



Australian Government

Department of Health

Office of the Gene Technology Regulator

**Gene Technology Technical Advisory Committee
48th Meeting 4 August 2015, Canberra
Communiqué**

This Communiqué covers matters considered at the 48th meeting of the Gene Technology Technical Advisory Committee (4 August 2015)

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 (the Regulations), 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 a commercial (general) release of a GMO.

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

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.

1. ADVICE ON APPLICATIONS – COMMERCIAL

1.1 DIR 137 – Commercial supply of attenuated GM influenza vaccines

AstraZeneca Pty Ltd has applied for a licence for the commercial supply of two types of genetically modified (GM) influenza vaccines: a seasonal flu vaccine to target currently circulating flu viruses; and one to target a pandemic flu strain, should one arise. GM vaccines based on the same attenuated strains as the GMOs are currently approved in United States of America (USA), Canada and the European Union. If approved in Australia the GMOs would be imported from overseas and distributed to healthcare facilities where the vaccines would be administered as a nasal spray by qualified health professionals to consenting patients.

Import and therapeutic use of the GM vaccines will require import authorisation from the Department of Agriculture and registration with the Therapeutic Goods Administration, respectively.

The Regulator sought advice from GTTAC on the following matters that have been identified by the Regulator as key issues to be considered in the preparation of the RARMP:

- Potential for accidental exposure of humans, animals or other organisms to the GM viruses, leading to harm; and
- Potential for reassortment of the GMOs and a circulating influenza strain, resulting in a pathogenic phenotype.

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

GTTAC discussed that these dealings with the GMO posed negligible risk to human health and the environment, including during the handling of the GMOs during transportation and in healthcare facilities. The committee considered the likelihood of a spill during transportation, and the possible need for information labels on vials or containers to better manage accidental exposure. GTTAC discussed the proposal by the applicant for a licence that would allow the applicant to vary the GMO strains each year to reflect the World Health Organisation recommendations on seasonal influenza strains.

RESOLUTION – GTTAC advised the Regulator that:

1. GTTAC agrees that the RARMP should consider issues identified [by the Regulator] in the agenda paper; and
2. GTTAC recommends that the Regulator consider:
 - a. Transport, storage, and disposal in the context of intended vaccine-delivery workforce and facilities
 - b. The need for labelling of packaging
 - c. The need for oversight of each new vaccine strain
 - d. Risk associated with incidental exposure

1.2 DIR 138 – Commercial release of canola genetically modified for dual herbicide tolerance and a hybrid breeding system

Bayer CropScience Pty Ltd (Bayer) has applied for a licence for commercial cultivation of GM canola variety InVigor® x TruFlex™ Roundup Ready® canola Australia-wide. The variety contains genes for a hybrid breeding system and tolerance to the herbicides glufosinate-ammonium and glyphosate. The GMO is the result of conventional breeding between GM InVigor® canola and GM TruFlex™ Roundup Ready® canola which are individually authorised for commercial release under licences DIR 021/2002 and DIR 127, respectively.

If a licence is issued, the GM canola and GM canola-derived products would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has assessed and approved food made from InVigor® canola and TruFlex™ Roundup Ready® canola. These approvals also cover InVigor® x TruFlex™ Roundup Ready® canola.

The Regulator requested advice from GTTAC on matters that have been identified by the Regulator as key issues to be considered in the preparation of the RARMP:

- the potential for the GM canola to be harmful to people through toxicity or allergenicity
- the potential for the GM canola to be harmful to other desirable organisms through toxicity
- whether the introduced hybrid breeding system and tolerance to two herbicides will increase the potential for InVigor® x TruFlex™ Roundup Ready® canola to spread and persist, leading to harm to the environment

- the potential for gene flow to other canola, including other commercially approved GM canola and non-GM herbicide tolerant canola, and whether this could lead to harm to the environment
- whether commercial release is likely to result in changes to agricultural practices that may have an adverse environmental impact
- any other key issues

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

GTTAC noted that GM InVigor® canola and GM TruFlex™ Roundup Ready® canola were individually authorised previously by the Regulator for commercial release. The committee discussed appropriate comparators for the GMO in the risk assessment.

RESOLUTION – GTTAC advised the Regulator that:

1. GTTAC agrees that the RARMP should consider issues identified [by the Regulator] in the agenda paper

1.3 DIR 139 - General Release of Canola Genetically Modified for Herbicide Tolerance

Pioneer Hi-Bred Australia Pty Ltd (Pioneer) is proposing commercial cultivation of the GM canola variety Optimum™ GLY Canola Australia-wide. The GM canola is modified for tolerance to the herbicide glyphosate. Field trials of Optimum™ GLY Canola have been conducted in Australia under licence DIR 114 since 2012.

If a licence is issued, the GM canola would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand has assessed and approved food made from Optimum™ GLY Canola.

