Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

30 November 2020

Communiqué

This Communiqué covers matters considered at the 22nd video conference of the Gene Technology Technical Advisory Committee (30 November 2020)

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[1].

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 176 – Limited and controlled release of white clover genetically modified for increased condensed tannins

Licence application DIR 176 from PTM Solutions Australia is for a field trial of white clover genetically modified for increased condensed tannins. The Committee noted the key points in the consultation RARMP including the conclusion that the proposed release poses negligible risks to people or the environment.

[1] Formerly the Legislative and Governance Forum on Gene Technology

Key topic discussed by the Committee included:

- the use of beehives and the proposed measures to restrict pollen flow from the GMOs, including the use of tents, pollen traps and pollen buffers
- the requirement to fence sites and notify the Regulator if the fence is damaged
- the long survival time for white clover seeds in the context of using burial to destroy GM plant material, noting that only vegetative material would be destroyed by burial and that inspections of the burial site for volunteers would be required in case some seeds were inadvertently buried.

Resolutions

GTTAC agreed to the following advice to the Regulator:

- The Committee agrees that all plausible risk scenarios have been identified.
- The Committee did not identify any additional information that should be considered.
- The Committee agrees with the overall conclusion of the RARMP.

DIR 177 - Clinical trial of genetically modified adenovirus for bladder cancer treatment

Licence application DIR 177 from Novotech Australia Pty Ltd for a clinical trial of GM adenovirus for bladder cancer treatment. The Committee noted the key points in the consultation RARMP including the conclusion that the proposed release poses negligible risks to the health and safety of people or the environment as a result of gene technology.

The Committee discussed the potential for expression of the introduced gene in other proliferative cells, such as stem cells. GTTAC noted that the GMO specifically targets cancer cells resulting in a 1000 fold increase in expression compared to healthy cells.

Other topics discussed by the Committee included matters that are the remit of the Therapeutic Goods Administration and Human Research Ethics Committees, including patient safety and whether data from clinical trials included sampling urine and stool to confirm that replication in non-cancer cells is minimal. The Committee agreed that given the history of safe use of similar technology on the market, and the data from clinical trials, the GMO is likely to pose negligible risk to human health and environmental safety.

The Committee discussed the stringent exclusion criteria for patients and agreed the measures imposed by the RARMP are adequate and manageable.

Resolutions

GTTAC agreed to the following advice to the Regulator:

- The committee agrees with the overall conclusions of the RARMP.
- The risk assessment identifies all plausible risk scenarios.
- The committee did not identify any additional information that should be considered.
- The committee agrees with the proposed exclusions and measures for limiting contact with at risk people.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR 178 – Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (MS11 x RF3 and MS11 X RF3 x MON 88302)

Licence application DIR 178 from BASF Australia is for the commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system in Australia.

The Committee discussed the specificity of the promoter used to express the *barstar* gene as part of the hybrid breeding system. GTTAC also discussed the herbicide tolerance trait of the GM canola, noting that herbicide use was the remit of the Australian Pesticides and Veterinary Medicines Authority.

Members noted the OGTR's approach to preparing RARMPs using information provided by the applicant as well as scientific literature, Australian and international assessments of similar GMOs, and any other information available.

Resolutions

GTTAC agreed to the following advice to the Regulator:

- The Regulator should consider the expression and function of the *barstar* gene in the MS11 line and any implication for the risk assessment.
- The Committee agreed that the matters identified in the agenda paper should be considered in the risk assessment.

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.