

Gene Technology Technical Advisory Committee

17 September 2013 Videoconference

Canberra

Communiqué

This Communiqué covers matters considered at the 4th videoconference of the Gene Technology Technical Advisory Committee (GTTAC) (17 September 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 on GTTAC are appointed by the Commonwealth Minister responsible for gene technology. The Committee is comprised of scientific and technical experts with skills and experience prescribed in the Act.

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

The Regulator must seek GTTAC advice on RARMPs prepared in respect of all Dealings Involving the Intentional Release of a GMO (DIR). The Regulator must also seek GTTAC advice during the preparation of the RARMP for all DIR applications involving the commercial release of a GMO.

A DIR may 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 issued 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 RARMPs – LIMITED AND CONTROLLED RELEASE

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

1.1 DIR 122 - Limited and controlled release of wheat genetically modified for enhanced yield stability

GTTAC noted that application DIR 122 from the Department of Environment and Primary Industries – Victoria (DEPI-Vic) is for a limited and controlled release of GM wheat modified for enhanced yield stability. The trial size is 2 ha and it is proposed to take place at a DEPI-Vic research station, Horsham, Victoria, between November 2013 and March 2015.

The primary purpose of the trial is to assess biomass and seed yield, and to improve drought tolerance of the GM wheat under Australian field conditions and generate data for possible future commercial release applications. The GM wheat 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 for previous GM wheat trials. The licence would impose stringent controls during the trial and extensive monitoring and management post-harvest to ensure the GMO does not persist after the trial. The licence would require the destruction of any GM plant material after the completion of the trial.

Key points discussed by the Committee:

- **Potential for dissemination by birds** – the Committee concluded that the likelihood of this occurring was low. However, GTTAC noted a proposal to grow the trial in the off-season and suggested that the RARMP could include further detail about potential for bird dispersal if GM wheat is grown in the off-season;
- **Potential for dissemination by rodents** – GTTAC noted the controls and measures in the RARMP to restrict dissemination of the GMO by rodents. GTTAC agreed that in the event of a rodent plague the GMO would be destroyed by the rodents, and the potential for dispersal of viable GM seed would be highly unlikely;
- **Potential for human health effects as a result of eating GM wheat products** - GTTAC noted that the applicant does not propose to use the GM wheat as food, but agreed that the RARMP should include consideration of risk involving fructose intolerance in people.
- **Potential for crossing between GM lines** - the Committee agreed that the RARMP should note that the probability of crossing between GM lines is low, and that the associated risks are negligible; and
- **References to similar trials overseas** - GTTAC suggested that more detail and referencing could be included in the RARMP to other trials with similar gene inserts approved overseas.

RESOLUTION:

GTTAC advised the Regulator that:

1. The Committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should further consider potential for dispersal of GM wheat by birds if grown in the off-season.

1.2 DIR 123 RARMP - Limited and controlled release of canola genetically modified for altered oil content

GTTAC noted that application DIR 123 from Nuseed Pty Ltd is for a limited and controlled release of GM canola modified for altered oil content. The trial is proposed to take place between March 2014 and March 2019. The GM canola trial would be planted at 4 sites (2 ha/site) in the first year, 6 sites (10 ha/site) in the second year and 10 sites (20 ha/site) in each subsequent year. All trial sites would be selected from 153 possible Local Government Areas in NSW, VIC and WA.

The primary purpose of the trial is to evaluate the agronomic characteristics, oil content and genetic stability of up to 200 lines of GM canola under field conditions and to generate data for possible future commercial release applications. The GM canola would not be permitted for use in human food or animal feed. The applicant proposes to use oil from crushed GM seed in a small-scale animal feeding study.

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 are similar to those used for past GM canola trials. The licence would impose stringent controls to restrict gene flow and extensive monitoring and management post-harvest to ensure the GMO does not persist after the trial. The licence would require the destruction of any GM plant material after the completion of the trial.

Key points discussed by the Committee:

- **Post-trial destruction requirements** - the Committee agreed that the OGTR should further consider the rationale for the destruction of GM plant material by burial;
- **Potential for pollen movement** - GTTAC agreed that information on pollen movement and outcrossing should be clarified and additional detail could be added to the RARMP in relation to bee mediated pollen movement;
- **Post-trial activities** - the Committee suggested that details about the use of non-viable seed for any animal feeding trials could be clarified, and that containment, transport and storage of GMOs would be conducted in accordance with guidelines issued by the Regulator; and
- **Isolation requirements** – the Committee noted that for trials where insect proof mesh would be used to restrict pollen movement, a smaller monitoring zone would be required.

RESOLUTION:

GTTAC advised the Regulator that:

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| <ol style="list-style-type: none">1. The Committee agrees with the overall conclusions of the RARMP; and2. The Regulator should further consider the basis for burial as means of disposal of GM canola. |
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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>.