGTR is preparing a RARMP for the application expected to be released for public comment and advice from experts, agencies, and authorities in July 2022.

GTTAC discussed the following key topic/s:

- the international status of the commercial approval of the GM Indian mustard and of GM canola with the same transformation event
- the range of natural variability of Indian mustard varieties, as provided in the application for comparison with the GM Indian mustard
- the cropping environments for Indian mustard and canola.

Resolution

- The Committee agreed that the matters identified by the office should be considered when preparing the RARMP.

GMO REGISTER

The GMO Register lists activities with approved GMOs that can be safely carried out by anyone, without needing a licence. Dealings with a GMO may be entered on the GMO Register when they have been licensed; and the Regulator is satisfied the dealings are sufficiently safe to be undertaken by anyone without the need for oversight by the licence holder. The Regulator may choose to seek advice from GTTAC on any entry to the GMO Register.

ADVICE ON CONSULTATION RARMPS – INCLUSION ON GMO REGISTER

Register 003 – Inclusion of dealings with MON-ØØØ73-7 canola, genetically modified for herbicide tolerance, on the GMO Register

The Regulator has initiated a process to consider including dealings with MON-ØØØ73-7 (also known as Roundup Ready®) canola genetically modified for herbicide tolerance on the GMO Register. The dealings have been authorised under licence DIR 020/2002 since 2003. A consultation version of a RARMP is available for public comment until 31 March 2022.

GTTAC discussed the RARMP and agreed to the following resolutions:

Resolutions

- The Committee agrees that the conclusions of all relevant previous RARMPs remain valid.
- The Committee considered that the information gathered was sufficient to identify any new risks.
- The Committee agrees with the overall conclusions of RARMP Reg-003 and that the dealings pose minimal risk.

OTHER ADVICE

ADVICE ON TECHNICAL AND PROCEDURAL GUIDELINES

PC3 Certification Guidelines

The Regulator has initiated a review of PC3 Certification Guidelines. These Guidelines set out the requirements for the certification of Physical Containment Level 3 (PC3) facilities. The new Guidelines are simplified into a modular form with supplementary guidance material.

GTTAC commended the OGTR on the review of the Guidelines and discussed some technical aspects regarding decontamination requirements.

Resolutions

- The Committee suggested the Regulator further consider conditions and requirements where an anteroom may be used for decontamination.
- The Regulator should consider streamlining inspection checklists when Guidelines have been finalised.
- The Committee had no further comment or suggested changes to the draft Guidelines.

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.