

**Gene Technology Technical Advisory Committee**  
**Meeting 18 December 2013**  
**Canberra**  
**Communiqué**

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***This Communiqué covers matters considered at the 44<sup>th</sup> meeting of the  
Gene Technology Technical Advisory Committee (GTTAC) (18 December 2013)***

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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 (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 APPLICATIONS – COMMERCIAL RELEASE**

GTTAC considered the following commercial release applications:

#### **1.1 DIR 124 - Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® III and Bollgard® III x Roundup Ready Flex®)**

Monsanto Australia Ltd has applied for a licence for the commercial release of two types of genetically modified (GM) cotton in Australia: insect resistant Bollgard® III and insect resistant/herbicide tolerant Bollgard® III x Roundup Ready Flex®.

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 considered.

GTTAC noted that Bollgard® III cotton was produced by conventional breeding between Bollgard® II cotton, a commercially released insect resistant GM cotton, and VIP3A cotton, a different insect resistant GM cotton that has not previously been commercially released in Australia. Bollgard® III x Roundup Ready Flex® cotton was produced by conventional breeding between Bollgard® II cotton, VIP3A cotton, and Roundup Ready Flex® cotton, a commercially released herbicide resistant GM cotton.

GTTAC also noted that the GM cottons would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has assessed and approved food made from the parent GM cottons. These approvals include food made from any offspring

produced through conventional breeding, and therefore cover Bollgard® III cotton and Bollgard® III x Roundup Ready Flex® cotton.

Key points discussed by the Committee:

- The potential for spread and persistence of the GMOs in northern Australia, given the different environmental conditions in that region.
- Potential effects of the *Vip3A* product on non-target invertebrate species.
- The potential for stacking between these GM cottons and commercially approved herbicide tolerant GM Liberty Link® cotton, and the possible impact of this on weed control in managed areas.

**RESOLUTION:**

GTTAC advised the Regulator that:

1. When preparing the RARMP, in addition to the issues outlined in the agenda paper the Regulator should consider the potential for stacking with other commercial GM cottons.

**1.2 DIR 125 - Commercial release of genetically modified live bacterial vaccine to protect chickens against pathogenic *E. coli***

Zoetis Australia Research & Manufacturing Pty Ltd has applied for a licence for the commercial release of a GM *Escherichia coli* vaccine for use in commercial poultry farms to protect chickens from *E. coli* infection. The GM *E. coli* has been modified by deletion of the essential *aroA* gene and cannot survive or multiply in chickens, and therefore cannot cause disease in chickens.

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 considered.

GTTAC noted that release of the GM vaccine will also require approval by the Australian Pesticides and Veterinary Medicine Authority (APVMA), which has primary responsibility for assessing the safety and efficacy of the vaccine for use in chickens. GTTAC also noted that the vaccine is already approved for use as a poultry vaccine in the USA and the EU.

The committee discussed a range of issues that should be considered in the RARMP, as detailed in the resolutions. The committee also discussed the following more general matters:

- The complementary roles of the APVMA and the OGTR in respect of this application.
- Similar vaccines with a long history of safe use.

**RESOLUTION:**

GTTAC advised the Regulator that:

When preparing the RARMP, in addition to the key issues outlined in the agenda paper the Regulator should consider:

1. The prevalence of Avian Pathogenic *E. coli* serotypes, and in particular type 078, in Australia;
2. Properties of the parent organism with potential to cause harm;
3. Whether the genetic modification may alter levels of *E. coli* metabolites in a manner which may cause harm;
4. Potential for the GMO to replicate and persist in the environment;
5. Pathways and levels of exposure of wild birds to the GMO as a result of vaccination in poultry houses and free range farms;
6. Training requirements for persons administering the vaccine;
7. Results of GMO-specific post marketing monitoring in the USA.

### 3. OTHER ADVICE

#### 3.1 Revised Biology Documents

Biology documents are prepared by the OGTR to provide an overview of baseline biology information relevant to risk assessment of genetically modified forms of the species that may be released into the Australian environment.

GTTAC provided advice on the content of revised and new sections of two biology documents: The Biology of *Brassica napus* L. (canola) and *Brassica juncea* (L.) Czern. & Coss. (Indian mustard); and The Biology of *Triticum aestivum* L. em Thell. (Bread Wheat). GTTAC commended the OGTR on the updates to the biology documents and provided some suggestions for improvement of the documents.

#### **RESOLUTION:**

GTTAC advised the Regulator that:

The Regulator should consider:

1. Updates to Sections 2.2 and 2.3, on Commercial uses and Cultivation in Australia respectively, in the wheat biology document;
2. Including further discussion in the canola and Indian mustard document of the production of canola-quality oil from Indian mustard, and the possibility that it may be commercially marketed in Australia as 'canola';
3. An amendment to the canola document to clarify item 9.1 on the proportion and amount of gene transfer over distance.

#### REPORTS/UPDATES

The Committee was updated on the progress of the Review of the Act and the implementation of the all governments' response to the review. 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 (11 June 2013), and a report from the committee's cross-member with the Gene Technology Ethics and Advisory Committee (GTECCC) on recent GTECCC activities.

#### 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>>.