Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

23 November 2016

Communiqué

This Communiqué covers matters considered at the 50th meeting of the Gene Technology Technical Advisory Committee (23 November 2016, 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, to publish committee resolutions given to the Regulator. The Communiqué also provides an overview of any other deliberations of 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 APPLICATIONS – COMMERCIAL RELEASE

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

Sanofi-Aventis Australia Pty Ltd has applied for a licence for the import, transport, storage and disposal of a live genetically modified (GM) dengue vaccine, Dengvaxia, as part of its commercial supply in Australia. GTTAC noted that the Therapeutic Goods Administration has responsibility for assessing the quality, safety and efficacy of vaccines for use in humans in Australia.

GTTAC noted that the following key matters had been identified for consideration in the RARMP:

- Potential for accidental exposure of humans or animals to the GM viruses leading to harm
- Potential for recombination events or mutations which change the viral characteristics and lead to a pathogenic phenotype.

Advice was sought from the committee in relation to these matters and on any other key issues that should be considered in the preparation of the RARMP for DIR 148.

GTTAC discussed the matters identified for inclusion in the RARMP and considered that the likelihood for transmission by mosquitoes or reversion to virulence was extremely low. The committee also discussed the potential for transmission of the GMO from a blood or organ donor.

Resolution – GTTAC advised the Regulator that:

- The committee agrees that the matters identified in the agenda paper should be considered in the RARMP
- In addition, the Regulator should consider the potential for spread of the vaccine virus via blood/organ donation pathways, and the need to monitor sero-conversion should inadvertent exposure occur.

ADVICE ON CONSULTATION RARMPS – COMMERCIAL RELEASE

DIR 143 – Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (GlyTol® and GlyTol TwinLink Plus®)

Bayer CropScience Pty Ltd has applied for a licence for the commercial release of two types of GM cotton: GlyTol® cotton, modified for herbicide tolerance and GlyTol TwinLink Plus® cotton, modified for both insect resistance and herbicide tolerance. If a licence is issued, the GM cottons and their products would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) has approved the use of material derived from these GM cottons in food.

The committee considered that the stacking of the individual GM lines is unlikely to pose any new risks not previously identified in the assessment of the parental lines. The committee noted that the small amount of uncertainty about the behaviour of cotton in northern Australia is because it has not been grown there commercially.

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should consider modifying the section on uncertainty to clarify that it relates to a lack of experience with growing GM cotton in northern Australia.

DIR 145 – Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 XtendFlex™ and XtendFlex™ cotton)

Monsanto Australia Ltd has applied for a licence for the commercial release of two types of GM cotton known as XtendFlex™ cotton, modified for herbicide tolerance and Bollgard® 3 XtendFlex™ cotton, modified for both insect resistance and herbicide tolerance. If a licence is issued, the GM cottons and their products would enter general commerce, including use in human food and animal feed. FSANZ has approved the use in food of material derived from these GM cottons.

As with DIR 143, the committee did not consider the stacking of the GM cotton lines posed any new risks beyond those identified for similar approved GM cottons. The committee discussed studies about toxicity of the introduced proteins to a range of insects including non-target insects.

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should consider clarifying the implication of recent references relating to the spectrum of toxicity of Cry proteins by making reference to previous assessments of Cry proteins

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 147 – Limited and controlled release of *Gossypium hirsutum* genetically modified for Insect resistance

Licence application DIR 147 from Monsanto Australia Ltd is for a limited and controlled release of GM cotton lines modified for insect resistance or herbicide tolerance. The proposed field trial would take place between March 2017 and July 2021 on up to 50 sites per year in Western Australia, New South Wales, Queensland, Victoria and the Northern Territory. The maximum combined area would be 50 ha in 2017, 100 ha in 2018, and 250 ha per year in 2019 and 2020, and the maximum planting size of individual trial sites would be 2 ha in 2017, 10 ha in 2018, and 50 ha per year in 2019 and 2020.

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. Key issues discussed by the committee:

- The large area and number of sites proposed for release
- The proposal to sell cotton lint from the trial, noting that material from the GMOs would not be used in human food or animal feed
- Uncertainty about the behaviour of cotton in northern Australia in the context of the proposed limits and controls
- Uncertainty about the potential range of insects, including Australian species, affected by the introduced proteins.

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should consider the relevance of uncertainty relating to growing GM cotton in northern Australia
- The committee supports the requirement for further research on non-target organisms, including beneficial species, prior to a large-scale or commercial release of the GMOs

DIR 146 - Consultation RARMP for DIR 146 – Limited and controlled release of banana genetically modified for disease resistance

The Queensland University of Technology is seeking approval to trial, under limited and controlled conditions, GM banana plants that have been modified for disease resistance. The field trial is permitted to take place at one site of up to 6 hectares in Litchfield Municipality, Northern Territory, for a period of 5 years.

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. The committee discussed the proposed measures to limit dispersal of the GMOs as well as the potential exposure of animals to the GMOs.

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should consider clarifying the need for fencing of the trial site/property or implementation of feral animal control measures
- The Regulator should consider clarifying the description of the likelihood and mitigation measures for extreme weather events

OTHER ADVICE

Review of the Gene Technology Regulations 2001

GTTAC was provided with an update on progress of the Regulator's technical review of the Gene Technology Regulations 2001 (the Regulations), and was asked for advice on gene drives and RNA interference, to inform the Regulator's technical review of the Regulations.

GTTAC discussed the use of Cas9-targetting of RNA to achieve similar results to RNAi techniques and referred to relevant publications. The committee discussed the containment requirements for working with GM gene drive organisms and the potential risk if a GM gene drive organism were accidentally released from containment.

Resolution

- Publications on Cas9-tagetting of RNA were provided to the OGTR
- GTTAC advised the Regulator that, depending upon the cargo and its effects, gene drive containing organisms may pose different risks if accidentally released from appropriate containment
    - Risks include risks to people and the environment, including the potential to adversely impact on populations/ecology
    - Evidence to support assessment of these risks is currently mostly theoretical; the Regulator should keep a watching brief on emerging data and evidence
    - Risks could be managed by giving further consideration to containment measures, guidelines and appropriate regulation

INFORMATION ITEMS AND REPORTS

An officer from the Department of Health provided the committee with an update on the upcoming review of the gene technology regulatory scheme.

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 June 2016.

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.