Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
Videoconference 9 March 2016[1]
Communiqué

This Communiqué covers matters considered at the 10th video conference of the Gene Technology Technical Advisory Committee (9 March 2016)

The Gene Technology Technical Advisory Committee (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.

The Regulator seeks advice from GTTAC on licence applications to work with genetically modified organisms (GMOs) and on Risk Assessment and Risk Management Plans (RARMPs) prepared for applications. The purpose of this Communiqué is to provide a brief overview of GTTAC's consideration of applications and RARMPs and, in accordance with the Gene Technology Regulations 2001, to publish 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 A GMO (DIR)

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

The Regulator must seek GTTAC advice during the preparation of a RARMP for DIR applications which do not qualify as limited and controlled under Section 50A of the Act. The Regulator must also seek advice from GTTAC on RARMPs that have been prepared for all DIR applications.

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.

ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 142 – Limited and controlled release of wheat genetically modified for enhanced nitrogen use efficiency and water use efficiency

The Victorian Department of Economic Development, Jobs, Transport and Resources is seeking approval for the limited and controlled release of wheat genetically modified for enhanced nitrogen use efficiency and water use efficiency. The different types of GM wheat plants will each contain one introduced gene out of the 23 genes being tested. The candidate genes are all derived from either perennial ryegrass or Antarctic hair grass.

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

The field trial is proposed to take place between May 2016 and May 2018 at one site in Horsham, Victoria, on a maximum area of 3 hectares per year. The purpose of the field trial is to evaluate the performance of the GM wheat under Australian field conditions. No GM plant material would be used for human food or animal feed.

GTTAC noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to the health and safety of people and the environment as a result of gene technology.

Key issues discussed by the committee:

- identified uncertainty, including the unknown function of one of the introduced genes, noting that additional data may be required to assess any future application with reduced limits and controls
- licence conditions for rodent control and how these are described in the RARMP
- expression of proteins by the root preferential promoter in tissues other than roots. GTTAC noted that for this limited and controlled release the expression pattern would not change the conclusions of the RARMP.

RESOLUTION – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should consider clarifying proposed monitoring and control measures for rodents to make terminology consistent throughout RARMP
- The Regulator should consider further clarifying the specificity of a promoter aimed for root specificity

ADVICE ON APPLICATIONS – COMMERCIAL

DIR 143 – Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (GlyTol® and GlyTol TwinLink Plus®)

Bayer CropScience is seeking approval for the commercial cultivation of two types of GM cotton Australia-wide. The first type, GlyTol® cotton, has been modified for herbicide tolerance. The second type, GlyTol TwinLink Plus® cotton, was produced by conventional breeding between four GM parental cottons and has been modified for both insect resistance and dual herbicide tolerance.

If a licence is issued, the GM cottons and their derived products would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) has approved the use of food derived from each of the parent GM cottons. These approvals also cover the GMOs proposed for release.

The Regulator requested advice from GTTAC on the following issues that have been identified for consideration in the preparation of the RARMP:

- the potential for the GM cottons to be harmful to the environment through weediness, particularly in northern Australia, given that the introduced genes confer insect resistance and herbicide tolerance
- the potential for the GM cottons to be harmful to people through toxicity or allergenicity
- the potential for the GM cottons to be harmful to other organisms, particularly non-target invertebrates, through toxicity
- the potential for gene flow to other cottons
- whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact .

GTTAC was also asked to provide advice on any other key issues that should be considered in the RARMP.

GTTAC noted that all of the introduced genes had been trialled and assessed previously, and that data from these previous trials would be used to inform the risk assessment. The committee also noted that when assessing the potential for the GM cottons to be harmful to other organisms, a wide range of organisms including livestock would be considered and information would be obtained from several sources.

RESOLUTION – GTTAC advised the Regulator that:

- The committee agrees with the issues identified by the office for consideration in the RARMP
- No new issues were identified for consideration

DIR 145 – Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard®3 × XtendFlex™ and XtendFlex™)

Monsanto Australia is seeking approval for the commercial cultivation of two types of GM cotton Australia-wide. XtendFlex™ cotton has been modified for herbicide tolerance, and Bollgard® 3 XtendFlex™ cotton has been modified for both insect resistance and tolerance to the same three herbicides. XtendFlex™ and Bollgard® 3 XtendFlex™ cottons were produced by conventional breeding between up to four parental GM cottons.

If a licence is issued, the GM cottons and their derived products would enter general commerce, including use in human food and animal feed. FSANZ has approved the use of food derived from each of the parent GM cottons. No further approvals are required from FSANZ for the GM cottons proposed for release.

The Regulator requested advice from GTTAC on the following issues that have been identified by the Regulator for consideration in the preparation of the RARMP:

- the potential for the GM cottons to be harmful to the environment through increased spread and persistence, given that the introduced genes confer insect resistance and multiple herbicide tolerances
- the potential for the GM cottons to be harmful to people through toxicity or allergenicity
- the potential for the GM cottons to be harmful to other organisms, particularly non-target invertebrates, through toxicity
- the potential for gene flow to other cottons
- whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact.

GTTAC was also asked to provide advice on any other key issues that should be considered in the RARMP. Members discussed the multiple herbicide tolerance trait and reiterated that herbicide resistance management comes under the regulatory oversight of the Australian Pesticides and Veterinary Medicines Authority.

RESOLUTION – GTTAC advised the Regulator that:

- The committee agrees with the issues identified by the office for consideration in the RARMP
- No new issues were identified for consideration

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 call the OGTR on 1800 181 030 or email ogtr@health.gov.au. RARMPs are also available on the OGTR website at http://www.ogtr.gov.au.