Gene Technology Technical Advisory Committee
Meeting 19 December 2012
Canberra
Communiqué

This communiqué covers matters considered at the 42nd meeting of the Gene Technology Technical Advisory Committee (GTTAC) (19 December 2012)

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 Legislative and Governance Forum on Gene Technology (formerly the Gene Technology Ministerial Council). All Committee members and expert advisers hold office on a part-time basis.

The Regulator seeks 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 GTTAC's consideration of applications and RARMPs and, in accordance with Regulation 29 of the Gene Technology Regulations 2001, any Committee resolutions provided to the Regulator regarding 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.

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 LICENCE APPLICATION – COMMERCIAL RELEASE

GTTAC considered the following commercial release application:

DIR 118 - Commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) pima cotton in Australia.

Monsanto Australia Ltd has applied for a licence for the commercial release of a herbicide tolerant genetically modified (GM) cotton. The species of cotton that has been modified is *Gossypium barbadense*, also known as pima cotton. GTTAC noted that the GM pima cotton proposed for release was produced using conventional breeding to transfer the genetic modification from approved Roundup Ready Flex® *G. hirsutum* cotton to non-GM pima cotton. GTTAC also noted that GM cotton and GM cotton-derived products from Roundup Ready Flex® pima cotton would enter general commerce, including use in human food and animal feed.

RESOLUTION:

GTTAC advised the Regulator that:

- When preparing the RARMP, the Regulator should consider the differences between *G. barbadense* and *G. hirsutum* where relevant.

2. ADVICE ON CONSULTATION RARMP – LIMITED AND CONTROLLED RELEASE

GTTAC considered the consultation RARMP prepared in response to the following application for a limited and controlled release:

DIR 117 - Limited and controlled release of wheat and barley genetically modified for altered grain composition or nutrient utilisation efficiency

GTTAC noted that the application from the Commonwealth Scientific and Industrial Research Organisation (CSIRO) was for a limited and controlled release of GM wheat and barley lines, modified for altered grain composition or nutrient utilisation efficiency. The trial is proposed to take place at one site in the shire of Narrabri, New South Wales.

The primary purpose of the trial is to assess the agronomic performance and grain composition of the GMOs under field conditions. The GM wheat and barley would not be permitted for use in human food or animal feed.

GTTAC noted the key points in the consultation RARMP including that the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment. GTTAC also noted the draft licence conditions, which are similar to those used for other recent wheat and barley licences.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should consider reviewing information on rodent activity from previous trials.

3. OTHER ADVICE

3.1 Draft revised Risk Analysis Framework

GTTAC considered a draft revised version of the *Risk Analysis Framework* (RAF). The RAF describes the Regulator's rationale and approach to risk analysis of genetically modified organisms. GTTAC noted that the primary audience of the RAF is OGTR staff, but that it is also intended to provide transparency on the use of risk analysis for decision-making on licence applications.

GTTAC also noted that the risk communication chapter was developed taking into account consultation with the Gene Technology Ethics and Community Consultative Committee (GTECCC) Risk Communication Working Group that also includes a GTTAC member.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Regulator should consider means of improving the readability and accessibility of the document; and
2. The Regulator should consider pre-meeting comments provided by members.

3.2 Draft application form for limited and controlled releases

GTTAC considered a draft DIR licence application form for limited and controlled releases of GM plants. GTTAC noted the rationale behind revising this application form and the major changes that are proposed. The new form aims to provide a clear link between the information requirements, the risk analysis process as described in the RAF, and the RARMPs prepared in response to licence applications. GTTAC also noted that a separate form for commercial release applications is also being developed by the OGTR.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Regulator should consider specific suggestions for changes to a number of questions; and
2. Where appropriate, the Regulator should consider a requirement for further information where 'no' is answered.

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 Office of the Gene Technology Regulator (OGTR) on 1800 181 030. RARMPs are also available electronically from our website at <http://www.ogtr.gov.au>.