



## Australian Government

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

### Gene Technology Technical Advisory Committee

17 June 2024

### Communiqué

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***This Communiqué covers matters considered at the 38<sup>th</sup> videoconference of the Gene Technology Technical Advisory Committee (17 June 2024)***

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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.

### **ADVICE ON CONSULTATION RARMPs – COMMERCIAL RELEASE**

#### **DIR 202 – Commercial supply of a live attenuated vaccine containing canine distemper virus and a genetically modified canine parvovirus (Nobivac Puppy DP Plus) for dogs.**

Licence application DIR 202 from Intervet Australia Pty Ltd is for the import, transport, storage, supply and disposal of a Genetically Modified (GM) parvovirus vaccine for dogs.

GTTAC noted the conclusion of the RARMP that risks to the health and safety of people or the environment from the proposed trial are negligible. The Committee discussed the following key topics:

- Potential of risks of recombination in outbreak areas, with consideration to licence conditions and approved vaccines in the market. Suggestion that oversight of circulating strains would be valuable.
- Decontamination requirements already in place in veterinary clinics following the use of vaccines and other standard vaccination protocols to be followed for use of this vaccine.

## Resolutions

- The Committee agreed that the risk assessment identifies all plausible risk scenarios by which the proposed dealings could potentially give rise to risks relating to the health and safety of people or the environment.
- The Committee agreed that the risk of generating a novel pathogenic Canine Parvovirus (CPV) strain resulting from the recombination of the GMO with other CPV, parvovirus or vaccine strains is negligible.
- The Committee agreed that the conditions proposed in the draft licence to prevent the recombination of the GMO with other CPV, parvovirus or vaccine strains are appropriate.
- The Committee noted that it would be valuable to monitor circulating viruses and whether recombination has occurred.
- The Committee agreed with the overall conclusion of the RARMP.

## **ADVICE ON CONSULTATION RARMPs – LIMITED AND CONTROLLED RELEASE**

### **DIR 204 – Limited and controlled release of wheat genetically modified for increased tolerance to environmental stress.**

Licence application DIR 204 from Trigall Australia Pty Ltd is for a field trial of GM wheat modified for increased tolerance to environmental stress. The trial would be conducted at up to 10 sites, with a maximum planting area of 20 hectares each year, for a period of 5 years.

GTTAC noted the conclusion of the RARMP that risks to the health and safety of people or the environment from the proposed release are negligible. The Committee discussed the following key topics:

- The similarities in the levels of gluten present in the GM wheat compared to the non-GM parental wheat and possible impacts, if any, to those with allergies – noting that this trial does not involve the use of the GM wheat in human food or livestock feed, and no harm has been observed in other countries where the GMO is grown commercially.
- Use of the GMO in the course of manufacture of something that is not a GMO, for example the production of flour and its testing.

## Resolutions

- The Committee agreed that the risk assessment identifies all plausible risk scenarios by which the proposed dealings could potentially give rise to risks relating to the health and safety of people or the environment.
- The Committee agreed that the measures to limit and control the release are appropriate for the trial.
- The Committee did not identify additional information that should be considered.
- The Committee agreed with the overall conclusion of the RARMP.

## ENQUIRIES

For all enquiries, please call the OGTR on 1800 181 030 or email [ogtr@health.gov.au](mailto:ogtr@health.gov.au).