



Australian Government

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

Gene Technology Technical Advisory Committee

15 August 2022

Communiqué

This Communiqué covers matters considered at the 31st videoconference of the Gene Technology Technical Advisory Committee (15 August 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 CONSULTATION RARMPs – LIMITED AND CONTROLLED RELEASE

DIR 192 – Clinical trial of a genetically modified (GM) chimeric Orthopoxvirus (CF33-hNIS) as a cancer treatment

Medpace Australia Pty Ltd is seeking approval for a clinical trial of a GM chimeric Orthopoxvirus as a cancer treatment. The GM virus has been designed to preferentially multiply in and kill cancer cells, and the trial would evaluate its safety and efficacy. The trial would take place at clinical trial sites and hospitals in Australia and involve up to 18 patients with solid tumours.

GTTAC noted the conclusion of the RARMP that risks to the health and safety of people or the environment from the proposed clinical trial are negligible. The Committee advised that the GMO would still be able to replicate in non-cancer cells but at reduced levels.

GTTAC discussed matters relating to the GMO and the parent organism and agreed that the genetic modifications would be unlikely to increase pathogenicity.

Other topics discussed by the Committee include:

- licence conditions that trial participants would be required to follow while undergoing treatment and for a period of time after each treatment
- exclusion criteria for clinical staff
- potential risks to clinical staff of needle stick injuries
- potential exposure of people to the GMO during processing of samples.

Resolutions

- The Regulator should further consider the terminology around replication competency of the GMO and its ability to replicate in non-cancerous cells.
- The Regulator should consider the risks posed by re-sheathing needles.
- The Committee agrees that the proposed limits and controls are appropriate.
- The Committee agrees with the overall conclusion of the RARMP.

ADVICE ON CONSULTATION RARMPs – COMMERCIAL RELEASE

DIR 190 – Commercial release of Indian mustard genetically modified for herbicide tolerance (RF3)

Licence application DIR 190 from BASF Australia Ltd is for commercial cultivation of GM Indian mustard modified for herbicide tolerance. BASF is seeking approval to commercially grow the GM Indian mustard in all agricultural cropping areas in Australia. The GM Indian mustard and its products would enter general commerce, including use in human food and animal feed.

GTTAC noted the conclusion of the RARMP that the proposed release poses negligible risks to the health and safety of people or the environment. The Committee considered the scale of Indian mustard (*juncea canola*) production in Australia and whether an increase would affect the risk assessment.

GTTAC discussed management of volunteers in the field and the limited ability of Indian mustard to survive outside the field. GTTAC also discussed multiple herbicide resistance traits present in the environment, noting that this licence would only authorise herbicide tolerance traits already available in canola and Indian mustard. Members were referred to a report commissioned by the Office of the Gene Technology Regulator (OGTR) in 2020 on herbicide tolerant traits, which is available on the OGTR [website](#).

Resolutions

- The Committee agrees that all plausible risk scenarios have been identified.
- The Regulator should further consider impacts of increased planting levels of *juncea canola* in the future.
- The Regulator should further consider the likelihood of stacking.
- The Committee agrees with the overall conclusion of the RARMP.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR 193 – Commercial supply of a genetically modified infectious laryngotracheitis vaccine for chickens

Licence application DIR 193 from Bioproperties Pty Ltd is for the commercial supply of a GM vaccine for chickens, Vaxsafe® ILT, to protect chickens against infectious laryngotracheitis (ILT)

virus. Vaccination in chicken farms throughout Australia is proposed and would be ongoing from the date of issue of the licence. The OGTR is preparing a RARMP for the application which is expected to be released for public comment in October 2022, and has identified the following matters to be considered:

- potential for accidental exposure of humans and animals to the GMO leading to harm
- potential for complementation and recombination of the GMO with other infectious laryngotracheitis (ILT) virus strains
- potential for the GMO to be harmful to the environment.

GTTAC discussed the proposed methods of administration of the vaccine, and the manufacture, packaging and transport of the GMOs. Members observed that these viruses tend to infect poultry more than wild bird species.

Resolutions

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

OTHER ADVICE

Advice on matters to be considered in the preparation of a RARMP for a proposed broad licence application for adeno-associated virus (AAV)-based gene therapies

GTTAC was asked for advice on a proposal for a broad DNIR licence for clinical trials with AAV-based gene therapies. The Committee discussed restricting the genes that could be used in the trial and agreed that defining this precisely would be important. Members did not see any issues with the use of various capsids in the GMO. The Committee discussed maintaining oversight while allowing a more streamlined approach to these clinical trials.

The Committee noted that:

- AAV-base gene therapy trials were first conducted around 20 years ago and long term toxicities were not identified with these early trials
- adverse events in clinical trials of AAV-based gene therapies relate to recipients and usually involve high doses of the treatment
- despite recent reports of adverse events in patients, AAV is still considered one of the safest gene therapy vectors.

Resolutions

- The Committee agrees that the matters identified by the office should be considered when preparing a RARMP.
- The Regulator should thoroughly consider the immune response to AAV and/or the GMO.
- The Regulator should consider further restrictions on the gene inserted and codifying the extent of the modification.

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](#).