Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
47th Meeting 8 April 2015, Canberra
Communiqué

This Communiqué covers matters considered at the 47th meeting of the Gene Technology Technical Advisory Committee (8 April 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. All committee members and expert advisers hold office on a part-time basis.

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 GMOS (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 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 genetically modified (GM) carnations that have been genetically 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.

GTTAC was provided an agenda paper that outlined key issues for consideration in the RARMP, and was asked for advice on any other issues that should be considered. 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.

RESOLUTION – GTTAC advised the Regulator that:

The Regulator should consider in the RARMP:

1. the effect of any proposed treatment of the GM carnations for devitalisation or lack of propagation; and
2. the potential for people to eat the GM carnations.

2. ADVICE ON CONSULTATION RARMPS – COMMERCIAL

2.1 DIR 132 - Commercial supply of a tumour-selective genetically modified virus for cancer therapy

Amgen Australia Pty Ltd (Amgen) has applied for a licence for the commercial supply of an attenuated (reduced virulence) GM *herpes simplex virus* 1 (HSV-1), referred to as Talimogene laherparepvec, for use as a prescription medicine in the treatment of cancer. The GMO would be administered to patients by injection directly into the tumour, and has been modified by removing specific viral genes to reduce its virulence and pathogenicity. GTTAC provided advice on matters the Regulator should take into account in preparing the RARMP for this application in September 2014 and members were now being asked for advice on the RARMP prepared by Regulator.

GTTAC noted that Amgen is proposing to use the GMO as a prescription only cancer treatment for patients with suitable solid tumours. Before the GMO can be used as a therapeutic, Amgen must also obtain regulatory approval from the Therapeutic Goods Administration (TGA), which has responsibility for assessing the safety and efficacy of the GMO for therapeutic use in humans.

Key issues discussed by the committee included:

- the interface between the gene technology legislation and the *Therapeutic Goods Act 1989*
- the potential for the GMO to persist in a dormant state (latency). However GTTAC agreed that the potential for latency is significantly reduced as a result of the attenuation of the GMO. In any case, potential latency would not affect the conclusion of the RARMP that any risks to the health and safety of people or the environment from the proposed dealings are negligible.

RESOLUTION – GTTAC advised the Regulator that:

1. The committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should consider clarification in the RARMP of background information and control measures regarding latency and containment of the GMO.

3. ADVICE ON CONSULTATION RARMPS – LIMITED AND CONTROLLED

3.1 DIR 133 – Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance

Bayer CropScience Pty Ltd (Bayer) has applied for a licence to conduct a limited and controlled release of GM cotton modified for insect resistance and tolerance to the herbicides glyphosate and/or glufosinate ammonium. The field trial is proposed to take place between July 2015 and

July 2021 at sites in New South Wales, Queensland and Western Australia. In the first year, up to 14 sites of up to 10 ha each would be grown, and in each of the following five years up to 20 sites of up to 30 ha. The total maximum planting area proposed is 3140 ha over the period of the trial[1].

GTTAC noted the key points in the consultation RARMP, including the conclusion that this field trial poses negligible risks to human health and safety and the environment. GTTAC discussed the draft licence conditions including that they permit Bayer to sell lint from GM cotton (cotton lint is used in textiles and clothing), but that no GM plant material from the trial is permitted to be used in human food or animal feed.

The committee also discussed the large scale of the proposed trial and referred to the operational policy document being prepared by the OGTR to clarify the criteria for considering a GM plant licence to be limited and controlled (see Section 4 under 'Other Advice' below).

RESOLUTION – GTTAC advised the Regulator that:

1. The committee agrees with the overall conclusions of the RARMP; and
2. The Regulator should consider clarification in the RARMP of:
   a. the potential for spread and dispersal of the GMO due to extreme weather events in northern Australia
   b. the definition of a natural waterway.

3.2 DIR 135 – Limited and controlled release of sugarcane genetically modified for enhanced sugar content (The University of Queensland)

The University of Queensland has applied for a licence to conduct a limited and controlled release of GM sugarcane modified for enhanced sugar content. The field trial is proposed to take place between August 2015 and May 2020 in two locations in Queensland. The maximum area of the trial would be five hectares of field planting plus an area of 0.125 hectares for plant handling, analysis and waste storage per growing season. GM sugarcane from the trial would not be used for human food or animal feed.

GTTAC noted the key points in the consultation RARMP, including the conclusion that this field trial poses negligible risks to the health and safety of people and the environment as a result of gene technology. GTTAC discussed the draft licence conditions which require a 6 m isolation zone around the GM sugarcane, but the RARMP concluded that a guard row of non-GM sugarcane was not necessary.

