

GTTAC Meeting - 14-15 November 2001, Canberra

COMMUNIQUE

The Gene Technology Technical Advisory Committee (GTTAC) held its inaugural meeting in Canberra on the 14th and 15th of November 2001. GTTAC was established by the *Gene Technology Act 2000* (the Act) as 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.

At the first meeting the Committee discussed a risk analysis framework for licence applications and provided scientific and technical advice at the request of the Acting Regulator on two applications for gene technology work currently before the Office of the Gene Technology Regulator (OGTR). The outcomes of these discussions are summarised below.

1. Risk Analysis Framework for Licence Applications Before the OGTR

The Act requires the Regulator to prepare a risk assessment and risk management plan for all licence applications. This Framework was developed to provide general guidance to applicants, evaluators and other stakeholders when identifying and assessing the risks posed by dealings of genetically modified organisms and to assist in determining the measures necessary to manage any such risks.

The Framework was developed by the OGTR in consultation with all States, Territories, Commonwealth Government Agencies, key stakeholders and the public. It takes into account the requirements of the Act, the *Gene Technology Regulations 2001* (the Regulations), and guidelines and risk assessment strategies in use in related agencies both in Australia and overseas.

GTTAC Resolved:

- GTTAC agreed that the Risk Assessment Framework should make clear the roles and responsibilities of other agencies such as Agriculture Fisheries and Forestry Australia (AFFA), the National Registration Authority (NRA) and the Australia New Zealand Food Authority (ANZFA) in the context of the new national regulatory system. GTTAC noted that the risk assessment framework would be formally reviewed in 12 months.

2. Agronomic Assessments and Seed Increase in Eastern Australia of Transgenic Cotton Expressing Cry1Ac and Cry 2Ab Genes from *Bacillus thuringiensis*.

Cotton Seed Distributors have applied for a licence for a large scale field trial of genetically modified insect resistant cotton (Bollgard II[®]). The cotton is derived from INGARD[®] (Bt) cotton which was approved for commercial release by the NRA, with the advice of the Genetic Manipulation Advisory Committee (GMAC), in 1996.

The trial is for seed increase and large-scale evaluation of agronomic performance of Bollgard II[®] cotton. Varieties crossed with Roundup Ready[®] cotton (approved for general release by the Minister for Health and Aged Care in September 2000, with advice from GMAC) are also to be trialled.

The release is proposed to be carried out on a total area of 480 hectares, at six sites in the Shires of Balonne and Emerald in Queensland. The field locations will all be south of latitude 22° South, that is within the area approved by the NRA for commercial release of INGARD[®] cotton and designated by the Minister for Health and Aged Cared for the release of Roundup Ready[®] cotton.

GTTAC Resolved:

- GTTAC recommended that the Regulator request additional information from Cotton Seed Distributors (CSD) regarding:
 - the levels of expression of the Cry1Ac and Cry2Ab proteins; and
 - the efficacy of the INGARD[®] and Bollgard II[®] genes endowing resistance to cotton plants against the target pest.
- GTTAC recommended that the Regulator request that Cotton Seed Distributors provide more detail on the mechanisms they intend to use to ensure segregation of seed both at the gin and for any associated transport.

3. Testing Protection of Cattle from Fluoroacetate.

Murdoch University has applied for a licence for a dealing that does not involve the intentional release of a GMO into the environment. The dealing involves inoculating cattle with rumen bacteria (*Butyrivibrio fibrisolvens*) which have been genetically modified to detoxify fluoroacetate (a compound poisonous to cattle which occurs in some native plants) and contain antibiotic resistance genes. The cattle will be monitored to see if the bacteria colonise the rumen in the cattle. The cattle will then be challenged with fluoroacetate.

The applicant has previously applied to GMAC for field trials of these GMOs (PR-45, PR-130 and PR130-X). GMAC's advice was that these trials should not proceed. This application differs from the previous ones in that the cattle will be housed in PC2 animal facilities in Werribee, Victoria. These facilities are managed by Commonwealth Scientific and Research Organisation (CSIRO).

GTTAC Resolved:

- GTTAC recommended that the Regulator seek additional information from the applicant with regard to:
 - the effective containment of the bacteria within the facility (in accordance with the Regulations, Schedule 4, Part 1, 1.1.4).
 - the management of unintentional release (in accordance with the Regulations, Schedule 4, Part 1, 1.1.4) including:
 - proposed methods of avoiding the unintentional release of the bacteria;
 - impacts that any unintentional release may have on human health and the environment; and
 - contingency plans that will be implemented in the event of an unintentional release.

GTTAC emphasised that any advice on this application should not be taken as an endorsement, or otherwise, of any future such applications.

**For all enquiries, please contact the Office of the Gene Technology Regulator on
1800 181 030 (free-call)**