Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

20 July 2020

Communiqué

This Communiqué covers matters considered at the 20th video conference of the Gene Technology Technical Advisory Committee (20 July 2020)

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. 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.

The Regulator must seek GTTAC advice during the preparation of a RARMP for DIR applications that 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 APPLICATIONS – COMMERCIAL RELEASE

DIR 174 – Commercial supply of a genetically modified cholera vaccine, Vaxchora®

Licence application DIR 174 from Biocelect Pty Ltd is for the import, transport, storage and disposal of a genetically modified (GM) cholera vaccine, Vaxchora®, as part of its commercial supply in Australia.

The Committee discussed the issues identified for consideration in the consultation RARMP being prepared by the Regulator, including possible pathways to environmental exposure and the potential for the GMO to persist in the environment. In addition, GTTAC raised the possibility of the GMO acquiring other genes via gene transfer leading to multidrug resistant bacteria, and the potential for these to form biofilms. GTTAC indicated the probability of this occurring is low, however recommended it be considered in the RARMP.

Resolutions

- The committee agrees that the matters identified in the agenda paper should be considered in the RARMP.
- The Regulator should consider risks that may be related to persistence in biofilms and the potential for development of multidrug resistance.

DIR 175 – Commercial release of canola (*Brassica napus*) genetically modified for herbicide tolerance and a hybrid breeding system

BASF Australia is seeking approval to commercially cultivate a GM canola line, which contains two introduced genes that form a hybrid breeding system and one introduced gene that confers herbicide tolerance. If a licence is issued it would permit cultivation Australia-wide, and products derived from the GM plants would enter general commerce, including use in human food and animal feed.

GTTAC noted that the principal purpose of the application is to use the GM canola as a parent line for canola production. The Committee discussed the issues identified for consideration in the consultation RARMP being prepared by the Regulator. Key matters considered included:

- transport of the GMO, which is not expected to differ from standard industry practices
- the potential for volunteer canola plants to occur and the weed management practices that could be employed to control them
- the possible effects on the GM canola of the insertion site of the introduced genes or the application of selection pressure.

In addition, GTTAC agreed that the RARMP should consider the potential for harm to result from gene flow to other sexually compatible species in addition to canola, particularly known weeds.

Resolutions

- The committee agrees that the matters identified in the agenda paper should be considered in the RARMP.
- The committee recommends that the potential for harm to result from gene flow to other sexually compatible species including canola should be considered in the RARMP.

DIR 173 – Commercial release of cotton (*Gossypium hirsutum*) genetically modified for herbicide tolerance (MON 88701)

Monsanto Australia is seeking approval for commercial cultivation of a GM cotton line (MON 88701) in Australia. If approved, the GM cotton could enter general commerce, including use in human food and animal feed. MON 88701 contains two introduced genes (*dmo* and *bar*) that confer tolerance to the herbicides dicamba and glufosinate, respectively.

GTTAC discussed the possibility of the GM cotton crossing with other herbicide tolerant GM cottons and acquiring tolerance to multiple herbicides. The Committee noted that this GM cotton line has already been approved for commercial release as a stack with both of the other approved GM herbicide tolerance traits under licence DIR 145.

GTTAC agreed to the following resolution.

Resolutions

- The Committee agrees with the overall conclusion of the RARMP.

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. DIR RARMPs are also available on the OGTR website.