Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

28 February 2018

Communiqué

This Communiqué covers matters considered at the 14th video conference of the Gene Technology Technical Advisory Committee (28 February 2018)[1]

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, to publish committee resolutions given to the Regulator. The Communiqué also provides an overview of any other deliberations of the committee.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO

Dealings involving the Intentional Release (DIR) of a GMO 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 which 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 156 - Limited and controlled release of buffalo grass genetically modified for herbicide tolerance and dwarf phenotype

Licence application DIR 156 from The Royal Melbourne Institute of Technology University is for a field trial of buffalo grass genetically modified (GM) for herbicide tolerance and dwarf phenotype.

GTTAC noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to the health and safety of people and the environment. GTTAC discussed issues concerning mowing of the GM buffalo grass, including production of aerosols, personal protective equipment, and the frequency of mowing required under the draft licence.

[1] The video conference was held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Perth and Melbourne.

The Committee also discussed the proposed control measures to minimise dispersal of the GMOs and to restrict pollen flow to non-GM buffalo grass outside the trial site, noting that this is the first field trial of GM buffalo grass in Australia.

Resolution:

The Regulator should further consider:

1. Aerosol exposure as a result of mowing GM buffalo grass.
2. Control measures to mitigate against unintended spread of GM buffalo grass beyond the trial site.
3. Control measures aimed at minimising flowering of the GM buffalo grass.

DIR 159 – Limited and controlled release of genetically modified insect-specific viruses as vaccines against *Kunjin virus* infection in farmed crocodiles

The University of Queensland has applied for a licence to conduct field trials to assess the efficacy and safety of two GMO vaccines for protection of farmed crocodiles from *Kunjin virus* infection.

GTTAC noted the key points in the draft consultation RARMP including the conclusion that this release poses negligible risks to the health and safety of people and the environment.

GTTAC discussed a range of topics, including:

- the role of the APVMA in regulating the GMOs, including the assessment of efficacy
- the methodology for testing for the presence of the GMO in the context of considering risks associated with processing for food
- the potential for transmission to mosquitoes, noting the RARMP considered this and found the risks were not greater than negligible
- the specificity of the GMOs to insects and the studies cited in the RARMP showing that the GMOs did not replicate in any of the vertebrate cells tested
- the potential for needle stick injuries and the measures in place to minimise exposure via this pathway

Resolution:

The Regulator should further consider:

1. Control measures to ensure risks associated with processing for food are adequately managed.
2. Risks arising from transmission to insects, including mosquitos.
3. Potential for the GMO to replicate in crocodiles and then be shed into the environment.

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 OGTR website.