Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

30 May 2017

Communiqué

This Communiqué covers matters considered at the 52nd meeting of the Gene Technology Technical Advisory Committee (30 May 2017, Canberra)

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 major issues discussed by the Committee.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO

Dealings involving the Intentional Release (DIR) of a GMO 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 which 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 CONSULTATION RARMPS – LIMITED AND CONTROLLED RELEASE

DIR 152 – Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance and yield improvement

Licence application DIR 152 from the University of Adelaide is for a field trial of GM wheat and barley plants that have been modified for enhanced yield or frost tolerance. The trial would take place at up to five sites, on a maximum of 3.75 hectares per growing season in South Australia, Western Australia and New South Wales, between July 2017 and January 2021. The risk assessment for DIR 152 concludes that this release poses negligible risks to the health and safety of people and the environment.

The Committee discussed the proposed licence conditions including measures that could be used to prevent livestock feeding and to minimise rodent activity.

Resolution – GTTAC advised the Regulator that:

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

DIR 153 – Limited and controlled release of sorghum genetically modified for grain quality traits

Licence application DIR 153 from the University of Queensland is for a field trial of GM sorghum plants that have been modified for increased seed protein content, increased seed protein digestibility, increased seed size and/or a larger number of seeds. The trial would take place between October 2017 and June 2020 in south-east Queensland.

GTTAC noted key 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.

The committee agreed with the additional information identified in the RARMP that may be required to assess a future application involving the GMOs, in particular regarding the potential for increased toxicity or allergenicity, and the potential for dispersal of sorghum seed by birds in Australia.

GTTAC discussed the draft licence conditions in some detail, including the measures to deter birds and the proposed isolation zone, noting that this is the first application to the Regulator for a trial of GM sorghum. The committee made specific suggestions for additional information to include in the RARMP, as detailed in the resolutions, as well as minor revisions to improve the document.

Resolution – GTTAC advised the Regulator that:

- The committee agrees with the overall conclusions of the RARMP
- The Regulator should further consider the potential for spread by birds
- The Regulator should further consider the potential for gene flow to nearby sorghum seed breeding activities
- The Regulator should consider providing further detail in relation to the grain traits of the parental sorghum lines (refer paragraph 113 of the consultation RARMP) and in relation to the potential for the GMOs to cross with *S. bicolor* subsp. *arundinaceum* (refer paragraph 147 of the consultation RARMP).
- The Regulator should consider some specific text revisions identified to improve readability and clarity

DIR 154 – Limited and controlled release of a GM vaccine for chickens, Vaxsafe® ILT

Bioproperties Pty Ltd has sought approval to trial, under limited and controlled conditions, a live attenuated GM vaccine, Vaxsafe® ILT, for the protection of chickens against *Infectious laryngotracheitis virus*. The proposed trial would take place on selected chicken farms in New South Wales and Victoria over a five year period.

GTTAC noted that the APVMA has issued a permit to Bioproperties Pty Ltd that includes instructions for the use, storage and disposal of the GM vaccine, and imposes biosecurity measures for poultry production. Key points discussed by the committee included:

- The selection of trial sites, including the location in relation to other farms and the capability of the facilities to confine the chickens
- The risk of exposure of wild birds to the GM vaccine
- The potential for spread of the GM vaccine by air or during disposal
- The potential for recombination of the GMO with other strains of the virus, noting that this would likely lead to an attenuated organism and that APVMA requirements would reduce the likelihood of recombination occurring

GTTAC was satisfied that any risks could be managed and agreed with the conclusion of the RARMP for DIR 154, that risks to the health and safety of the environment from the proposed release are negligible.

Resolution – GTTAC advised the Regulator that:

- The Committee agrees with the overall conclusions of the RARMP
- The Regulator should further consider trial locations where birds are able to be appropriately contained during the virus shedding period.
- The Regulator should further consider potential consequences of infection in other birds

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR 155 – Commercial release of canola genetically modified for omega-3 oil content (DHA canola)

NuSeed Pty Ltd is seeking approval for commercial cultivation of a GM canola line, DHA canola, in Australia. DHA canola has been modified for production of long chain omega-3 polyunsaturated fatty acids in the seed oil. GTTAC was advised that the following key matters had been identified for consideration in 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 trait of altered oil content will increase the potential for the GM canola to spread and persist, leading to harm to the environment
- the potential for harm to result from gene flow to other sexually compatible Brassica species.

Advice was sought from the Committee in relation to these and any other issues that should be considered in preparation of the RARMP for this application.

GTTAC noted that data from the field trial of the GMO conducted under DIR 123 had been included in the application for DIR 155. GTTAC discussed other approvals required, including an import permit from the Department of Agriculture and Water Resources, and approval from Food Standards Australia New Zealand for food made from the GM canola.

Resolution – GTTAC advised the Regulator that:

- The Committee agrees that the Regulator should consider those matters identified in the agenda paper when preparing the RARMP

OTHER ADVICE

The Biology of sorghum

Biology documents are prepared by the OGTR to provide an overview of baseline biology information relevant to risk assessment of genetically modified forms of the species.

GTTAC reviewed the biology document prepared for sorghum, which is available on the Biology Documents page of the OGTR website. The Committee commended the OGTR on the document and suggested a number of edits to improved clarity and readability. The Committee noted the importance of these documents as references that are widely used both in Australia and overseas.

Resolution – GTTAC advised the Regulator that:

- The Regulator should consider making some minor changes to help improve understanding by a non-scientific audience
- The Regulator should consider further reference to relevant Food and Agriculture Organisation (UN) or Food Standards Australian New Zealand documents
- The Regulator should consider adding some further details about germination/dormancy studies

INFORMATION ITEMS AND REPORTS

GTTAC was informed that the Regulator has become aware that unauthorised genetically modified (GM) petunias have entered the Australian and international markets. The Committee was updated on actions being taken by the OGTR including liaising with the Australian based importers. Further information is available via the Inadvertent Dealings page of the OGTR website.

GTTAC received a report from the cross member with the Gene Technology Ethics Committee (GTECCC) on recent activities of GTECCC. GTTAC also received reports from the Chair and from the Regulator that provided updates on relevant activities undertaken since the previous face-to-face GTTAC meeting in February 2017.

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 call the OGTR on 1800 181 030 or email ogtr@health.gov.au. RARMPs are also available on the GMO Record page of the OGTR website.