Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

12 March 2019

Communiqué

This Communiqué covers matters considered at the 55th meeting of the Gene Technology Technical Advisory Committee (12 March 2019, 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.

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 (the Regulations), 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 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 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 165 – Limited and controlled release of wheat genetically modified for altered iron uptake, transport and bioavailability

Licence application DIR 165 from The University of Melbourne is for a field trial of GM bread wheat genetically modified for altered iron uptake, transport and bioavailability. The trial would take place between April 2019 and December 2023 on up to 10 sites per year in the wheat belt in several States, with a maximum combined area of 20 ha per year.

The Committee noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to people or the environment. Key topics discussed by the Committee included:

- the scale of the proposed trial
- cadmium levels in the GM and non-GM wheat
- the low likelihood that workers milling the wheat could inhale enough cadmium to pose any health concerns

- the use of genome editing, noting that genome editing machinery would not be authorised to be present in the GMOs being released
- the potential for the applicant to breed the GMOs which could lead to the stacking of multiple introduced genes.

GTTAC agreed to the following resolutions.

Resolutions

- The committee agrees with the conclusion of the RARMP.
- The Regulator should consider:
  - whether testing of gene edited plants is required prior to field release
  - including discussion of stacking in the RARMP
  - whether the scale of the release represents additional risks for people or the environment.

DIR 166 – Limited and controlled release of *Cicer arietinum* (chickpea) genetically modified for drought and other environmental stress tolerance

Licence application DIR 166 from the Queensland University of Technology is for a field trial of GM chickpea modified for drought or other abiotic stress tolerance. The trial would be conducted at a single site at Walkamin Research Station in Queensland, with a maximum planting of 3 hectares each year, and would run from July 2019 until December 2024.

The Committee noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to people or the environment. GTTAC agreed that the requirement to submit a contingency plan would manage any risk associated with cyclones, and also noted that the risk is significantly reduced by chickpea planting being largely outside of the cyclone season.

GTTAC observed that knowledge of the unmodified parent species is based on data generated under typical chickpea growing conditions, and noted that the proposed trial site is outside typical chickpea growing regions.

GTTAC agreed to the following resolutions.

Resolutions

- The committee agrees with the conclusions of the RARMP.
- The Regulator should further consider the relevance of published agronomic information noting that the trial will be conducted outside of normal chickpea growing areas.

DEALINGS NOT INVOLVING THE INTENTIONAL RELEASE OF A GMO

The Regulator may seek GTTAC advice on RARMPs prepared for an application for Dealings Not involving an Intentional Release (DNIR) into the environment. DNIR licences include research work with GMOs undertaken in physical containment facilities (eg certified by the Regulator) or clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 594 – A cytomegalovirus prophylactic vaccine (V160) for use in clinical trials

Merck Sharp & Dohme (Australia) submitted licence application DNIR 594 to conduct clinical trials with an attenuated GM human cytomegalovirus (HCMV). The GMO is based on HCMV but contains a number of attenuating mutations, plus genetic modifications that make it dependent on a synthetic compound for replication. Up to 107 women aged 16 – 35 years are proposed to participate in the trial in Australia, as part of a global Phase 2 clinical trial.

The Committee discussed possible pathways to unintentional exposure of people to the GMO. Specifically, the Committee considered:

- the potential for the GMO to leak from the injection site, noting that the GMO would be replication defective
- the potential for recipients of blood, tissue and organ donations made by trial participants to be unintentionally exposed to the GMO.

GTTAC agreed to the following resolutions.

Resolutions

- The committee agrees with the conclusions of the RARMP.
- The Regulator should consider including measures to limit the potential for recipients of blood, tissue and organ donations to be unintentionally exposed to the GMO.
- The Regulator should consider measures to contain the vaccine post removal of bandages.

OTHER ADVICE

The Biology of *Cicer arietinum* L. (chickpea)

Biology documents are prepared by the OGTR to provide an overview of baseline biology information relevant to risk assessment of genetically modified forms of the species.

GTTAC reviewed the biology document prepared for chickpea commended the OGTR on the development of a thorough reference document. Members made some minor suggestions to improve clarity and consistency in the document.

INFORMATION ITEMS AND REPORTS

The Committee received an update from the Department of Health on the Third Review of the National Gene Technology Scheme and progress towards implementation to date.

The Committee received routine reports on relevant activities undertaken since the previous face-to-face GTTAC meeting in April 2018 from the cross-member with the Gene Technology Ethics Committee, the Chair and the Regulator.

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 GMO Record page of the OGTR website.