Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

23 October 2017

Communiqué

This Communiqué covers matters considered at the 13th video conference of the Gene Technology Technical Advisory Committee (23 October 2017)[1]

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 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 deliberations of the committee.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO

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

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 – COMMERCIAL RELEASE

DIR 155 – Commercial release of canola genetically modified for Omega-3 oil content (DHA canola)

Licence application DIR 155 from Nuseed Pty Ltd is for a commercial release of GM canola with altered Omega-3 oil content.

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. The Committee discussed the potential for a fitness advantage to be conferred to pest animals consuming the canola. This was considered in the RARMP and not identified as a substantive risk.

Members noted that the GM canola has been assessed to be as safe as conventional canola, and that no adverse events have been reported for other GM canola since the first commercial release in Australia.

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

Resolution – GTTAC advised the Regulator that:

- The Regulator should further consider the potential for pest species to gain a fitness advantage from consuming the genetically modified (GM) canola
- The Committee agrees with the overall conclusions of the RARMP.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR 157 – Commercial release of cotton genetically modified for insect resistance (COT102)

Syngenta has applied for a licence for commercial cultivation of a GM cotton line in Australia. The plant material and products derived from the GM cotton would enter general commerce, including use in animal feed. GTTAC noted that the following key matters had been identified for consideration in the RARMP:

- Potential for the GM cotton to be harmful to the environment through increased weediness, given that the introduced gene confers insect resistance
- Potential for the GM cotton to be harmful to people through toxicity or allergenicity
- Potential for the GM cotton to be harmful to other desirable organisms, particularly non-target invertebrates, through toxicity
- Potential for harm from gene flow to other cottons
- Whether commercial release is likely to result in changes to agricultural practices that may have an environmental impact.

Advice was sought from the committee in relation to these matters and on any other key issues that should be considered in the preparation of the RARMP for DIR 157. The committee discussed the rapid biodegradation of Bt toxin in the environment in the context of its potential release from roots.

Resolution – GTTAC advised the Regulator that:

- The Committee agrees with issues identified in the agenda paper for consideration in the RARMP
- No further matters were identified by the Committee for consideration in the RARMP.

DIR 158 – Commercial release of *Carthamus tinctorius* L. genetically modified for High Oleic Acid Composition

GO Resources has applied for a licence for the commercial release of two lines of GM safflower with high oleic acid composition in Australia. If a licence is issued, the oil derived from the GM safflower is intended for commercial industrial oil production.

GTTAC noted that the following key matters had been identified for consideration in the RARMP:

- Potential for GM safflower to be harmful to people through toxicity or allergenicity
- Potential for GM safflower to be harmful to desirable organisms through toxicity
- Potential for increased weediness of GM safflower causing harm to the environment
- Potential for harm from gene flow to other related species.

Advice was sought from the committee in relation to these matters and on any other key issues that should be considered in the preparation of the RARMP for DIR 158.

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the issues identified in the agenda paper for consideration in the RARMP
- The Regulator should consider possible benefits for pest species consuming the GM safflower or safflower meal.

INFORMATION ITEMS AND REPORTS

An officer from the Office of Gene Technology Regulator provided the committee with an update on the technical review of the *Gene Technology Regulations 2001.* This was followed by an update from an officer from the Department of Health on the third review of the National Gene Technology Scheme.

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.