Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

23 February 2021

Communiqué

This Communiqué covers matters considered at the 25th video conference of the Gene Technology Technical Advisory Committee (23 February 2021)

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 CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 179 – Clinical trial with a genetically modified *Vaccinia virus* based treatment for solid cancerous tumours

Novotech (Australia) Pty Ltd is seeking approval for a clinical trial of genetically modified (GM) *Vaccinia virus* to treat solid cancerous tumours. The proposed treatment uses a GM *Vaccinia virus*, which has been designed to preferentially multiply in, and kill cancer cells.

GTTAC noted the conclusion of the RARMP that risks to the health and safety of people and the environment from the proposed clinical trial are negligible. The Committee had a wide-ranging discussion of the risk assessment covering a number of topics, including:

- Training of laboratory staff involved in processing blood samples from trial participants and the labelling requirements for such samples

- Uncertainty, including around the applicant's view that the GMO selectively replicates in cancer cells and whether the findings from non-clinical studies in a model species would be transferrable when the GMO is administered in humans
- The different delivery methods proposed and possible effects on biodistribution, noting that similar risk management methods would remain appropriate, including provision of a contingency plan by the applicant in case of a spill
- The exclusion criteria for both trial participants and staff
- The hygiene requirements for trial participants, noting that some of the requirements were only relevant in the unlikely event that pustules developed.

GTTAC also briefly discussed some topics relating to efficacy and patient safety, noting that these considerations are the remit of the Therapeutic Goods Administration.

GTTAC agreed to the following resolutions.

Resolutions

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

ADVICE ON CONSULTATION RARMPS – COMMERCIAL RELEASE

DIR 175 – Commercial release of canola (*Brassica napus*) genetically modified for herbicide tolerance and a hybrid breeding system (MS11)

Licence application DIR 175 from BASF Australia Ltd is for the commercial cultivation of genetically modified (GM) canola line MS11. The GM canola contains introduced genes for herbicide tolerance and a hybrid breeding system and is intended for use as a parental line for breeding and seed multiplication.

GTTAC noted the conclusion of the RARMP that risks to the health and safety of people or the environment from the proposed dealings are negligible. The Committee discussed integrated weed management options noting that the use of herbicides is in the regulatory remit of the Australian Pesticides and Veterinary Medicines Authority.

GTTAC agreed to the following resolutions.

Resolutions

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

DIR 182 – Commercial supply of recombinant COVID-19 vaccine

Janssen-Cilag Pty Ltd is seeking approval for the import, transport, storage and disposal of a GM COVID-19 vaccine, as part of its commercial supply as a vaccine in Australia.

GTTAC noted the conclusion of the RARMP that risks to the health and safety of people or the environment from the proposed supply are negligible. Key topics discussed by the Committee included:

- the possibility of the GMO integrating into the human genome, noting that the Committee had discussed this at its 23rd video conference held 14 December 2020 and concluded the rate would be extremely low
- the very low likelihood that this GM vaccine could recombine with other GM vaccines such as the one being produced by AstraZeneca, should both be administered to the same person
- the potential for the GM vaccine to be released into sewage.

GTTAC agreed to the following resolutions.

Resolutions

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

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.