COMMUNIQUE
No. 26

This is the 26th communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the 36th meeting of GTTAC, held on 14 October 2009.

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 091 – Widestrike™ Insect Protection Cotton

The application, from Dow AgroSciences, involves the commercial release of genetically modified Widestrike™ cotton into the Australian environment south of latitude 22°S without specific containment measures. 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 the identified risks had been adequately characterised and assessed in the RARMP prepared for this application;*
- *that they supported the Post Release Review measures proposed in the RARMP; and*
- *that they did not identify any additional information that should be considered.*

2. ADVICE ON LICENCE APPLICATION – COMMERCIAL RELEASE

GTTAC considered 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 a live GM viral vaccine as a prescription medicine. GTTAC noted that an application had also been made to the Therapeutic Goods Administration (TGA) to include IMOJEV™ on the Australian Register of Therapeutic Goods (ARTG) as a prescription medicine, and that they would be assessing data on the quality, safety and efficacy of the GM vaccine for use in humans. The TGA had requested advice from the Regulator to inform its assessment of IMOJEV™. Members noted that this was the first application received by the OGTR for a live recombinant viral vaccine and that the TGA would play a key role in the assessment of any risks to human safety.

RESOLUTION:
GTTAC advised the Regulator that the following matters should be taken into account in the development of the RARMP for DIR 098:

- *the potential for transmission of the GM vaccine to people, animals and insects;*
- *the potential for viral recombination with wild type flavivirus.*

GTTAC advised the Regulator that, in advising the TGA with regard to DIR 098, he should consider that:

- *There is very limited potential for transmission of the GM vaccine to people, animals and insects;*
- *Viral recombination with wild type flavivirus is highly unlikely to occur.*

3. 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:

3.1 DIR 096 – Limited and controlled release of sugarcane genetically modified for herbicide tolerance

GTTAC noted that the application from BSES involved the intentional release of up to 6,000 lines of sugarcane genetically modified for herbicide tolerance on a limited scale and under controlled conditions. The trial was proposed to take place at six locations in Queensland on a maximum of 26 hectares between November 2009 and November 2015.

RESOLUTION:
GTTAC agreed that the RARMP for DIR 096 adequately identifies and addresses risks to people and the environment.

3.2 DIR 097 – Limited and Controlled Release – Clinical Trial of a Candidate Vaccine against *Human respiratory syncytial virus* (RSV) and *Human parainfluenza virus type 3* (hPIV3)

GTTAC were informed that the purpose of the proposed clinical trial was to investigate the safety and tolerability of multiple doses of the GM vaccine in RSV and hPIV3 seronegative children aged from 6 to less than 24 months of age, and in unscreened infants 2 months of age. Secondary objectives of the study were to examine the immunogenicity, viral shedding and genotypic stability of the GM vaccine.

RESOLUTION:

- *GTTAC advised the Regulator that the potential for increased shedding of the GM virus should be taken into account in finalising the RARMP for DIR 097:*
- *GTTAC advised the Regulator that data on shedding of the GM virus, infection and disease in animals, and on the genetic stability of the GM virus, might be required in support of any future application for commercial release.*

4 OTHER ADVICE:

4.1 Review Of The Gene Technology Regulations 2001

The Committee received a summary of the advice given by GTTAC members Out-of-Session, together with an explanation of how that advice had been taken into account in finalizing the drafting instructions. GTTAC noted that draft amendments were currently being prepared by the Office of Legislative Drafting and Publishing in the Attorney General's Department, and that public consultation on the draft amendments would include consultation with States and Territory Governments, Institutional Biosafety Committees (IBCs) and GTTAC.

RESOLUTION:
GTTAC noted the progress made in the Review of the Gene Technology Regulations 2001 and thanked the OGTR for the comprehensive feedback on the committee's Out-of-Session advice.

4.2 Review Of GTTAC Out-Of-Session Procedures

GTTAC agreed to implement some changes to the procedures for advice requested by the Regulator Out-of-Session. The changes will provide more clarity and will ensure that advice to the Regulator represents a consensus of the committee.

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