Gene Technology Technical Advisory Committee
45th Meeting 20 February 2014
Canberra
Communiqué

This Communiqué covers matters considered at the 45th meeting of the Gene Technology Technical Advisory Committee (GTTAC)

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 ministerial Legislative and Governance Forum on Gene Technology. 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 other major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

Dealings Involving the Intentional Release of GMOs (DIRs) can involve the limited and controlled release (clinical trial or field trial) or commercial (general) release of a GMO.

The Regulator must seek advice from GTTAC on RARMPs for 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.

The RARMP for every DIR licence application is also released for public consultation. Information on how to obtain copies of applications and RARMPs for DIR applications is provided at the end of this document.

1. ADVICE ON LICENCE RARMP – LIMITED AND CONTROLLED RELEASE

GTTAC considered the following RARMP for a limited and controlled release application:

DIR 126 RARMP - Clinical trial of a genetically modified vaccine against Cholera (PaxVax Australia Pty Ltd)

PaxVax Australia Pty Ltd (PaxVax) has applied for a licence for a clinical trial in Australia of a genetically modified (GM) vaccine against Cholera. GTTAC was provided an agenda paper that outlined key issues for consideration in the RARMP, and was asked for advice on any other issues that should be addressed.

GTTAC noted that the proposed trial would involve the inoculation of volunteers via oral ingestion of the GMOs. GTTAC also noted that, in addition to a licence from the Regulator, PaxVax would need to meet the Therapeutic Goods Administration (TGA) requirements for the clinical trial. The same vaccine strain was previously approved by the Regulator and the TGA and marketed in Australia, but that manufacturer ceased production of the vaccine in 2004 for commercial reasons. No adverse risks to health were previously reported in relation to the vaccine.

GTTAC noted that this application had attracted significant comment in social media, largely as a result of misunderstandings about the trial. The OGTR's actions in response to this included providing updated information on the OGTR website to correct the misinformation.

GTTAC agreed that the GM vaccine poses a low risk of transmission; however GTTAC advised that the RARMP could include more detail on management of potential transmission to young children. GTTAC also suggested that co-vaccination, particularly with the typhoid vaccine, should be considered in the RARMP.

Additional key points discussed by the Committee:

- there would be negligible risk of reversion of the vaccine strain to wild type during clinical trials
- preparation and batch testing method proposed by PaxVax was adequate

RESOLUTION:

GTTAC advised the Regulator that:

- GTTAC agrees with the overall conclusion of the RARMP [that the risks to the health and safety of people or the environment from the proposed trial are negligible]
- The Regulator should further consider potential exposure of contacts under two years of age
- The Regulator should further consider other possible exclusions relating to other vaccinations

2. ADVICE ON LICENCE APPLICATION – COMMERCIAL RELEASE

GTTAC considered the following commercial release application:

DIR 127 - Commercial release of canola genetically modified for herbicide tolerance (Monsanto Australia Pty Ltd)

Monsanto Australia Pty Ltd has applied for a licence for the commercial release of GM herbicide tolerant canola variety MON 88302 in Australia. GTTAC was provided an agenda paper that outlined key issues for consideration in the risk assessment, and was asked for advice on any other key issues that should be addressed in the preparation of the RARMP.

GTTAC suggested that the RARMP should make it clear that the applicant is seeking approval to grow the GM canola in any part of Australia, although not all areas are currently suited to growing canola, in particular the northern parts of the country.

GTTAC discussed the potential increase in the use of glyphosate on the GM crop and possible resulting impacts on the environment. In particular, GTTAC discussed the potential increase in selective pressure for development of herbicide tolerant weeds. GTTAC suggested the RARMP could include consideration of these issues, but noted that the Australian Pesticides and Veterinary Medicines Authority has regulatory responsibility for herbicide use and resistance management.

Additional key points discussed by the Committee:

- the potential for gene flow to other canola, including other commercially approved GM canola and non-GM herbicide tolerant canola
- the potential allergenicity and toxicity of the GM canola

RESOLUTION:

GTTAC advised the Regulator that, when preparing the RARMP, in addition to the issues outlined in the agenda paper, the Regulator should consider:

- Clarifying whether the assessment will consider growing of the GM canola in canola growing areas or all of Australia
- Potential for development of herbicide resistant weeds and related environmental impacts

REPORTS/UPDATES

The Committee was updated on the progress towards implementation of the recommendations from the 2011 review of the Act. GTTAC received a report from the Regulator that provided updates on activities undertaken by the Regulator and the OGTR since the previous face-to-face GTTAC meeting (18 December 2013). GTTAC members offered best wishes to the Regulator, Dr Joe Smith, who retired on 21 March 2014. The Chair thanked the Dr Smith for his contributions to the regulatory scheme and noted that the Australian regulatory system for gene technology is highly regarded by international stakeholders.

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. RARMPs are also available electronically from our website at <http://www.ogtr.gov.au>.