Gene Technology Technical Advisory Committee

COMMUNIQUE
No. 20

This is the twentieth communiqué of the Gene Technology Technical Advisory Committee (GTTAC). It covers matters considered at the thirtieth meeting of GTTAC, held on 15 May 2007.

GTTAC is a statutory advisory committee 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 input from GTTAC on applications for licences to conduct dealings with genetically modified organisms (GMOs), as well as comments on the Risk Assessment and Risk Management Plans (RARMPs) that are prepared for these applications and form the basis of the Regulator's decision whether to issue a licence.

The purpose of this Communiqué is to provide a brief overview of the applications and RARMPs considered by GTTAC and the advice 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 (DIRs) of GMOs into the Australian environment are dealings that are undertaken outside of a certified physical containment facility. DIRs may involve the limited and controlled release (field trial) of a GMO or other (eg a commercial or general) release of a GMO.

A Risk Assessment and Risk Management Plan (RARMP) is prepared in respect of every licence application for a DIR licence and released for public comment as part of the consultation process for these applications. Information on how to obtain copies of applications and RARMPs for DIRs is provided at the end of this document.

Advice on Applications

DIR 072/2006 – Yorktown Technologies: Commercial release of GloFish expressing red, green and yellow fluorescent proteins

Yorktown Technologies has submitted an application to import and supply GM zebrafish (*Danio rerio*) to the Australian wholesale and retail ornamental aquarium fish trade.

Three lines of GM zebrafish are proposed for import that express either red, green or yellow fluorescent proteins. The red, green and yellow GM zebrafish lines will contain genes derived from reef coral species: *DsRed2* (from *Discosoma sp.)*, *ZsGreen1* or *ZsYellow1* (from *Zoanthus sp.),* respectively. The GM zebrafish will be collectively traded as GloFish™.

GTTAC discussed the applicant with consideration of risks that may be associated with the release of the GM zebrafish and the availability of information about its fitness.

GTTAC advised the Regulator that the fluorescent proteins are not likely to result in toxicity/allergenicity to humans and other organisms, and noted that data from previous releases in the US and Singapore would be useful in the preparation of the RARMP.

DIR 073/2007 – Deltapine Australia Pty Ltd: Limited and controlled release of GM insect resistant and insect resistant/herbicide tolerant cotton

The OGTR has received an application from Deltapine Australia Pty Ltd to conduct field trials of up to four GM cotton lines on up to 50 sites with a maximum total area of 500 hectares over three growing seasons.

The four cotton lines contain either the *vip3A* or the *cry1Ab* insect resistance gene, or both, and one line, which contains both of these genes, also contains the genetic modification commercially known as Roundup Ready Flex®, which comprises two copies of the herbicide tolerance gene *cp4 epsps*.

The aims of the proposed field trial are to conduct early stage research to: evaluate the agronomic performance and efficacy of the GM cotton lines; collect data to support future applications to the OGTR and other regulators (including investigating the impact of the GM cotton on non-target organisms); breed, select and test new cotton lines; and produce seed for use in further studies or future trials, subject to additional approvals.

The Committee discussed matters related to the application including the implications of gene stacking, possible effects on non-target organisms and seed disposal, particularly the proposal that some seed be disposed of by burial.

GTTAC advised the Regulator that it is important that burial sites be monitored.

DIR 074/2007 – Monsanto Australia Ltd: Limited and controlled release of insect and herbicide tolerant *Gossypium barbadense*

GTTAC considered an application from Monsanto Australia Ltd to trial three GM *Gossypium barbadense* cottons on up to three sites in the first year and up to ten sites in the second year to a maximum total area of 26 hectares, over two summer growing seasons.

Bollgard II® *G. barbadense* contains two insect resistance genes (*cry1Ac* and *cry2Ab*) derived from the common soil bacterium *Bacillus thuringiensis*. Roundup Ready Flex® *G. barbadense* contains two copies of the herbicide tolerance gene, *cp4 epsps*, derived from *Agrobacterium tumefaciens*. Roundup Ready Flex®/Bollgard II® *G. barbadense* will be

produced by conventionally crossing Roundup Ready Flex® *G. barbadense* and Bollgard II® *G. barbadense*. *G*. *hirsutum* containing the same genetic modifications is grown commercially as Bollgard II® cotton, Roundup Ready Flex® cotton and Roundup Ready Flex®/Bollgard II® cotton respectively.

The Committee discussed whether the application posed new risks due to the taxonomically distinct species. The Committee discussed the issues of outcrossing and weediness, and whether the associated risks would likely be the same as with GM *G. hirsutum*.

GTTAC requested that the OGTR provide the Committee with a number of the appendices to the application regarding agronomic performance and additional information on the effectiveness of pollen traps for further consideration and comment when the RARMP is provided to the Committee.

Advice on RARMPs

GTTAC considered the consultation RARMPs prepared by the OGTR in response to the following applications:

DIR 071/2006 – Victorian Department of Primary Industries: Limited and controlled release of GM drought tolerant wheat

The Victorian Department of Primary Industries has applied for approval of a limited and controlled release of up to 30 GM wheat lines modified to enhance drought tolerance. The small scale field trial would be carried out at two sites in Horsham and Mildura, Victoria, on a maximum total area of 0.315 hectares over one growing season.

The purpose of the proposed trial is to conduct early stage ('proof of concept') research to evaluate the agronomic performance, including yield, of the GM wheat lines under rain-fed, drought prone conditions. Seed would also be collected and retained for analysis and, if any lines are selected for further development for possible future trials (subject to additional approvals).

GTTAC advised the Regulator that:

- the Committee agrees with the risk assessment by the OGTR; and
- the Committee agrees that the proposed licence conditions are appropriate to contain the release to the location, size and duration of the trial. However, it is not necessary that the fence surrounding the trial site be rabbit-proof.

Dealings Not Involving the Intentional Release of Genetically Modified Organisms

Dealings Not Involving the Intentional Release of GMOs (DNIRs) are dealings that are usually undertaken within a certified facility (so that the organism is physically contained) and where the personnel involved in the dealing have been assessed as having adequate training and experience for the task. These are typically laboratory-based projects.

DNIR 415/2007 – University of Western Australia: A phase I/II human gene therapy trial to establish the base line safety and efficacy following a single subretinal injection of rAAV.sFlt-1 for the treatment of exudative age related macular degeneration (AMD)

The OGTR has received an application from the University of Western Australia to conduct a phase I/II clinical trial of a GM replication defective *Adeno-associated virus* in patients suffering exudative AMD. The purpose of the trial is to assess the safety and tolerability of a single subretinal injection of the GM AAV vector encoding sFlt-1, a naturally occurring protein that inhibits an angiogenic process which contributes to the disease.

The Committee noted that, if successful, the proposed trial methods compared favourably with current medical treatments for AMD. GTTAC also discussed risks associated with the trial, including new information raised in a recently published paper on a human gene therapy trial using a replication defective AAV vector on haemophiliacs.

GTTAC advised the Regulator that the new information on the risks associated with AAV should be considered in the RARMP and the information be referred to the NHMRC and the TGA for their consideration. The Committee agreed with the risk assessment and the proposed licence conditions prepared by the OGTR.

Presentations

The following presentations were made to GTTAC:

- *Drosophila melanogaster*: a short history
- Post Release Review (PRR) Framework for Commercial Release of GMOs in Australia
- Overview of anticipated amendments to the *Gene Technology Act 2000* and Gene Technology Regulations 2001

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 Free-call hotline on 1800 181 030. The RARMPs are also available electronically from our website at http://www.ogtr.gov.au