Advice was sought from GTTAC on the following matters that have been identified by the Regulator as key issues to be considered in the preparation of the RARMP:

- the potential for the GM canola to be harmful to people through toxicity or allergenicity
- the potential for the GM canola to be harmful to other desirable organisms through toxicity
- whether the introduced herbicide tolerance trait will increase the potential for the GM canola to spread and persist, leading to harm to the environment
- the potential for gene flow to other canola, including other GM or non-GM herbicide tolerant canola, and whether this could lead to harm to the environment

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

GTTAC discussed the potential for the introduced gene to acetylate amino acids including non-protein amino acids in the context of presence in the food chain. GTTAC noted that acetylation is a natural process that occurs in cells including human.

RESOLUTION – GTTAC advised the Regulator that:

1. GTTAC agrees that the RARMP should consider issues identified [by the Regulator] in the agenda paper.
2. GTTAC recommends that the Regulator consider the potential for acetylation of other amino acids and their role in the food chain

2. ADVICE ON CONSULTATION RARMP – COMMERCIAL

2.1 DIR 134 - Commercial import and distribution of genetically modified carnations with altered flower colour

International Flower Developments Pty Ltd has applied for a licence for the commercial import and distribution of GM carnations that have been modified for altered flower colour. The aim of the application is to import cut carnation flowers for use in the commercial flower trade in Australia. There is no intention to grow these GM flowers in Australia. If a licence is issued, harvested cut-flowers of the GMOs would be imported and distributed in the same way as other cut carnation flowers in the floristry industry.

Members noted that this application relates to cut flowers only and not whole plants. Similar GM carnation varieties already exist on the GMO Register in Australia and can be propagated, grown and distributed.

GTTAC was provided a draft consultation RARMP prepared by the Regulator which concluded that the proposed release poses negligible risks to the health and safety of people and the environment as a result of gene technology. Advice was sought by the Regulator from GTTAC on the following issues:

- Does the risk assessment identify all the risk scenarios by which the proposed release could potentially give rise to risks relating to the health and safety of people or the environment?
- Is the characterisation of the risk scenarios identified adequate?
- Is there additional relevant information that should be considered?

GTTAC considered whether the GMO would require labelling in Australia as a GMO not intended for use as a therapeutic or food. The committee discussed the potential for people to eat the GM carnations, noting that the GMOs produce increased levels of some anthocyanins, which are claimed to be beneficial to health. GTTAC agreed that consuming anthocyanins would not pose a risk, particularly if consumed in low doses.

GTTAC discussed the effect of glyphosate treatment on pollen in the GMO, agreeing that glyphosate reduces pollen production.

RESOLUTION – GTTAC advised the Regulator that:

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| 1. GTTAC agrees with the overall conclusions of the RARMP |
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3. ADVICE ON CONSULTATION RARMP – LIMITED AND CONTROLLED

3.1 DIR 136 – Limited and controlled release of cotton genetically modified for enhanced fibre quality

Commonwealth Scientific and Industrial Research Organisation (CSIRO) has applied for a licence to conduct a limited and controlled release of GM cotton. The GM plants have been modified for altered fibre quality.

The field trial is proposed to take place between October 2015 and May 2018 on a site belonging to CSIRO in New South Wales. The maximum area of the trial would be one hectare per year. The aim of this field trial is to evaluate the field performance and fibre quality of the GM cotton. CSIRO has proposed a number of controls to restrict the spread and persistence of the GM cotton plants and their genetic material in the environment. GM cotton from the trial would not be used for human food or animal feed.

GTTAC noted that the GM cotton lines in DIR 136 are new and have not been previously approved by the Regulator or other authorities in Australia or internationally.

GTTAC was provided a draft consultation RARMP prepared by the Regulator which concluded that the proposed release poses negligible risks to the health and safety of people and the environment as a result of gene technology. Advice was sought by the Regulator from GTTAC on the following issues:

- Does the risk assessment identify all plausible risk scenarios by which the proposed release could give rise to risks to the health and safety of people or the environment?
- Are the measures to limit and control the release appropriate for the trial?
- Is there any additional key information that should be considered?
- Does the committee agree with the overall conclusions of the RARMP?

GTTAC discussed the potential for allergenicity to the pectin methylesterase proteins (PME) expressed in the GMOs and the effectiveness of proposed personal protective equipment for individuals working with the GMO during processing to limit contact or inhalation of PMEs.

RESOLUTION – GTTAC advised the Regulator that:

1. GTTAC agrees with the overall conclusions of the RARMP.
2. GTTAC recommends that the Regulator consider the effectiveness of proposed use of personal protective equipment in limiting exposure to GM material

INFORMATION ITEMS AND REPORTS

GTTAC received a report from the acting Regulator that provided updates on activities undertaken by the Regulator and the OGTR since the previous GTTAC meeting (April 2015).

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 phone the OGTR on 1800 181 030. RARMPs are also available electronically from the OGTR website at <<http://www.ogtr.gov.au>>.