Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

14 April 2020

Communiqué

This Communiqué covers matters considered at the 19th video conference of the Gene Technology Technical Advisory Committee (14 April 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.

GTTAC members were appointed by the Minister for Aged Care and Senior Australians and Minister for Youth and Sport, Senator the Hon Richard Colbeck, for a three year term commencing 1 February 2020. The term of the previous Committee expired on 31 January 2020

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 – LIMITED AND CONTROLLED RELEASE

DIR 171 – Clinical trial of genetically modified Influenza vaccine (H3N2 M2SR)

Licence application DIR 171 from Clinical Network Services is for a clinical trial of a live genetically modified (GM) vaccine for the protection of people against *Influenza (flu) virus* infection.

The proposed trial would be conducted at up to four medical facilities, where up to 240 trial participants would be vaccinated over a three year period. The trial would assess the safety and effectiveness of the GM vaccine for children.

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

The Committee discussed several topics related to the potential for the GMO to spread or persist, including:

- how quickly the GMO would be cleared by trial participants
- how long trial participants would remain on the trial site post-inoculation
- the potential for spread of the GM vaccine to caregivers/parents
- the potential for the GM vaccine to persist in the clinical facilities.

In addition, members discussed the ages of the trial participants in the context of appropriate dose rates, and the potential for reassortment between the GMO and non-GM influenza.

GTTAC agreed to the following resolutions.

Resolutions

- The Regulator should consider clarifying timeframes for clearance after administration and whether related risk management measures are warranted.
- The Regulator should further consider whether PPE [Personal Protective Equipment] is appropriate for caregivers/parents or any other people present at administration.
- The Regulator should further consider risks associated with administration to children.
- The Regulator should further consider the risks associated with possible reassortment.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR 173 – Commercial release of cotton (*Gossypium hirsutum*) genetically modified for herbicide tolerance

Monsanto Australia is seeking approval for commercial cultivation in Australia of a GM cotton line (MON 88701) that has been modified for herbicide tolerance. If a licence is issued, the GM cotton could enter general commerce, including use in human food and animal feed.

MON 88701 contains two introduced genes (*dmo* and *bar*) that confer tolerance to the herbicides dicamba and glufosinate, respectively. The modification in MON88701, in combination with other insect resistance and herbicide tolerance traits, has been approved for commercial release under licence DIR 145.

GTTAC discussed the issues identified for consideration in the consultation RARMP being prepared by the Regulator for this application, including weediness and invasiveness, as well as the analysis of genotype stability.

Members discussed the use of herbicide tolerance traits more broadly. The Committee was advised that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is responsible for regulating herbicides, and there are reciprocal consultation requirements between OGTR and APVMA.

GTTAC agreed to the following resolutions.

Resolutions

- The Committee agrees that those matters outlined in the agenda paper should be considered when preparing the RARMP.
- The Committee did not identify any other matters that should be considered.

OTHER ADVICE

REG-002 – Proposal to include dealings with cut flowers of GM carnations on the GMO Register

International Flower Developments has applied to include import, transport and disposal of cut flowers from three GM carnation lines on the GMO Register. The carnations are modified for flower colour and produce flowers with blue/purple colour, which is otherwise not found in carnations. If included on the GMO Register, the dealings with the GM carnations could be conducted by anyone without the need for a licence. Dealings with similar GM carnations were included on the GMO Register in 2007.

GTTAC briefly discussed the treatment of all imported GM and non-GM carnations, and agreed to the following resolutions.

Resolutions

- The Committee agrees that the conclusions of RARMP for DIR 134 remain valid.
- The information gathered for this application is sufficient and no new information was identified.
- 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.

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.