Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

7 January 2021

Communiqué

This Communiqué covers matters considered at the 24th video conference of the Gene Technology Technical Advisory Committee (7 January 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 APPLICATIONS – COMMERCIAL RELEASE

DIR 180 – Commercial supply of genetically modified COVID-19 vaccine

Licence application DIR 180 from AstraZeneca Pty Ltd is for the import, transport, storage and disposal of a genetically modified (GM) COVID-19 vaccine as part of its commercial supply as a vaccine in Australia. The Committee noted that the Therapeutic Goods Administration has regulatory responsibility for evaluating the efficacy of the vaccine and patient safety.

The Committee discussed a range of risk scenarios including the potential for the GMO to:

- recombine with wild type chimpanzee adenovirus or other adenoviruses
- interact with SARS-CoV-2
- integrate into the human genome
- cause antibody-dependent enhancement.

GTTAC agreed that all of these scenarios are very unlikely and pose negligible risk to people or the environment in the context of the activities being assessed.

Resolutions

- The risk assessment identifies all plausible risk scenarios by which the proposed dealings could potentially give rise to risks relating to the health and safety of people or the environment.
- The committee agrees with the overall conclusion of the RARMP.

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.