Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

19 October 2020

Communiqué

This Communiqué covers matters considered at the 21st video conference of the Gene Technology Technical Advisory Committee (19 October 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 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. 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.

The Regulator must seek GTTAC advice during the preparation of a RARMP for DIR applications that 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 – COMMERCIAL RELEASE

DIR 174 – Commercial supply of a genetically modified cholera vaccine, Vaxchora®

Licence application DIR 174 from Biocelect Pty Ltd is for the import, transport, storage and disposal of a genetically modified (GM) cholera vaccine, Vaxchora®, as part of its commercial supply in Australia.

The Committee noted the key points in the consultation RARMP including the conclusion that the proposed dealings pose negligible risks to people or the environment. GTTAC discussed the potential for harm from the vaccine strain acquiring one or more antibiotic resistance genes, and agreed this did not impact the conclusion that the risks are negligible.

Other topics discussed by the Committee included:

- information that could be included on the label, noting that the Therapeutic Goods Administration has regulatory oversight of labelling requirements
- studies demonstrating the safety of the vaccine in young children
- the timing of vaccine administration before patients travel overseas, and that it would be unlikely that vaccinated travellers were still shedding.

Resolutions

- The Regulator should consider including further information in the RARMP about risks associated with multi-drug resistance.

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.