COMMUNIQUE
No. 28

This is the 28th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 38th meeting of GTTAC, held on 23 November 2010.

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 Gene Technology Ministerial Council. All Committee members and expert advisers hold office on a part-time basis.

The Regulator receives advice from GTTAC on Risk Assessment and Risk Management Plans (RARMPs) prepared in respect of applications for licences to conduct dealings with genetically modified organisms (GMOs).

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any resolutions the Committee has provided to the Regulator with regard to those applications and RARMPs.

The Communiqué also provides an overview of any other major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Dealings Involving the Intentional Release of GMOs (DIRs) involve the limited and controlled release (field trial) of a GMO or a commercial (general) release of a GMO.

The RARMP for every DIR licence application is released for public comment as part of the consultation process. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

GTTAC Advice

The Regulator must seek GTTAC advice on RARMPs prepared in respect of all DIR applications.

The Regulator must also seek GTTAC advice during the preparation of the RARMP for all DIR applications which are **not** assessed as 'limited and controlled' under Section 50A of the Act.

1. ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

GTTAC considered the Consultation RARMPs prepared in response to the following applications for limited and controlled releases:

1.1 DIR 105 –Limited and controlled release of canola genetically modified for herbicide tolerance

GTTAC noted that the GM canola from Monsanto had been modified to contain a gene derived from a common soil bacterium. Expression of the gene in the GM canola plants is expected to confer tolerance to herbicides containing glyphosate. The GM canola would not be used in human food or animal feed. The trial is proposed to take place over four years, from March 2011 to December 2014. Sites may be located in canola growing regions in 46 possible local government areas (LGAs) in New South Wales, 28 possible LGAs in Victoria and 53 possible LGAs in Western Australia.

RESOLUTION:

- GTTAC advised the Regulator that the potential for spread and persistence of the GM canola as a result of 'windrowing' should be considered.
- GTTAC advised the Regulator that the Brassica napus biology document should be reviewed to ensure it captures wind dispersal and growers' observations.
- GTTAC advised that the Regulator reconsider wording of conditions relating to isolation zones to improve clarity.

1.2 DIR 107 – Limited and controlled release of banana genetically modified for disease resistance.

GTTAC noted that the application from the Queensland University of Technology involved the intentional release of GM banana into the environment on a limited scale and under controlled conditions. Cavendish and Lady Finger bananas would be genetically modified for disease resistance, primarily to Fusarium wilt (Panama disease) and Yellow sigatoka (leaf spot).

A trial is proposed to take place at one site in the local government area (LGA) of Litchfield Municipality, Northern Territory, on a maximum area of 1.5 ha between November 2010 and November 2014.

RESOLUTION:

- GTTAC advised the Regulator that means of clearly separating GM and non-GM banana plants should be considered.
- GTTAC advised the Regulator that the potential for unintended effects had been adequately considered in the RARMP.

DEALINGS NOT INVOLVING INTENTIONAL RELEASE

Dealings not involving the intentional release of GMOs (DNIRs) are dealings that are usually undertaken within a facility where the organism is physically contained.

2. ADVICE ON CONSULTATION RARMPS – DEALINGS NOT INVOLVING INTENTIONAL RELEASE

GTTAC considered the Consultation RARMPs prepared in response to the following application for dealings not involving intentional release:

2.1 DNIR 496-Characterisation of the molecular determinants of host range and pathogenicity for Henipaviruses

GTTAC discussed the RARMP prepared by the Regulator in response to an application from the CSIRO and noted that the application concerns:

- the generation of plasmids encoding the GM viral genomes;
- transfecting mammalian cells lines with the GM plasmids expressing mutant or chimeric Hendra virus (HeV) or Nipah virus (NiV) to produce replication competent genetically modified (GM) virus particles;
- infecting mammalian tissue culture cells with the GM virus particles to characterise viral infectivity using *in vitro* assays;
- inoculating ferrets, mice, fruit bats, pigs and horses with the GM virus particles; and
- histological and immunological characterization.

GTTAC noted that the dealings with plasmids will be conducted in PC3 facilities and dealings with the GM viruses will be conducted in PC4 facilities and noted that infection in the general population was unlikely. GTTAC discussed possible risks to health and safety of staff undertaking the dealings, including administering the GMO to animals. GTTAC also noted that all reasonable precautions have already been proposed.

RESOLUTION:

- GTTAC advised the Regulator to consider further references relating to the consequence assessment for Risk Scenario 2*
- GTTAC advised the Regulator to consider having formalised responses to unexpected circumstances such as infected or symptomatic staff member.

*Risk scenario 2: exposure to replication competent GM Henipavirus (or tissue culture cells that contain GM Henipavirus) that has the capacity to infect humans leading to disease or death

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 phone the OGTR on 1800 181 030. The RARMPs are also available electronically from our website at <http://www.ogtr.gov.au>.