



# Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 159

## **Decision**

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the limited and controlled release of a genetically modified organism (GMO) into the environment. The University of Queensland (UQ) will conduct field trials to assess the efficacy and safety of two GMO vaccines for protection of farmed crocodiles from *Kunjin virus* infection.

Veterinary medicines must be approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA), which provides a national registration scheme for agricultural and veterinary chemical products under the *Agricultural and Veterinary Chemicals Code Act 1994* (AgVet Code), including vaccines. Therefore, in addition to approval by the Regulator, UQ would require a permit from APVMA to supply and use the GM vaccine for the purpose of animal research.

A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with the requirements of the Gene Technology Act 2000 (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide ranges of experts, agencies and authorities, and the public. The RARMP concludes that the proposed field trial poses negligible risks 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 application**

Application number	DIR 159
Applicant	The University of Queensland
Project Title	Limited and controlled release of genetically modified insect-specific viruses as vaccines against <i>Kunjin virus</i> infection in farmed crocodiles <sup>1</sup>
Parent organism	Two insect-specific flaviviruses, ISFa and ISFb <sup>2</sup>
Modified genes	Insertion of two genes from a naturally attenuated strain of <i>Kunjin virus</i> <sup>2</sup>
Proposed release date	Once all the required approvals have been granted
Proposed duration	5 years
Proposed locations	Two crocodile farms in Litchfield Council in the Northern Territory
Primary purpose	To study the safety and efficacy of two genetically modified insect-specific viruses as vaccines against <i>Kunjin virus</i> infection in farmed crocodiles

*Kunjin virus* is a mosquito-borne virus endemic in the Northern Territory. Its primary host is birds but it also infects and causes disease in other animals (in particular, horses) and people. In crocodiles, *Kunjin*

<sup>1</sup> The title of the project as submitted by the applicant is "Recombinant insect-specific viruses as non-infectious vaccines against *Kunjin virus* infection in farmed crocodiles".

<sup>2</sup> The specific details relating to the identity of the parent organisms, the design, construction and genetic modifications of the GMO, including the *Kunjin virus* genes, corresponding proteins and their function, have been declared as Confidential Commercial Information (CCI) under section 185 of the Act. CCI is made available to the prescribed experts and agencies.

*virus* infection is largely non-symptomatic but may result in the development of skin lesions, which interfere with subsequent processing for leather and leather goods manufacturing. The proposed field trials, involve inoculation of up to 2,800 juvenile crocodiles with the GMO vaccines, would take place at the Darwin Crocodile Farm, Bees Creek, Northern Territory; and Janamba Crocodile Farm, Middle Point, Northern Territory. Crocodiles would be harvested approximately 18-30 months after inoculation, and processed for crocodile products on site at the crocodile farms. As is common in veterinary vaccine trials, the products of vaccinated crocodiles could enter general commerce, including use in human food or animal feed.

### ***Risk assessment***

The risk assessment concludes that risks to the health and safety of people and the environment from the proposed release are negligible. No specific risk treatment measures are required to manage these negligible risks.

The risk assessment process considers how the genetic modifications and proposed activities conducted with the GM viruses 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 limits and controls), relevant previous approvals and current scientific/technical knowledge. Both the short and long term impact are considered.

Credible pathways to potential harm that were considered included exposure of people or insects to the GMOs and the potential for recombination with other viruses. Potential harms that were considered in relation to these pathways included adverse immune response, increased disease in people or animals, and impacts on insect biodiversity.

The principal reasons for the conclusion of negligible risks are the phenotype of the GMOs, in particular their limited host range and lack of ability to replicate in vertebrates, and suitability of the controls proposed by the applicant.

### ***Risk management plan***

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 limited and controlled release, the licence includes limits on the size, location and duration of the release, as well as a range of controls to minimise the potential for the GMOs 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.

**Office of the Gene Technology Regulator, MDP 54, GPO BOX 9848 CANBERRA ACT 2601**

**Telephone: 1800 181 030**

**E-mail: [ogtr@health.gov.au](mailto:ogtr@health.gov.au)**

**[OGTR website](#)**