

Gene Technology Technical Advisory Committee

Meeting 11 June 2013

Canberra

DRAFT Communiqué

This Communiqué covers matters considered at the 43rd meeting of the Gene Technology Technical Advisory Committee (GTTAC) (11 June 2013)

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 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 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.

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

1. ADVICE ON CONSULTATION RARMP – COMMERCIAL RELEASE

GTTAC considered the consultation RARMP prepared in response to the following commercial release application:

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

DIR 118 is an application from Monsanto Australia Ltd for the commercial release of herbicide tolerant (Roundup Ready Flex® MON 88913) GM pima cotton in Australia. GTTAC noted that they had previously provided advice on matters relevant to the preparation of the RARMP for licence application DIR 118, and that they were now being asked to provide advice on the RARMP prepared by the Regulator.

GTTAC noted that the GM pima cotton (*Gossypium barbadense*) 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.

GTTAC discussed the RARMP prepared for DIR 118 and noted that the risk assessment concludes that this release poses negligible risks to the health and safety of people and to the environment. Key points that were discussed by GTTAC included:

- The similarity between *G. barbadense* and *G. hirsutum* and the application of data from one species to the other;
- That the herbicide tolerance trait would not affect the weediness of the GM pima cotton in the absence of the herbicide.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Committee agrees with the overall conclusions of the RARMP; and
2. The risk assessment identifies all relevant risk scenarios; and
3. There is no additional relevant information that should be considered.

2. ADVICE ON CONSULTATION RARMPs – LIMITED AND CONTROLLED RELEASE

GTTAC considered the consultation RARMPs prepared in response to the following limited and controlled release applications:

2.1 DIR 120 - Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

GTTAC noted that application DIR 120 from Monsanto Australia is for a limited and controlled release of GM cotton modified for insect resistance and herbicide tolerance. The trial is proposed to take place between October 2013 and October 2019, on up to ten sites per year at 10 ha/site for the first two years of the trial and up to 20 sites per year at 30 ha/site thereafter. Sites will be selected from 56 local government areas in Western Australia, NSW and Queensland.

The primary purpose of the trial is to assess the agronomic performance of the GM cottons under Australian field conditions and generate data for possible future commercial release. The GM cotton 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 that the draft licence conditions are similar to those used for other recent GM cotton licences with the exception of the proposed isolation zone, which has been reduced from 3km to 1.5km on the basis of recent literature on gene flow.

Key points that were discussed by GTTAC included:

- Issues that may need further consideration in the risk assessment for an application for commercial release of these GM cotton lines, including potential effects on non-target invertebrate species and the implication of multiple herbicide tolerance traits for control of volunteers.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Committee agrees with the overall conclusions of the RARMP; and
2. The risk assessment identifies all relevant risk scenarios; and
3. There is no additional relevant information that should be considered.

2.2 DIR 121 - Limited and controlled release of safflower genetically modified for increased levels of oleic acid

GTTAC noted that application DIR 121 from CSIRO is for a limited and controlled release of GM safflower modified for increased levels of oleic acid, and that this is the first application for release of GM safflower in Australia.

The trial is proposed to take place over three growing seasons between September 2013 and March 2016. The GM safflower would be grown only in the ACT in the first season, and in the ACT, in Wagga Wagga in NSW, and near Narrabri in NSW in the second and third seasons. A maximum area of 1 hectare per season would be grown in each locality.

The primary purpose of the trial is to evaluate the agronomic performance of up to 190 lines of GM safflower under field conditions. The GM safflower 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, some of which are novel because this is the first licence application for a limited and controlled release of GM safflower.

Key points that were discussed by GTTAC included:

- The likelihood of seed dispersal by birds, and the potential consequence if it occurred, in the context of the scale of the proposed release and the draft licence conditions;
- The limits and controls for the trial, including the basis for the distance of the proposed exclusion zone;
- The potential ambiguity of the wording in the RARMP arising from the fact that the marker genes express a protein although the silencing construct does not.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should further consider measures to limit dispersal; and
3. The Regulator should consider clarifying the potential for the silencing construct to produce a protein.

OTHER ADVICE

Double stranded RNA (dsRNA) techniques

GTTAC considered recent publications related to dsRNA mediated gene silencing, including Zhang et al 2011¹ and Heinemann et al 2013² (referred to as the Environment International paper) and discussed the risk assessment by the Office of the Gene Technology Regulator (OGTR) of GM crops developed using these techniques.

¹ Zhang, L., et al. "Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA." *Cell Res* 22 (2011): 107-26.

² Heinemann, J. A., Sarah. Z. Agapito-Tenzen, and J. A. Carman. "A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments." *Environment International* 55 (2013): 43-55.

GTTAC noted that Food Standards Australia New Zealand (FSANZ) had published a comprehensive response³ to the Environment International paper, which concluded that the weight of scientific evidence published to date does not support the view that small dsRNAs in foods are likely to have adverse consequences for humans. GTTAC were advised that the OGTR had discussed the Environment International paper with FSANZ and had reached the same conclusions.

GTTAC further noted that all limited and controlled releases of GM plants developed using dsRNA techniques approved to date include licence conditions preventing the use of plant material from the trials in the human food or animal feed supply.

GTTAC were advised that the OGTR's approach to future risk assessment of crops developed using dsRNA silencing techniques is to continue to monitor the literature on this topic, and to assess licence applications on a case-by-case basis taking into account all relevant literature available at the time. GTTAC noted that the committee provides advice on the assessment of all DIR licence applications, including those involving the use of dsRNA techniques

RESOLUTION:

GTTAC advised the Regulator that:

1. The Committee agrees with the current and proposed future approach of the OGTR to the assessment of GM plants modified using gene silencing; and
2. The Regulator should continue to monitor and review the relevant scientific literature and include any developments in future applicable DIR risk assessments.

REPORTS

The Committee received a report from the Regulator that provided updates on activities undertaken by the Regulator and the OGTR since the previous GTTAC meeting (19 December 2012). A report was also received 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>>.

³ See <http://www.foodstandards.gov.au/consumer/gmfood/Pages/Response-to-Heinemann-et-al-on-the-regulation-of-GM-crops-and-foods-developed-using-gene-silencing.aspx>