RESOLUTION – GTTAC advised the Regulator that:

1. The committee agrees with the overall conclusions of the RARMP;
2. The Regulator should consider a provision that allows removal of developing flower heads that occur early on specific plants; and
3. The Regulator should consider clarifying in the RARMP:
   a. outcomes and likelihood of crosses with GM plants from other field trials
   b. the total area to be planted
   c. the description regarding restrictions on the use of the GMO in food or feed.

[1] The final DIR 133 licence issued to Bayer permits a maximum planting area of 120 hectares per year in the first two years and 600 hectares per year in the following four years, which is smaller than initially proposed by the applicant and considered by GTTAC.

OTHER ADVICE

4. LIMITED AND CONTROLLED RELEASE OPERATIONAL POLICY DEVELOPMENT

GTTAC was updated on the development of an operational policy about what constitutes a limited and controlled DIR licence application for GM plants. Section 50A, which defines the category of limited and controlled DIRs, was introduced in the 2007 amendments to the Act. Limited and controlled DIR applications (typically field trials) have a streamlined assessment process compared to 'standard' DIR applications (eg commercial release). In order to be considered a limited and controlled release, a licence application must meet specific criteria: that the principal purpose of the application is to conduct experiments, and that the applicant proposes appropriate limits and controls on the dealings with the GMO.

GTTAC discussed the policy document being developed by the OGTR to assist the Regulator to determine whether a GM plant licence application meets the criteria of a limited and controlled release. The document will consider the legislation, consistency with current practice in the OGTR, information collected from monitoring inspections, advice received on limited and controlled RARMPs and comparable policies of international gene technology regulatory agencies.

RESOLUTION – GTTAC advised the Regulator that:

1. The Regulator should take into account in the development of an operational policy on limited and controlled release applications the following:
   a. clarification of interpretation of section 50A (4)(a) of the *Gene Technology Act 2000*
   b. eliciting from applicants greater clarification of intent with regard to experimentation
   c. exploring scale as a proxy for assessing whether a given licence application qualifies as a limited and controlled release.

5. COMMERCIAL PLANT DIR LICENCE APPLICATION FORM

GTTAC considered a draft DIR licence application form for commercial or general releases of GM plants. GTTAC noted that this form complements the updated DIR licence application form for limited and controlled releases of GM plants, which was introduced in December 2013. Two draft documents were provided to GTTAC for comment: a new application form and a set of example answers. The example answers are intended to provide guidance for applicants and illustrate the kind of information used in conducting risk analysis.

RESOLUTION – GTTAC advised the Regulator that:

1. The Regulator should consider:
   a. in the example answers the reference should be to any area in Australia not just current growing areas
   b. adding other organisms to P31 – 13.4, as in 13.1 and 13.2
   c. giving opportunity for applicants to add new information or alternative interpretations in Part 14
   d. clarifying the rationale and examples for unintended changes in Part 9.11

6. NEW TECHNOLOGIES

GTTAC was provided with background information relating to new technologies, including new plant breeding techniques, and the scope of Australian regulation of GMOs as determined by the legal definitions in the Act and the Regulations. The broad definitions in the Act are moderated by technical exclusions in Schedules to the Regulations. It was noted that these exclusions were drafted prior to the advent and use of these new techniques and that in light of technology

developments, the clarity of the wording of some these exclusions could be improved. The presentation sought GTTAC's views on a technical review of the Regulations by the Regulator to address the clarity of regulatory coverage of organisms generated with new technologies and to ensure regulation is commensurate with risk. It was also noted that the Regulator had conducted two previous technical reviews of the Regulations. GTTAC was informed that policy approval would be required from the Commonwealth Minister responsible for gene technology, and that any amendments would also require agreement of a majority of states and territories.

RESOLUTION – GTTAC advised the Regulator that:

1. The committee supports a review of the Regulations.
2. Technical issues to consider:
   a. ability to detect the modification from some technologies may not be feasible, and differentiating changes obtained through gene technology from random events may be difficult in some cases
   b. similar technologies may produce modified organisms that differ in whether or not they are considered to be classified as GMOs
   c. focus on risk as the starting consideration to determine the need for regulatory oversight.

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 (September 2014). The committee was reminded of the upcoming 6th National Institutional Biosafety Committee Forum on 29-30 April 2015, and members of GTTAC were encouraged to attend.

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>.