# Questions & Answers on licence DIR 159 – field trial of genetically modified (GM) vaccines for farmed crocodiles

**What does this licence allow?**

The University of Queensland has received approval from the Gene Technology Regulator to trial two live genetically modified (GM) insect-specific viruses for the protection of crocodiles against Kunjin virus. *Kunjin virus* infection in crocodiles can produce skin lesions which impact the processing of crocodile skin for leather goods. The field trial is permitted to take place between May 2018 and May 2023 on two crocodile farms in the Northern Territory. A total of up to 2800 juvenile crocodiles may be inoculated during the trial.

**What is the purpose of the trial?**

The trial would assess the efficacy and safety of the GM vaccines for crocodiles under farm conditions.

**How have the GM vaccines been created?**

The parent organisms are two distinct insect-specific viruses normally associated with mosquitoes in northern Australia. These viruses are not known to cause disease in infected mosquitoes and are not able to replicate or cause disease in humans or other animals.

To generate the GM vaccine strains, two genes that code for Kunjin virus proteins were introduced in place of the corresponding genes of the parental viruses. The GMOs are intended stimulate an immune response in the crocodiles to protect against Kunjin virus infection.

**What controls are imposed on this release?**

A range of licence conditions have been imposed to limit the size, location and duration of the release, as well as restrict the spread and persistence of the GMOs and their introduced genetic material. Control measures include limiting access to the site to authorised staff; keeping inoculated crocodiles physically separated from non-inoculated crocodiles; and appropriate waste disposal. Inoculated crocodiles could enter general commerce, including use in human food or animal feed, however this would only be permitted once testing confirms that the GM viruses are no longer present. A full list of the control measures is detailed in the licence.

**What other regulatory processes apply to this trial?**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates agricultural and veterinary chemical products, including veterinary vaccines. For commercial products, the normal form of approval is through registration. The APVMA also issues permits to allow the limited use of an unregistered product in certain circumstances, for example to enable collection of data to support an application for registration (e.g. safety and efficacy). The APVMA can impose conditions on the use of veterinary products in registrations and permits. The licence holder must get a research permit from the APVMA before the trial can begin.

**Want more information?**

A number of documents relating to this decision are available on the DIR 159 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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