Australian Government
Department of Health
Office of the Gene Technology Regulator

5 March 2018

Summary of the Risk Assessment and Risk Management Plan (Consultation version)

for

Licence Application No. DIR 159

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application for the intentional release of a genetically modified organism (GMO) into the environment. It qualifies as a limited and controlled release application under the *Gene Technology Act 2000* (the Act). The University of Queensland (UQ) proposes to 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.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed field trial poses negligible risks to human health and safety and the environment. Licence conditions have been drafted for the proposed field trial. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

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 *Kunjin virus* infection in farmed crocodiles [1]
Parent organism:	Two insect-specific flaviviruses, ISFa and ISFb[2]

[1] 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".

[2] 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, are under consideration as Confidential Commercial Information (CCI) under section 185 of the Act. Any confidential information will be made available to the prescribed experts and agencies.

Modified genes:	Insertion of two genes from a naturally attenuated strain of *Kunjin virus*[2]
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 *Kunjin virus* 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 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 would take place at the Darwin Crocodile Farm, Bees Creek, Northern Territory; and Janamba Crocodile Farm, Middle Point, Northern Territory and involve inoculation of up to 2,800 juvenile crocodiles with the GMO vaccines. 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 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 GMO 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. Draft licence conditions are detailed in Chapter 4 of the RARMP.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the draft 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 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.