Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee Videoconferences 18 December 2014 and 29 January 2015[1] Communiqué

This Communiqué covers matters considered at the 6th and 7th videoconferences of the Gene Technology Technical Advisory Committee (18 December 2014 and 29 January 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 conduct dealings 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 Regulation 29 of the Gene Technology Regulations 2001, 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 are not assessed 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 CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

At the videoconference held on 18 December 2014, GTTAC considered the consultation RARMPs prepared for limited and controlled release applications for genetically modified (GM) wheat and GM safflower.

1.1 DIR 130 – Limited and controlled release of wheat genetically modified for improved grain quality

GTTAC noted that application DIR 130 from Murdoch University is for a limited and controlled release of GM wheat that has been modified for improved grain quality by the introduction of either one or two genes that code for glutenin proteins. The proposed field trial would take place over

[1] The videoconferences were held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Hobart, Melbourne and Perth.

three growing seasons on single site in a multiuser facility in Western Australia, with a maximum area of 0.06 hectares per year.

GTTAC noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to the health and safety of people and the environment. GTTAC also noted that the draft licence conditions are similar to those for previous GM wheat trials conducted in multiuser facilities.

Key points discussed by the committee:

- Additional data that might be needed for a commercial release application, including the potential for the GM wheat to be allergenic;
- GTTAC noted that any commercial release of GM wheat in Australia would also require assessment and approval from Food Standards Australia New Zealand;
- Licence conditions relating to inspections during and after the trial, in the context of OGTR's operational experience;
- Appropriateness of specific conditions in the draft licence that would minimise the likelihood of mixing seed from different trials grown concurrently at this multiuser facility.

RESOLUTION – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP; and
- The Regulator should consider further data on allergenicity that may be required for any future commercial release application.

1.2 DIR 131 – Limited and controlled release of safflower genetically modified for high oleic acid composition

GTTAC noted that application DIR 131 from the Commonwealth Scientific and Industrial Research Organisation (CSIRO) is for a limited and controlled release of GM safflower that has been modified for high oleic acid composition. The proposed field trial would take place between January 2015 and August 2019 at 45 sites in Queensland, Victoria, New South Wales, Australian Capital Territory and Western Australia. The maximum cumulative planting area of the trial would be 850 hectares over four growing seasons.

GTTAC noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to the health and safety of people and the environment. GTTAC also noted that the draft licence conditions are similar to those for the previous GM safflower trial conducted under licence DIR 121.

Key points discussed by the committee:

- The large area and number of sites proposed for the trial and what the Regulator considers delimits a limited and controlled release;
- The committee confirmed that the GMO and derived products would not be used in human food or animal feed, and noted that FSANZ is responsible for food safety assessment and food labelling, including GM food.

RESOLUTION – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP; and
- The Regulator should consider whether the proposed limits are appropriate for this trial and whether larger trial sites can be adequately managed.

DEALINGS NOT INVOLVING THE INTENTIONAL RELEASE OF GMOS (DNIR)

2. ADVICE ON DNIR RARMPS

The Regulator may seek GTTAC advice on RARMPs prepared for a DNIR application. DNIRs are dealings with a GMO that is not intentionally released into the environment. DNIR licences include research work with GMOs required to be undertaken in physical containment facilities (eg certified by the Regulator) or clinical trials undertaken in clinical facilities.

At the videoconference held on 29 January 2015, GTTAC considered the RARMP prepared for a DNIR application for a clinical trial of a potential malaria vaccine.

2.1 DNIR 554 – Production and clinical trial of a genetically-modified *Plasmodium falciparum* blood stage vaccine

GTTAC noted that application DNIR 554 from Queensland Institute of Medical Research (QIMR) is for a clinical trial with human volunteers that aims to assess the safety and efficacy of GM *Plasmodium falciparum* as a potential malaria vaccine.

GTTAC noted the key points in the RARMP including that no risks to people or the environment greater than negligible were identified.

GTTAC also noted the following:

- the GMO is not expected to be more pathogenic than the non-GM (wild type) *P. falciparum*;
- QIMR has conducted a number of clinical trials involving non-GM *P. falciparum* and all procedures for this trial would be carried out by trained personnel in accordance with approved clinical site procedures;
- the proposed trial would need to meet the Therapeutic Goods Administration requirements and would require approval from, and oversight by, a human research ethics committee.

RESOLUTION – GTTAC advised the Regulator that:

1. GTTAC agrees with the overall conclusions of the RARMP, that the risk assessment identifies all plausible risk scenarios, and that the proposed containment measures and work practices are appropriate.
2. In addition, GTTAC also advises that the Regulator consider the following issues for inclusion and/or clarification in the RARMP in the context of procedures and practices used for clinical trials related to infectious diseases, in particular clinical trials with non-genetically modified *Plasmodium falciparum*, regarding:

a) *exclusion criteria* for trial participants.
– clarify that only adults will be trial participants.
– GTTAC considers there is a very low probability of participants becoming pregnant during the trial given the measures proposed and the small number of participants (n=16). However, it suggests that the Regulator consider additional exclusion criteria such as restricting the trial to male participants or excluding females of child-bearing age in order to address the issue of contra-indication for the drug Riamet in pregnancy. It further advises that the RARMP include consideration of alternative treatments to Riamet that would be suitable for treatment of pregnant women.

b) *potential mosquito vectors* of *P. falciparum*:
– include any additional information that clarifies the potential for *Anopheles annulipes* to act as a vector, in the context of the taxonomic diversity within the species, the identity of strains present in the Brisbane area, and seasonal variations in prevalence, and consider in these contexts potential measures to minimise exposure of trial participants to mosquitos
– consider whether the likelihood of vector-mediated transmission could be further reduced by conducting the trial outside the mosquito season, e.g. during the winter months

c) *dose schedule*: include information to enable comparisons with previous trials of non-GM *P. falciparum*

d) *notification* of participant status to emergency workers or other authorities: in order to minimise potential for parenteral transmission should participants be involved in an accident during the trial period (e.g. traffic accident). GTTAC advises consideration of contingency requirements in the context of standard clinical precautions and current praxis and requirements for human clinical trials involving pathogens, including for non-GM *P. falciparum*.

e) *travel* of trial participants:
– clarify and ensure consistency regarding limitations on domestic and international travel

f) *level of anticipated attenuation* of the GM *P. falciparum* and proposed containment measures:
– ascertain whether any additional information is available on the role and function of the *kahrp* gene in relevant animal models, including non-human primates, that could inform the risk assessment
– take account in proposed containment measures of measures used in previous clinical trials of non-GM *P. falciparum*

OTHER ADVICE

3. Biology documents

3.1 The biology of *Carthamus tinctorius* L. (safflower)

At the 18 December 2014 video conference, GTTAC reviewed the draft biology document 'The biology of *Carthamus tinctorius* L. (safflower), which was prepared by the OGTR to provide baseline biology information relevant to the risk assessment of GM safflower, including for DIR 131. GTTAC provided some suggestions for improvement of the document, and this feedback will be incorporated before the document is published on the OGTR website.

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 our website http://www.ogtr.gov.au.