



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

## **Gene Technology Technical Advisory Committee**

**26 July 2021**

**Communiqué**

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***This Communiqué covers matters considered at the 26<sup>th</sup> video conference of the Gene Technology Technical Advisory Committee (26 July 2021)***

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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 Gene Technology Ministers' Meeting.

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. It does not include information which is treated as Confidential Commercial Information in accordance with the Act.

### **DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO**

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

For commercial releases, the Regulator must seek GTTAC advice twice. The first consultation is on matters to consider when preparing the RARMP and the second is on the RARMP itself. For limited and controlled releases, the Regulator must seek GTTAC advice only once on the RARMP.

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 178 – Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system (MS11× RF3 and MS11 × RF3 × MON 88302)**

Licence application DIR 178 from BASF Australia Ltd is for the commercial cultivation of genetically modified (GM) canola with a hybrid breeding system and herbicide tolerance. The GM canola lines are proposed to be grown in all canola growing areas in Australia, and their products would enter general commerce, including use in human food and animal feed

GTTAC noted the conclusion of the RARMP that risks to the health and safety of people or the environment from the proposed dealings are negligible. The Committee discussed the proposal to breed the intermediate lines in Australia and agreed this did not pose additional risks.

## **Resolutions**

- The Committee agrees all plausible risk scenarios have been identified.
- The Committee did not identify any additional relevant information.
- The Committee agrees with the overall conclusion of the RARMP.

## **DEALINGS NOT INVOLVING THE INTENTIONAL RELEASE OF A GMO**

The Regulator may seek GTTAC advice on RARMPs prepared for an application for Dealings Not involving an Intentional Release (DNIR) into the environment. DNIR licences include research work with GMOs undertaken in physical containment facilities (e.g. certified by the Regulator) or clinical trials undertaken in clinical facilities.

### **ADVICE ON DNIR RARMPs**

#### **DNIR 639 - Investigating the genetic basis of dengue and chikungunya virus resistance to Wolbachia**

Monash University has applied for a licence to investigate, in contained facilities, the determinants that might confer resistance to Wolbachia, a bacterium that inhibits replication of these viruses.

GTTAC noted that the RARMP concludes that the proposed release poses negligible risks to the health and safety of people and the environment. The Committee discussed the replication capacity of the GM viruses and suggested additional data on this would be informative if available. GTTAC discussed the possible routes for inadvertent release of the GMOs presented in the risk scenarios in the RARMP and agreed the risks were negligible.

## **Resolutions**

- The Committee agrees with the overall conclusions of the RARMP.
- The Committee did not identify any other plausible risk scenarios.
- The Committee agrees with the work practices.
- The Regulator should consider whether further information on possible increased replicative capacity of passaged virus may assist risk management.

## **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 (DIR) of GMOs into the environment, please call the OGTR on 1800 181 030 or email [ogtr@health.gov.au](mailto:ogtr@health.gov.au). DIR RARMPs are also available on the [OGTR website](#).