Australian Government
Department of Health
Office of the Gene Technology Regulator

4 September 2019

Summary of Licence Application DIR 170

The University of Queensland (UQ) has made an application under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

Project Title	Trial of genetically modified vaccines against *Ross River virus* infection in horses [1]
Parent organism	*Vaccinia virus* (Copenhagen strain)
Principal purpose	To study the efficacy of genetically modified (GM) *Vaccinia*-based vaccines in protecting horses against *Ross River virus* (RRV) infection
Genetic modifications	**GMO 1:** Deleted genes: • *A39R* gene, involved in the evasion of the host immune system - attenuation • *B7R-B8R* genes, involved in the evasion of the host immune system - attenuation • *D13L* gene, essential for viral assembly - renders the virus replication incompetent Added genes: • *S26* structural polyprotein gene of the Chikungunya virus - antigen expression • *prME* structural polyprotein gene of the Zika virus - antigen expression **GMO 2:** Deleted genes: • *C3L* gene, involved in the evasion of the host immune system - attenuation • *D13L* gene, essential for viral assembly - renders the virus replication incompetent Added gene: • *S26* structural polyprotein gene for RRV - antigen expression **GMO 3:** Deleted genes: • *D13L* gene, essential for viral assembly - renders the virus replication incompetent Added gene: • *DsRed Express2* gene, a modified fluorescent protein from coral – visual marker
Proposed limits	
Proposed period of release	January 2020 - December 2023
Proposed release size	A maximum of 40 horses would be vaccinated
Proposed location	Equine facility yards and paddocks at the UQ Gatton Campus, Queensland

[1] The title of the project as supplied by the applicant is 'Ross River virus vaccine protection of horses'.

This application proposes a trial of *Vaccinia*-based GM vaccine candidates for protection of horses against *Ross River virus* (RRV). Various strains of *Vaccinia* virus were used worldwide as vaccines against smallpox, eventually leading to the declaration of eradication of smallpox in 1980. The *Vaccinia* strain used as the vaccine vector in this application has been modified to improve its safety while still eliciting an immune response.

RRV is a mosquito-borne virus endemic to Australia and islands in the South Pacific. It is responsible for a non-lethal but debilitating tropical disease known as Ross River fever. RRV infects humans and various other mammals, including horses. Common disease symptoms in people include joint pain, rash and fever; and in horses joint pain and swelling, ataxia, fever and lethargy. The introduced genes encode a number of proteins from RRV and closely related viruses that are intended to elicit a protective immune response against RRV.

Supply of veterinary products also requires approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA). UQ will need to apply to the APVMA for a permit to allow the supply and limited use of the GM vaccines for the purpose of conducting research.

Proposed Controls include:

- ensuring the GM vaccines are administered to horses by authorised staff
- isolating the vaccinated horses in the trial site for at least 6 months after vaccination
- monitoring for the presence of GMOs after vaccination
- only permitting trained and authorised staff access to the trial, and
- transporting, storing and disposing of the GMOs in accordance with the current Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*.

Consideration as a limited and controlled release (field trial)

This application is considered to be a limited and controlled release application under section 50A of the Act, as the Regulator was satisfied that:

- its principal purpose is to enable the applicant to conduct experiments and
- the proposed limits and controls are such that consultation with prescribed experts, agencies and jurisdictions is not required before preparing the consultation version of the RARMP.

Next steps

The gene technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

The Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering the application including the proposed limits and controls in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment, from the proposed release.

At this stage, the consultation RARMP is expected to be released for comment in **early-November 2019**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

Other information available from the OGTR website:

- information on Australia's national scheme for regulation of gene technology
- information on the DIR application process.

Please use the contact details below, if you:

- would like a copy of the application - please include the identifier DIR 170
- have any questions about the application or the legislated evaluation process
- wish to register on the mailing list.

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