Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
29 November 2022
Communiqué

This Communiqué covers matters considered at the 58th meeting of the Gene Technology Technical Advisory Committee (29 November 2022)

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 – LIMITED AND CONTROLLED RELEASE

DIR 194 – Limited and controlled release of perennial ryegrass genetically modified for increased metabolisable energy content

Grasslanz Technology Australia Pty Limited is requesting a licence to grow GM perennial ryegrass modified for increased metabolisable energy content. The trial would run from April 2023 until December 2028, with a maximum total area of 12.5 hectares planted. The GM perennial ryegrass grown in this field trial would not be used in human food or commercial animal feed.

GTTAC had a thorough discussion about several matters relating to allergenicity, as reflected in the Committee's resolutions. GTTAC also discussed the areas of uncertainty identified in the RARMP and the potential for animals and birds to spread viable seed.

Resolutions

GTTAC agreed to the following advice to the Regulator:

- The Committee agrees that all plausible risk scenarios relating to the health and safety of people or the environment have been identified.
- The Regulator should reconsider the consequence assessment of the potential harm of increased allergenicity to people from the presence of cysteine oleosin in GM plant material.
- The Committee agrees that the conditions proposed in the draft licence manage the risk of harm to people arising from the potential allergenicity of the introduced cysteine oleosin in the context of the current consequence assessment, but this may need review following reconsideration of the consequence assessment of the potential harm of increased allergenicity to people from the presence of cysteine oleosin in GM plant material.
- The Committee agrees that the proposed pollen control measures are sufficient to manage risks associated with potential pollen spread.
- The Committee agrees that the other measures to limit and control the release are appropriate.
- The Regulator should further consider areas of uncertainty including in relation to the distribution and levels of cysteine oleosin in GM plant material, including pollen.
- The Committee does not agree with the current overall conclusion of the RARMP in relation to the health and safety of people, and recommends that the Regulator reviews this conclusion following reconsideration of the consequence assessment of the potential harm of increased allergenicity to people from the presence of cysteine oleosin in GM plant material.

ADVICE ON CONSULTATION RARMPS – COMMERCIAL RELEASE

DIR 191 – Commercial import and distribution of chrysanthemum genetically modified for altered flower colour

International Flower Developments is seeking approval for commercial import and distribution of five types of GM chrysanthemum modified to have blue or violet flower colour. If a licence is issued, cut flowers of GM chrysanthemum would be imported into Australia and sold to the public in the same way as non-GM flowers are imported and sold.

GTTAC discussed the potential for propagation of the GMOs in the context of the herbicide treatment required for cut chrysanthemums by the Department of Agriculture, Fisheries and Forestry.

Resolutions

GTTAC agreed to the following advice to the Regulator:

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

DIR 193 – Commercial supply of a genetically modified vaccine against infectious laryngotracheitis virus (ILTV) in chickens

Bioproperties Pty Ltd is requesting a licence for the transport, storage and disposal of a GM vaccine against ILTV in chickens, as part of its commercial supply in Australia. GTTAC noted the vaccine must also be authorised by the Australian Pesticides and Veterinary Medicines Authority.

GTTAC discussed the following matters:

- The proposal to administer the vaccine to chickens in commercial poultry farms where there is a history or risk of ILTV infection or in the event of an outbreak in the region.
- the likelihood of recombination with other strains of the virus occurring and the measures in place that would reduce this
- the consequence of recombination occurring, including possible reversion to a wild type strain.

Resolutions

GTTAC agreed to the following advice to the Regulator:

- The Committee agrees that all plausible risk scenarios relating to the health and safety of people or the environment have been identified.
- The Regulator should reconsider the likelihood and consequence assessment of the risk of generating a novel pathogenic ILTV strain due to the recombination of the GMO with other wild-type ILTV or vaccine strains.
- The Committee agrees that the conditions proposed in the draft licence to prevent the recombination of the GMO with other ILTV, or vaccine strains of the GMO are appropriate.
- The Committee considers that all relevant current information has been considered, with some areas of uncertainty remaining.
- The Regulator should consider post-marketing surveillance in areas of outbreak to monitor for the emergence of pathogenic strains.
- The Committee agrees with the overall conclusion of the RARMP.

REPORTS

The Committee received routine reports on relevant activities undertaken since the previous face-to-face GTTAC meeting in April 2018 from the cross-member with the Gene Technology Ethics and Community Consultative Committee, the Chair and the Regulator.

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.