Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

20 & 21 February 2017

Communiqué

This Communiqué covers matters considered at the 51st meeting of the Gene Technology Technical Advisory Committee (20 & 21 February 2017, Canberra)

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.

GTTAC members were appointed by the Assistant Minister for Rural Health, the Hon Dr David Gillespie MP, commencing 1 February 2017 for a three year term. The term for the previous Committee expired on 31 January 2017.

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 major issues discussed by 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 – COMMERCIAL RELEASE

DIR 148 – Commercial supply of Dengvaxia, a live attenuated genetically modified (GM) dengue vaccine

Licence application DIR 148 from Sanofi-Aventis Australia Pty Ltd is for the import, transport, storage and disposal of a live GM dengue vaccine, Dengvaxia, as part of its commercial supply in Australia. GTTAC was informed that the Therapeutic Goods Administration (TGA) will assess quality, safety and efficacy of the vaccine.

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 as a result of gene technology.

GTTAC considered the likelihood and implications of unintended exposure to the vaccine. GTTAC also discussed reporting of severe adverse effects (SAEs) globally and locally, including TGA's pharmacovigilance requirements. GTTAC noted that Dengvaxia has already been commercially distributed widely internationally, with very few SEAs reported.

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should consider providing advice to the TGA about risks to people that may be accidentally exposed to the vaccine
- The Regulator should consider investigating whether any adverse events or incidents reported overseas may be relevant to include in the RARMP

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 151 – Limited and controlled release of wheat genetically modified for disease resistance, drought tolerant, altered oil content and altered grain composition

Licence application DIR 151 from CSIRO is for a limited and controlled release of GM wheat modified for disease resistance, drought tolerance, altered oil content and altered grain composition. The GM wheat would be grown on two field trial sites of up to one hectare each in NSW and the ACT. The risk assessment for DIR 151 concludes that this release poses negligible risks to the health and safety of people and the environment.

The Committee discussed proposed licence conditions including the measures to restrict access of animals to the trial site, and agreed that the proposed limits and controls are appropriate. GTTAC noted that small scale animal and human nutritional trials would only be undertaken if approved by an Animal Ethics Committee or a Human Research Ethics Committee, respectively.

Resolution – GTTAC advised the Regulator that:

- the committee agrees with the overall conclusions of the RARMP

DEALINGS NOT INVOLVING THE INTENTIONAL RELEASE OF A GMO

The Regulator may seek GTTAC advice on RARMPs prepared for a DNIR application. DNIR licences are for dealings with a GMO(s) that are not intentionally released into the environment. DNIR licences include research work with GMOs required to be undertaken in physical containment facilities (eg certified by the Regulator) or clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 570 – Characterisation of the molecular determinants of host responses and pathogenicity of Filoviruses

CSIRO has applied for a licence to generate, in contained facilities, GM Filoviruses and study the genes involved in pathogenesis, host responses, host range and cross-species transmission. GTTAC noted that the risk assessment concludes that the proposed dealings with the GMOs pose negligible to moderate risks to the health and safety of people and the environment.

GTTAC discussed the containment level and work practices appropriate for working with filoviruses and decontaminated materials. GTTAC also discussed the risk of accidental exposure to the GMOs, including during transport. Although the possible consequences of accidental exposure were assessed as anywhere between marginal and major, the level of containment required adequately manages the risks, which the committee agreed were negligible to moderate.

Resolution – GTTAC advised the Regulator that:

- The Regulator should consider clarifying the location and containment level for materials that are worked on after irradiation
- The Regulator should consider clarifying transport arrangements for the GMO
- The Regulator should further consider the appropriate containment level for transfection of cells
- The committee agrees with the overall conclusions of the RARMP

INFORMATION ITEMS AND REPORTS

OGTR staff provided the Committee with information on the gene technology regulatory scheme, the role of GTTAC, and the Regulator's approach to risk analysis. GTTAC received a report from the Regulator that provided updates on relevant activities recently undertaken by the Regulator and the OGTR.

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.