Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

23 April 2018

Communiqué

This Communiqué covers matters considered at the 54th meeting of the Gene Technology Technical Advisory Committee (23 April 2018, 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 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 158 – Commercial release of *Carthamus tinctorius* L genetically modified for High Oleic Acid Composition

GO Resources Pty Ltd is seeking approval for commercial cultivation of safflower that is genetically modified (GM) for high oleic acid content. Plant material from the GM safflower would enter general commerce, including use in industrial oil production and animal feed. It is not intended to be used for human food.

The Committee discussed the germination rate of the GMO in the context of weediness, acknowledging that weediness was considered in the RARMP. The Committee noted that oleic acid is present broadly in the environment, and agreed that an increase in content in the GMO would not pose any additional risks to human health or the environment.

Resolution

- The Committee agrees with the overall conclusions of the RARMP.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 162 – Limited and controlled release of *Triticum aestivum* genetically modified for enhanced rust disease resistance

Licence application DIR 162 from the CSIRO is for a limited and controlled release of GM bread wheat and durum wheat modified to improve resistance to rust disease. The trial would take place from September 2018 to September 2023 in Ginninderra (ACT) and Boorowa (NSW) on a maximum area of up to 40 m^2 per season.

The Committee noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to people or the environment.

The Committee discussed the proposed control measures for limiting dispersal of GM pollen and seed, and the possible increase in the ability of the GM plants to survive under high disease pressure. It was agreed that the limits and controls for this trial would adequately manage any risks, noting that the RARMP identified issues that may need to be addressed before any future commercial release.

Resolution

- The Committee agrees with the overall conclusions of the RARMP; and
- The Regulator should consider whether the risk of dispersal of GM wheat seeds by rabbits has been adequately addressed in the RARMP.

DIR 161 – A genetically modified respiratory syncytial virus (RSV) vaccine for use in clinical trials

DIR 161 is a licence application from Clinical Network Services to conduct clinical trials of a GM vaccine against respiratory syncytial virus. The GM vaccine would be administered to up to 350 healthy adult volunteers by intranasal spray at specialised clinical facilities over a five year period.

The Committee discussed the size of the proposed trial, the low likelihood of the GMO causing symptoms, and exclusion criteria for “at risk” groups of people, including children and the elderly.

The Committee discussed the genetic modifications and agreed that the use of codon de-optimisation would result in the GMO being attenuated. The committee further discussed the possible effects of the additional amino acid mutations on the properties of the GMO.

Resolution

- The Regulator should:
  - consider clarifying trial exclusion on the basis of immunodeficiency, age and pregnancy;
  - further consider controls around the numbers of trial participants;
  - further consider attenuation of the GMO and risks related to transmission;
  - consider clarifying potential symptoms that may be associated with the GMO;
  - consider the impact of amino acid mutations, other than codon de-optimisation, on attenuation of the GMO; and
- The Committee agrees with instructions in relation to blood and organ donation.

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 583 – Phase 3 Study of ADXS11-001 Administered Following Chemoradiation as Adjuvant Treatment for high risk Locally Advanced Cervical Cancer: AIM2CERV.

Novotech Australia submitted licence application DNIR 583 for Phase 3 clinical trials of an attenuated GM *Listeria monocytogenes* administered as a cancer vaccine. Up to 32 patients with cervical cancer are proposed to participate over the period of the licence.

The Committee discussed a number of issues in relation to the GMO, including shedding, the use of antibiotics, attenuation of the GMO, and the requirement for a contingency plan.

The Committee agreed that the GMO could be considered a risk group 1 organism according to the classification of the AS/NZS 2243.3:2010 – *Safety in laboratories - Microbiological safety and containment*, but suggested the Regulator should consider how the GMO is handled when in a concentrated solution.

The Committee considered a number of matters in relation to risk of inadvertent exposure to clinical staff, including the use of biosafety hoods, the risk of needle stick injuries, requirements to wear personal protective equipment, and labelling of the GMO in storage.

Resolution

- The Regulator should:
  - further consider risks to clinical staff involved in the trial; and
  - consider appropriate labelling of GMOs in the clinical facilities.
- The Committee agrees that the GMO could be considered as a risk group 1 organism; however the Regulator could consider control measures appropriate for preparing or handling concentrated GMO.

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 an update from the OGTR on the Technical Review of the Regulations.

The Committee received routine reports on relevant activities undertaken since the previous face-to-face GTTAC meeting in December 2017 from the cross member with the Gene Technology Ethics Committee (GTECCC), 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.