Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

18 December 2017

Communiqué

This Communiqué covers matters considered at the 53rd meeting of the Gene Technology Technical Advisory Committee (18 December 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.

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 157 – Commercial release of cotton genetically modified for insect resistance (COT102)

Syngenta Australia Pty Ltd is seeking approval for commercial cultivation in Australia of a cotton line, COT102, that has been genetically modified (GM) for insect resistance. Plant material from the GM cotton would enter general commerce, including use in human food and animal feed.

COT102 contains one introduced insect resistance gene, which has previously been approved by the Regulator for commercial release in combination with other insect resistance genes and, in some cases, herbicide tolerance genes. The Committee noted that insect resistance management is the responsibility of the Australian Pesticides and Veterinary Medicines Authority and the cotton industry Transgenic and Insect Management Strategy (TIMS) Committee.

Resolution – GTTAC advised the Regulator that:

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

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 160 – Limited and Controlled Release of perennial ryegrass genetically modified for fructan biosynthesis

Licence application DIR 160 from the Department of Economic Development, Jobs, Transport and Resources in Victoria is for a field trial of GM perennial ryegrass plants that have been modified for fructan biosynthesis. The trial would take place between May 2018 and June 2020 at one site in south-west Victoria on a maximum area of 160 m^2.

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

Topics discussed by the Committee included:

- the proposed licence conditions including measures to contain the plant material
- pollen movement in the context of both allergenicity and gene flow, noting the distinction between viable and non-viable pollen
- areas of uncertainty that may need to be addressed to assess future applications, including additional characterisation of the GM plants with respect to toxicity, allergenicity and weediness.

Resolution – GTTAC advised the Regulator that:

- The Committee agrees with the overall conclusion of the RARMP.
- The Regulator should further consider the potential for long distance pollen flow.

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 580 – MVA-NP+M1: A new Influenza vaccine for use in human clinical trials

DNIR 580 from Clinical Network Services Pty Ltd is a licence application to conduct Phase 1 clinical trials to assess a GM Vaccinia virus as a vaccine for the prevention of influenza A.

The Committee briefly considered the potential for the GMO to recombine with other strains of the virus and noted that the likelihood is extremely low.

The Committee discussed proposed procedures around dressing of the injection site; clinical waste disposal; informing medical practitioners of relevant licence conditions; and transport of the GMO and blood samples. The Committee agreed that the risk associated with the proposed dealings is negligible, in the context of the proposed licence conditions.

Resolution – GTTAC advised the Regulator that:

- The Committee agrees with the overall conclusions of the RARMP.
- The Regulator should consider some further clarification around waste disposal methods and spill kits for transportation.

OTHER ADVICE

Technical Review of the Gene Technology Regulations 2001

The Regulator is conducting a Technical Review of the Regulations to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs, and to ensure that new technologies are regulated in a manner commensurate with the risks they pose. GTTAC advice was sought on proposed amendments relating to notifiable low risk dealings and exempt dealings, which are a subset of the proposals on which OGTR commenced public consultation on 30 November 2017.

GTTAC discussed the proposed amendments grouped into the following topics:

- Viral vectors with no host
- Clarifying wording relating to outcome of modifications
- Cloned viral genomes
- New exempt hosts
- Clarifying risk group considerations
- Gene drive GMOs

Overall the Committee was satisfied that these proposed amendments do not raise any concerns. The Committee discussed the clarity and effectiveness of some of the terminology used in the draft amendments. The Committee agreed with the OGTR that in the absence of more information about the risks associated with gene-drives, a cautious approach is warranted.

Resolution – GTTAC advised the Regulator that:

- The Committee supports the intention of the proposed changes.
- The Regulator should consider:
  - the wording of viral vectors with no host;
  - the use of virions in the wording for cloned viral genomes;
  - clarifying the wording of gene drives or providing additional notes or guidance.

Biology Documents

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 documents prepared for the Mediterranean fruit fly, buffalo grass and a microalga. The Committee commended the OGTR on the documents and agreed to the following resolutions:

The Biology of *Ceratitis capitata* Wiedemann (Mediterranean fruit fly)

Resolution – GTTAC advised the Regulator that:

- The Committee endorses the biology document.
- The Regulator should consider some specific text revisions to improve internal consistency.

The Biology of *Stenotaphrum secundatum* (Walter) Kuntze (buffalo grass)

Resolution – GTTAC advised the Regulator that:

- The Committee endorses the biology document.
- The Regulator should consider some specific text revisions to improve clarity.

The Biology of *Nannochloropsis oceanica* Suda & Miyashita (a microalga)

Resolution – GTTAC advised the Regulator that:

- The Committee endorses the biology document.
- The Regulator should consider:
  - some specific text revisions to improve clarity;
  - providing detail on harvesting methods.

INFORMATION ITEMS AND REPORTS

GTTAC received a report from the cross member with the Gene Technology Ethics Committee (GTECCC) on recent activities of GTECCC. GTTAC also received reports from the Chair and from the Regulator that provided updates on relevant activities undertaken since the previous face-to-face GTTAC meeting in May 2017.

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.