COMMUNIQUE
No. 27

This is the 27th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 37th meeting of GTTAC, held on 10 May 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 RARMP – COMMERCIAL RELEASE

GTTAC considered the consultation RARMP prepared in response to the following commercial release application: DIR 098 – GM live viral vaccine to protect against Japanese encephalitis (IMOJEV™)

Sanofi Pasteur Ltd have applied for a licence to release the live GM viral vaccine IMOJEV™ as a prescription medicine. GTTAC noted that they had previously provided advice to the Regulator on this application prior to the development of the RARMP, as required for commercial releases.

RESOLUTION:

GTTAC advised the Regulator:

- *That risks to people and the environment have been adequately characterised and assessed in the RARMP prepared for DIR 098.*
- *That no additional information that should be considered was identified.*

2. 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:

2.1 DIR 101 – Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

GTTAC noted that the application from Monstanto Australia Limited involved the intentional release of GM cotton lines with stacked insect resistance traits derived by conventional breeding of existing GM cottons previously licensed by the Regulator. The trial was proposed to take place on up to 50 sites per season in up to 34 local government areas in Queensland, New South Wales and Western Australia over four years.

RESOLUTION:

- *GTTAC advised that the Regulator should consider clarifying which sites will have a 20m pollen trap and which sites will have a 3km isolation zone.*
- *GTTAC advised the Regulator that data on the effects on non-target arthropods, specifically pollen beetles, bees and hover flies should be considered as a requirement to support any future application for commercial release.*

2.2 DIR 102 – Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance

GTTAC was informed that the purpose of the proposed dealing is to assess growth and yield characteristics under field conditions. The trial will take place on three sites, two in the LGAs of Marion and Wakefield (SA) and one in Corrigin (WA), of up to 0.75 ha/growing season from 2010 to 2015.

RESOLUTION:

- *GTTAC advised the Regulator that risks to people and the environment have been adequately characterised and assessed in the RARMP prepared for DIR 102.*
- *GTTAC advised that the Regulator should consider re-wording of the licence conditions to reflect that the fence at the site is to keep out 'domestic livestock' rather than 'large animals'.*

2.3 DIR 099 – Limited and controlled release of Wheat and barley genetically modified for altered grain composition or nutrient utilisation efficiency

GTTAC noted that the trial involves two sites in the Shire of Narrabri (NSW) and the Shire of Corrigin (WA) of up to 2.0 ha from 2010 to 2013. The purpose of the trial is to assess the growth and yield characteristics of the GMOs, and assess changes in grain composition.

RESOLUTION:

- *GTTAC advised the Regulator that risks to people and the environment have been adequately characterised and assessed in the RARMP prepared for DIR 099.*
- *GTTAC advised the Regulator that the wording of the RARMP and licence conditions be modified to reflect that access by livestock is to be prevented at the proposed site in Narrabri.*

2.4 DIR 100 – Limited and controlled release of wheat genetically modified for enhanced carbon assimilation in drought and heat prone environments

GTTAC was informed that the proposed release would be conducted at a 0.1ha site in the Redland local government area in Queensland from 2010 to 2013. The purpose of the trial is to evaluate the agronomic properties of the GM wheat lines grown under field conditions (i.e rain fed, drought prone).

RESOLUTION:

- *GTTAC advised the Regulator that risks to people and the environment have been adequately characterised and assessed in the RARMP prepared for DIR 100.*
- *GTTAC advised the Regulator that no additional information that should be considered was identified.*

3 OTHER ADVICE:

Review Of The Gene Technology Regulations 2001

The Committee was given a presentation on the progress of the review of the Gene Technology Regulations 2001, with particular reference to the discussion documents which had been prepared for the public consultation on the review. GTTAC noted that the information was being presented for discussion only and that the Committee was not being asked for advice as a formal request for advice would be sent out-of-session when the discussion documents had been finalised.

RESOLUTION:
GTTAC noted that a formal request for advice would be circulated following the meeting.

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>.