Gene Technology Technical Advisory Committee

21 May 2014 Videoconference[1]

Communiqué

This Communiqué covers matters considered at the 5th videoconference of the Gene Technology Technical Advisory Committee (GTTAC) (21 May 2014)

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 licence applications to conduct dealings with genetically modified organisms (GMOs) and on Risk Assessment and Risk Management Plans (RARMPs) prepared in respect of applications. 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 given to the Regulator. 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 (DIR) of a GMO can involve the limited and controlled release (clinical trial or field trial) of a GMO or a 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 DIR applications which are not assessed as limited and controlled under Section 50A of the Act.

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

1. ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

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

DIR 128 – Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance or micronutrient uptake

GTTAC noted that application DIR 128 from the University of Adelaide is for a limited and controlled release of wheat and barley genetically modified (GM) for abiotic stress tolerance or micronutrient uptake. The applicant proposes to trial up to 1262 lines of GM wheat and barley between June 2014 and December 2019 in South Australia and Western Australia on a maximum total area of 2.5 hectares per year. The purpose of the trial is to evaluate candidate genes for improving yield potential under field conditions.

GTTAC noted the key points in the consultation RARMP including the conclusions that this release poses negligible risks to the health and safety of people and the environment. GTTAC also noted that the draft licence conditions are similar to those for previous GM wheat and barley trials. The licence would impose stringent controls during the trial and extensive monitoring and management post-harvest to ensure the GMOs do not persist after the trial.

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[1] The videoconference was held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Hobart, Melbourne and Perth.

Key points discussed by the committee:

- The large number of lines in the application in the context of the proposed limits and controls;
- Uncertainty about the function of some of the introduced genes and their potential effect on traits of the GMOs, and the need to address this uncertainty for future large scale or commercial releases;
- The low likelihood that GM seed or pollen could leave a trial site and result in any harm.

RESOLUTION:

GTTAC advised the Regulator that:

1. The committee agrees with the overall conclusions of the RARMP and the proposed limits and controls;
2. The Regulator should consider further acknowledging uncertainty regarding potential for the introduced genes for abiotic stress tolerance and micronutrient uptake to result in increased survival of the GMOs or increases in toxicity or allergenicity, including in the summary table [Table 5];
3. The committee notes that this application involves a large number of lines, and suggests the Regulator consider the upper limits of what qualifies as a limited and controlled release;
4. The Regulator should consider seeking information on the results of the trial to inform future applications for release of any of these GM lines, with respect to the potential risks to human health and the environment;
5. The Regulator should consider clarifying the text in RARMP regarding other government approvals;
6. The committee commends Table 5 as a useful device to summarise causal pathways.

2. ADVICE ON CONSULTATION RARMPS – COMMERCIAL RELEASE

GTTAC considered the consultation RARMP prepared for the following commercial release application:

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

DIR 124 is an application from Monsanto Australia Ltd for the commercial release two types of GM cotton: Bollgard® III cotton, which contains three genes that confer insect resistance (*cry1Ac, cry2Ab* and *vip3A*); and Bollgard® III x Roundup Ready Flex® cotton, which contains the same three insect resistance genes and also two copies of the *cp4 epsps* gene that confers herbicide tolerance. GTTAC noted that they had previously provided advice on matters relevant to the preparation of the RARMP and that they were now being asked for advice on the consultation RARMP prepared by the Regulator.

GTTAC noted that the GMOs were produced by conventional breeding between other GM cottons; two approved for commercial release (Bollgard® II and Roundup Ready Flex® cottons) and a third that has been grown in Australian field trials (VIP3A cotton). If approved, the GM cottons and cotton-derived products would enter general commerce, including use in human food and animal feed. GTTAC noted that Food Standards Australia New Zealand has approved the use of material from these GM cottons in food. The GM cottons would also be subject to regulation by the Australian Pesticides and Veterinary Medicines Authority as an agricultural chemical product due to their production of insecticidal substances.

GTTAC advised the Regulator that:

Resolutions:

1. The committee agrees with the overall conclusions of the RARMP;
2. The committee agrees that the RARMP identifies all plausible risk scenarios by which the proposed release could give rise to risks to human health and safety or the environment;
3. The Regulator should further consider the potential for interaction between the introduced Cry and Vip proteins;
4. The Regulator should consider clarifying the wording in the RARMP regarding Vip3A specificity and conclusions about potential toxicity;
5. The Regulator should consider clarifying the description in the RARMP of weed management practices undertaken by Councils on roadsides.

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>.