



28 February 2019

Summary of Licence Application DIR 167

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	<p>Deleted genes:</p> <ul style="list-style-type: none">• <i>A39R</i> gene, involved in the evasion of the host immune system – attenuation• <i>D13L</i> gene, essential for viral assembly – renders the virus replication incompetent <p>Introduced genes:</p> <ul style="list-style-type: none">• Human <i>Ubiquitin c</i> – efficient processing of introduced antigenic protein; and• S26-structural polyprotein of the Chikungunya virus (GMO 1) – antigen expression; or• S26-structural polyprotein of the Ross River virus (GMO 2) – antigen expression
Proposed period of release	July 2019 - December 2023
Proposed release size	A maximum of 40 horses would be vaccinated: up to 24 horses in the first year, and up to 16 in the second year
Proposed location	Yards and paddocks (less than 2 ha in total) at the UQ Gatton Campus, Queensland

This application proposes a trial of vaccinia-based GM vaccine candidates for protection of horses against 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.

Ross River virus (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.

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.

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

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
- only permitting trained and authorised staff access to the trial and
- transporting and storing 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 **mid-May 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 and
- 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 167
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

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