Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
Videoconference 21 December 2015[1]
Communiqué

This Communiqué covers matters considered at the 9th video conference of the Gene Technology Technical Advisory Committee (21 December 2015)

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 ministerial 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 major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO (DIR)

Dealings involving the Intentional Release (DIR) of a GMO can involve the limited and controlled release (clinical trial or field trial) or the commercial (general) release of a GMO.

The Regulator must seek advice from GTTAC on RARMPs for all DIR applications. The Regulator must also seek GTTAC advice during the preparation of the RARMP for DIR applications which do not qualify as limited and controlled under Section 50A of the Act.

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 138 – Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system

Bayer CropScience Pty Ltd is seeking approval for the commercial cultivation of canola genetically modified (GM) with a hybrid breeding system and tolerance to the herbicides glyphosate and glufosinate. The GM canola variety, known as InVigor® x TruFlex™ Roundup Ready® canola, is the result of conventional breeding between GM InVigor® canola and GM

[1] The videoconference was held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Hobart, Melbourne and Perth.

TruFlexTM Roundup Ready® canola, both of which were previously authorised by the Regulator for commercial release.

If approved, the GM canola would be grown in all canola growing areas in Australia, and its products would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) has assessed and approved food made from InVigor ® canola and TruFlex™ Roundup Ready® canola. These approvals also cover InVigor® x TruFlex™ Roundup Ready® canola.

Members were reminded that GTTAC is consulted twice on commercial DIR applications and that the committee provided advice on the preparation of the RARMP for DIR 138 during the first round of consultation that occurred at the 48th GTTAC meeting in August 2015.

GTTAC discussed the RARMP for DIR 138, which concludes that this release poses negligible risks to the health and safety of people and to the environment. Members discussed the dual herbicide tolerance trait and noted that herbicide resistance management comes under the regulatory oversight of the Australian Pesticides and Veterinary Medicines Authority.

RESOLUTION – GTTAC advised the Regulator that:

GTTAC agrees with the overall conclusion of the RARMP and raises no further issues

DIR 139 – Commercial release of canola genetically modified for herbicide tolerance

Pioneer Hi-Bred Australia Pty Ltd is seeking approval for the commercial scale release of GM canola variety Optimum™ GLY Canola. The GM canola contains an introduced gene that is intended to confer tolerance to the herbicide glyphosate. As with DIR 138, if this GM canola is approved it would enter general commerce, including use in human food and animal feed. FSANZ has assessed and approved food made from Optimum™ GLY Canola.

Members were informed that GTTAC's advice on the preparation of the RARMP, provided at the 48th GTTAC meeting in August 2015, was taken into account and discussed in the consultation RARMP.

GTTAC discussed the RARMP for DIR 139, which concludes that this release poses negligible risks to the health and safety of people and to the environment. Members discussed the metabolites produced as a result of the introduced gene, and noted that the GM canola had a similar agronomic performance to control canola, indicating the genetic modification was not affecting the GMO at a phenotype level.

RESOLUTION – GTTAC advised the Regulator that:

GTTAC agrees with the overall conclusion of the RARMP and raises no further issues

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 140 – Clinical trial of a genetically modified virus for treatment of liver cancer

Clinical Network Services Pty Ltd is seeking approval to conduct a Phase 3 clinical trial of a GM virus for treatment of patients with advanced liver cancer. The trial would involve up to 50 adult volunteers and would take place in hospitals throughout Australia. The GMO is a live vaccinia virus genetically modified to preferentially kill cancer cells and trigger an immune response against the tumour.

GTTAC noted that, as the trial involves the use of a therapeutic product, it must also meet Therapeutic Goods Administration requirements and will require approval from, and oversight by, a Human Research Ethics Committee.

Members discussed the RARMP for DIR 140, noting that the risk assessment concludes that the proposed clinical trial poses negligible to low risks to human health and safety and the environment. Members also noted the exclusion of at-risk people (such as pregnant women and the immunocompromised) from the trial. GTTAC discussed a number of issues which are captured in the committee's advice to the Regulator below.

RESOLUTION – GTTAC advised the Regulator that:

1. The Regulator should consider whether exclusion of patients with at-risk contacts is warranted
2. The Regulator should consider whether exclusion of patients with animal contacts is warranted
3. The Regulator should further consider recombination with other pox viruses
4. The Regulator should consider whether occlusive bandages should be used during the trial
5. The committee agrees with the overall conclusions of the RARMP

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 at http://www.ogtr.gov.au.