

Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee 17 January 2017 Communiqué

This Communiqué covers matters considered at the 12th video conference of the Gene Technology Technical Advisory Committee (17 January 2017)¹

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 CONSULTATION RARMPS - LIMITED AND CONTROLLED RELEASE

DIR 149 – Limited and controlled release of Indian mustard genetically modified for altered oil content

Licence application DIR 149 from Nuseed Pty Ltd is for a limited and controlled release of GM Juncea canola plants with altered oil content. The proposed field trial would take place over five years between April 2017 and May 2022, with trial sites selected from 102 possible local government areas in New South Wales, Victoria and Queensland. The trial would be conducted at a maximum of 4 sites of up to 2 hectares (ha) per site in 2017, 10 sites of up to 5 ha per site in 2018, and 15 sites of up to 10 ha per site in each subsequent year.

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 pollination of the GMOs in the context of the proposed limits and controls, and the

¹ The video conference was held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Hobart and Melbourne.

proposed animal feeding experiments with non-viable material from the GMOs. Approval from an animal ethics committee would be obtained before conducting any experiments.

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should consider clarifying licence conditions that relate to use of non-viable plant material for animal studies

DIR 150 – Limited and controlled release of potato genetically modified for disease resistance

The Queensland University of Technology is seeking approval to trial, under limited and controlled conditions, GM potato plants modified for disease resistance. The field trial would take place at one site of up to 0.1 hectares in Redland City, Queensland, for a period of two years.

GTTAC noted that this is the first application to trial GM potatoes to be considered by the committee, although previous trials of GM potatoes were conducted in Australia under the former voluntary system overseen by the Genetic Manipulation Advisory Committee. 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.

Main issues discussed by GTTAC:

- proposed measures to minimise the potential for dispersal of the GMOs, including use of a fence
- post-harvest monitoring requirements, including that any volunteer potato plants found would be destroyed by treatment with a herbicide such as glyphosate
- analysis of the GMOs including expression analysis and identification of homologous genes
- additional information identified in the RARMP that may be needed to assess an application to commercially release the GMOs, including the levels of natural toxins in the GM potatoes

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should consider clarifying whether a recent search for homologous genes has been undertaken
- The Regulator should consider clarifying whether any gene expression analysis has been performed in the glasshouse

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.