



Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 214

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional release of a genetically modified organism (GMO) into the environment. A Risk Assessment and Risk Management Plan (RARMP) for this application has been prepared by the Regulator in accordance with the Gene Technology Act 2000 (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concluded that the proposed trial poses negligible risk to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

The University of Queensland (UQ) proposes to conduct a trial using a genetically modified (GM) adenovirus vaccine in horses.

Rhodococcus equi is a soil-borne bacterium that causes a severe respiratory disease in young horses, known as rattles. The GM vaccine has been designed to express the *R. equi* virulence protein VapA and be replication deficient. A maximum of 10 young horses contained within UQ Gatton's facilities would receive intramuscular injections and intranasal instillations with the GM vaccine, with the aim of evaluating the vaccine's safety and efficacy.

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 vaccine for the purpose of conducting research.

The application

Project Title	Trial of a genetically modified (GM) vaccine for the prevention of respiratory disease in horses.
Parent organism	Human adenovirus 5 (HAdV5)
Genetic modifications	<p>Deleted genes:</p> <ul style="list-style-type: none">• Viral early-transcribed region 1 (E1) - to render virus unable to replicate.• Viral early-transcribed region 3 (E3) - to improve the transgene carrying capacity of the viral vector and increase the host immune response to the vector. <p>Introduced gene:</p> <ul style="list-style-type: none">• Virulence-associated protein A (VapA) from <i>Rhodococcus equi</i> - Expression of the VapA
Principal purpose	The proposed trial aims to evaluate the immunogenicity, safety and efficacy of a genetically modified (GM) vaccine for the prevention of severe respiratory disease (rattles) in horses
Previous trials	The proposed study would be the first trial to be conducted with the GMO
Limits and controls	

Duration	5 years
Locations	A contained trial site in Gatton, Queensland (UQ Gatton Campus)
Controls	<ul style="list-style-type: none"> • only registered veterinarians would administer the GMO • only trained and authorised personnel would access the animal enclosures • a maximum of 10 horses would be administered with the GMO • personnel would use personal protective equipment (PPE) • transport, storage and disposal of the GMO would be carried out according to the Regulator's <i>Guidelines for the Transport, Storage and Disposal of GMOs</i>

Risk assessment

The risk assessment process considers how the genetic modifications and proposed activities conducted with the GMO might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application (including proposed controls), relevant previous approvals and current scientific/technical knowledge. Both short- and long-term impacts are considered.

Credible pathways to potential harm that were considered included the potential exposure of people or animals to the GMO; and the potential for the GMO to transfer or acquire genetic material from other viruses. The potential for the GMO to be released into the environment and its effects were also considered.

The risk assessment concludes that the trial poses negligible risks to human health and safety and to the environment. No specific risk treatment measures are required to manage these negligible risks. Important factors in reaching the conclusions of the risk assessment included that the GM vaccine is replication incompetent, and unintended exposure to the GMOs would be minimised by the limits and controls.

Risk management

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a trial, the licence includes limits on the number of horses vaccinated, types of facilities used, limits on the duration of the trial, as well as a range of controls to minimise the potential for the GMO to spread in the environment. In addition, there are several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any unintended effects.